## Contents

The following blog posts were originally published on The Lancet United States of Health Blog, which closed on December 31, 2018.

### 2018

<table>
<thead>
<tr>
<th>No.</th>
<th>Title</th>
<th>Author(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The underappreciated difficulty of the family caregiver for hospice patients</td>
<td>L Beresford</td>
</tr>
<tr>
<td>2</td>
<td>Congressman Tom Reed serves as a hospice patient care volunteer</td>
<td>L Beresford</td>
</tr>
<tr>
<td>3</td>
<td>Bad batch: synthetic marijuana overdoses on the rise</td>
<td>R Cooney and A van Dorn</td>
</tr>
<tr>
<td>4</td>
<td>A layover in the land of The Lancet</td>
<td>C Sacristán</td>
</tr>
<tr>
<td>5</td>
<td>Trump administration’s Medicaid work rules hit a snag</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>6</td>
<td>An advance directive designed for living with dementia</td>
<td>L Beresford</td>
</tr>
<tr>
<td>7</td>
<td>Sepsis: a prolific but under-recognized mass killer</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>8</td>
<td>Besieged EPA Chief still committed to Trump agenda</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>9</td>
<td>AAN issues new guidelines on disease-modifying therapies in MS, including switching, stopping and pregnancy</td>
<td>J Otrompke</td>
</tr>
<tr>
<td>10</td>
<td>Point of view Educating physicians won’t solve burnout</td>
<td>Special Guest Blogger</td>
</tr>
<tr>
<td>11</td>
<td>Is emotional intelligence the missing link for medicine at the end of life?</td>
<td>L Beresford</td>
</tr>
<tr>
<td>12</td>
<td>In the Open podcast—episode 2</td>
<td>R Cooney</td>
</tr>
<tr>
<td>13</td>
<td>Study presented at AACR and published in The Lancet Respiratory Medicine may set new standard for rare sarcoma</td>
<td>J Otrompke</td>
</tr>
<tr>
<td>14</td>
<td>The growing threat of antibiotic resistance and the growing need for antibiotic stewardship</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>15</td>
<td>No barrier to CDC research on gun violence—except funding</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>16</td>
<td>Some children may now receive sex change hormone therapy before 16: ENDO guideline</td>
<td>J Otrompke</td>
</tr>
<tr>
<td>17</td>
<td>Point of view On the Parkland mass-shooting: it’s time for #GunSafetyNow</td>
<td>Special Guest Blogger</td>
</tr>
<tr>
<td>18</td>
<td>point of view Hospices respond to community grief caused by opioid overdoses</td>
<td>L Beresford</td>
</tr>
<tr>
<td>19</td>
<td>Onco-cardiology—targeting the double heart break</td>
<td>J Otrompke</td>
</tr>
<tr>
<td>20</td>
<td>Single payer healthcare debate takes the stage in managed care</td>
<td>J Otrompke</td>
</tr>
<tr>
<td>21</td>
<td>Point of view Dismantling institutional discrimination in healthcare by empowering minority women professionals</td>
<td>Special Guest Blogger</td>
</tr>
<tr>
<td>22</td>
<td>Point of view A whole-system approach to improving cardiovascular health in women</td>
<td>Women’s Heart Alliance</td>
</tr>
<tr>
<td>23</td>
<td>Equality, parity, and visibility</td>
<td>R Cooney</td>
</tr>
<tr>
<td>24</td>
<td>Advance care directives: making plans for future medical care</td>
<td>L Beresford</td>
</tr>
<tr>
<td>25</td>
<td>CDC director resigns over financial conflict of interest</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>26</td>
<td>After a weekend of negotiations and demonstrations, shutdown disrupts health agencies and services</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>27</td>
<td>One-hundred years after influenza catastrophe, is the US pandemic-ready?</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>28</td>
<td>Temporary CHIP funding falls short</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>29</td>
<td>Alex Azar’s controversial qualifications</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>30</td>
<td>The recent rise of cannabinoid hyperemesis syndrome</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>31</td>
<td>Coordinated care is taking on opioid abuse in one rural community</td>
<td>M B Nierengarten</td>
</tr>
<tr>
<td>32</td>
<td>Bursting superpower: obesity in the United States</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>33</td>
<td>Does government quality website capture what matters to hospice patients?</td>
<td>L Beresford</td>
</tr>
<tr>
<td>34</td>
<td>Patents, licenses and drug prices</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>35</td>
<td>DACA, a dream deferred?</td>
<td>R Cooney</td>
</tr>
<tr>
<td>36</td>
<td>Does government quality website capture what matters to hospice patients?</td>
<td>L Beresford</td>
</tr>
<tr>
<td>37</td>
<td>Hepatitis C in the US—a bigger issue than HIV</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>38</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>39</td>
<td>Listen in—the conversations we need to have about racism, health, and medicine</td>
<td>R Cooney</td>
</tr>
<tr>
<td>40</td>
<td>When the option is the end of life</td>
<td>L Beresford</td>
</tr>
<tr>
<td>41</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>42</td>
<td>Advance directives: planning for the end</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>43</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>44</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
</tbody>
</table>

### 2017

<table>
<thead>
<tr>
<th>No.</th>
<th>Title</th>
<th>Author(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>53</td>
<td>Temporary CHIP funding falls short</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>54</td>
<td>Alex Azar’s controversial qualifications</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>55</td>
<td>The recent rise of cannabinoid hyperemesis syndrome</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>56</td>
<td>Coordinated care is taking on opioid abuse in one rural community</td>
<td>M B Nierengarten</td>
</tr>
<tr>
<td>57</td>
<td>Bursting superpower: obesity in the United States</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>58</td>
<td>Does government quality website capture what matters to hospice patients?</td>
<td>L Beresford</td>
</tr>
<tr>
<td>59</td>
<td>Patents, licenses and drug prices</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>60</td>
<td>DACA, a dream deferred?</td>
<td>R Cooney</td>
</tr>
<tr>
<td>61</td>
<td>Does government quality website capture what matters to hospice patients?</td>
<td>L Beresford</td>
</tr>
<tr>
<td>62</td>
<td>Hepatitis C in the US—a bigger issue than HIV</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>63</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>64</td>
<td>Listen in—the conversations we need to have about racism, health, and medicine</td>
<td>R Cooney</td>
</tr>
<tr>
<td>65</td>
<td>When the option is the end of life</td>
<td>L Beresford</td>
</tr>
<tr>
<td>66</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>67</td>
<td>Advance directives: planning for the end</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>68</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
</tbody>
</table>
## Contents (continued)

<table>
<thead>
<tr>
<th>Page</th>
<th>Title</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>87</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>88</td>
<td>Research in the lurch—unanticipated funding cuts jeopardize teen pregnancy prevention programs</td>
<td>R Cooney</td>
</tr>
<tr>
<td>91</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>93</td>
<td>ACA repeal fails in Senate (for now)</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>94</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>95</td>
<td>All hands on deck—addressing the nation’s opioid epidemic</td>
<td>R Cooney</td>
</tr>
<tr>
<td>98</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>100</td>
<td>CMS prepares for launch of comparative hospice data</td>
<td>L Beresford</td>
</tr>
<tr>
<td>102</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>104</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>106</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>108</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>110</td>
<td>Gamechangers—who is playing, who is being played?</td>
<td>R Cooney</td>
</tr>
<tr>
<td>112</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>113</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>115</td>
<td>Telespsychiatry: making treatment available to Americans in under-served locations</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>116</td>
<td>Hospice and opioids, part II: an agency-wide quality approach</td>
<td>L Beresford</td>
</tr>
<tr>
<td>118</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>120</td>
<td>Hospice and opioids: finding a safe balance</td>
<td>L Beresford</td>
</tr>
<tr>
<td>122</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>124</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>125</td>
<td>Hospice houses for the homeless fill a growing need in an aging society</td>
<td>L Beresford</td>
</tr>
<tr>
<td>127</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>128</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>129</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>130</td>
<td>Raising awareness to end Parkinson’s</td>
<td>R Cooney</td>
</tr>
<tr>
<td>132</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>134</td>
<td>Plotting the course for improving health</td>
<td>R Cooney</td>
</tr>
<tr>
<td>136</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>138</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>140</td>
<td>Invasion of privacy—a new bill may give employers access to genetic testing information</td>
<td>R Cooney</td>
</tr>
<tr>
<td>142</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>144</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>146</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>147</td>
<td>An alarming trend in fatty livers</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>149</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>150</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>151</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>152</td>
<td>Berkeley doctor wants to help California patients, hospices with aid-in-dying law</td>
<td>L Beresford</td>
</tr>
<tr>
<td>154</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>156</td>
<td>The Women’s March and what is at stake</td>
<td>M B Nierengarten</td>
</tr>
<tr>
<td>157</td>
<td>Identifying and treating “super-utilizers”</td>
<td>R Cavanaugh</td>
</tr>
<tr>
<td>159</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>160</td>
<td>CBO scores potential fallout from Affordable Care Act repeal</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>161</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
</tbody>
</table>

### 2016

<table>
<thead>
<tr>
<th>Page</th>
<th>Title</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>162</td>
<td>Year in review</td>
<td></td>
</tr>
<tr>
<td>165</td>
<td>Voices in medicine</td>
<td></td>
</tr>
<tr>
<td>167</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>168</td>
<td>Biomedical research bill becomes law, but critics raise concerns over long-term implementation</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>169</td>
<td>This week in health and medicine</td>
<td>A van Dorn</td>
</tr>
</tbody>
</table>
Contents (continued)

170  This week in health and medicine
    A van Dorn
171  Emergence of the corporate palliative care sector
    L Beresford
173  This week in health and medicine
    A van Dorn
174  Where next for US health and health care?
    Richard Lane
175  This week in health and medicine
    A van Dorn
176  This week in health and medicine
    A van Dorn
177  How should hospices handle legalized medical marijuana?
    L Beresford
180  Making children’s dental health part of primary care
    N Laniado
181  This week in health and medicine
    A van Dorn
183  The Global Burden of Disease 2015
    A van Dorn
184  This week in health and medicine
    A van Dorn
185  This week in health and medicine
    R Cooney and A van Dorn
186  EpiPen’s price-gouging response “sickens” Congressional panel
    S Jaffe
187  Mental health and the White House
    R Cooney
191  This week in health and medicine
    R Cooney and A van Dorn
192  The kratom bomb—DEA moves to fast-track scheduling herbal drug
    R Cooney
193  This week in health and medicine
    R Cooney and A van Dorn
194  Hillary Clinton proposes mental health care reforms
    S Jaffe
195  Palliative care seeks its place in managed care
    L Beresford
197  This week in health and medicine
    R Cooney and A van Dorn
198  This week in health and medicine
    R Cooney and A van Dorn
199  This week in health and medicine
    R Cooney and A van Dorn
200  This week in health and medicine
    R Cooney and A van Dorn
201  Zika virus continues to spread, CDC issues Florida travel advisory
    S Jaffe
202  Congress, contracts, and cancer: challenges in Native American health
    R Cooney
205  This week in health and medicine
    R Cooney and A van Dorn
206  Democrats back Clinton, progressive platform at DNC in Philadelphia
    S Jaffe
207  This week in health and medicine
    R Cooney and A van Dorn
208  This week in health and medicine
    R Cooney and A van Dorn
209  Republican Party lays out platform for Election 2016
    S Jaffe
210  This week in health and medicine
    R Cooney and A van Dorn
211  Obama rejects Zika funding approved during Democrats’ sit-in
    S Jaffe
212  Biden pleads for open data for cancer moonshot
    S Jaffe
213  Paris Climate Change agreement to be signed in New York
    S Jaffe
214  Zika response threatened by funding shortage
    S Jaffe
215  Congress wrangles over funding for Zika research
    S Jaffe
216  Shkreli pleads the Fifth on drug price hikes
    S Jaffe
217  Increasing access to mental health services—a sensible strategy for reducing gun violence
    R Honberg
218  Black and white and gray all over
    R Cooney
219  Some Congress members say a 1980 law may curb rising drug prices
    S Jaffe
220  Budget boon for biomedical research
    S Jaffe
221  Paris climate change agreement faces hurdles in the USA
    S Jaffe
222  Gene editing—a revolution from stem to stern
    R Cooney
223  As drug prices go up, some point consumers up north
    S Jaffe
224  Stopping the drug resistance health threat
    A Friedman
225  No bones about it
    R Cooney
226  Can you hear me now?
    S Jaffe
227  Drug pricing—the bitter pill
    R Cooney
228  Precision medicine and smartphones
    S Jaffe
229  US House of Representatives possibly “injured” by ACA spending, judge OKs lawsuit
    S Jaffe
230  Billions served but Cleveland Clinic says no thanks to McDonald’s
    S Jaffe
<table>
<thead>
<tr>
<th>Page</th>
<th>Title</th>
<th>Author(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>231</td>
<td>Making gun violence an open target</td>
<td>R Cooney</td>
</tr>
<tr>
<td>232</td>
<td>Home-care workers</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>233</td>
<td>Clean Power Plan</td>
<td>S Jaffe</td>
</tr>
<tr>
<td>234</td>
<td>Faulty towers</td>
<td>R Cooney</td>
</tr>
<tr>
<td>235</td>
<td>21st Century Cures</td>
<td>R Cooney</td>
</tr>
<tr>
<td>236</td>
<td>World Hepatitis Day 2015</td>
<td>R Cooney</td>
</tr>
<tr>
<td>237</td>
<td>Protecting porn</td>
<td>R Cooney</td>
</tr>
<tr>
<td>238</td>
<td>Immunotherapy comes of age</td>
<td>R Cooney</td>
</tr>
<tr>
<td>239</td>
<td>WHO takes a big step to promote cancer treatment worldwide</td>
<td>Jarvis and S Kishore</td>
</tr>
<tr>
<td>241</td>
<td>HIV in the heartland</td>
<td>R Cooney and A van Dorn</td>
</tr>
<tr>
<td>242</td>
<td>American College of Physicians at 100</td>
<td>R Cooney</td>
</tr>
<tr>
<td>243</td>
<td>The General principle</td>
<td>R Cooney</td>
</tr>
<tr>
<td>244</td>
<td>Biosimilars breaking ground</td>
<td>R Cooney</td>
</tr>
<tr>
<td>245</td>
<td>Ethics and Ebola</td>
<td>R Cooney</td>
</tr>
<tr>
<td>246</td>
<td>Complements to your health</td>
<td>R Cooney</td>
</tr>
<tr>
<td>247</td>
<td>Planning families, planning futures</td>
<td>R Cooney</td>
</tr>
<tr>
<td>248</td>
<td>Clinical trial data: share and share alike</td>
<td>R Cooney</td>
</tr>
<tr>
<td>249</td>
<td>New Year’s resolution: commit to memory</td>
<td>R Cooney</td>
</tr>
<tr>
<td>250</td>
<td>Year in review</td>
<td>Lancet USA 2014</td>
</tr>
<tr>
<td>251</td>
<td>Getting a move on</td>
<td>R Cooney</td>
</tr>
<tr>
<td>252</td>
<td>Veterans uncovered</td>
<td>A van Dorn</td>
</tr>
<tr>
<td>253</td>
<td>Windows and Gates: bringing global health home</td>
<td>R Cooney</td>
</tr>
<tr>
<td>254</td>
<td>Honoring veterans</td>
<td>R Cooney</td>
</tr>
<tr>
<td>255</td>
<td>Towards Universal Health Coverage: lessons the GOP can learn from the Latin American experience</td>
<td>Gupta V</td>
</tr>
<tr>
<td>256</td>
<td>The battle for a surgeon general</td>
<td>R Cooney</td>
</tr>
<tr>
<td>257</td>
<td>Planning up a storm</td>
<td>R Cooney</td>
</tr>
<tr>
<td>258</td>
<td>Federal agencies questioned about US Ebola response</td>
<td>R Cooney</td>
</tr>
<tr>
<td>259</td>
<td>An auspice for hospice care</td>
<td>R Cooney</td>
</tr>
<tr>
<td>260</td>
<td>Graying the dragon</td>
<td>R Cooney</td>
</tr>
<tr>
<td>261</td>
<td>Organ donation: the gift of life</td>
<td>R Cooney</td>
</tr>
<tr>
<td>262</td>
<td>In remembrance</td>
<td>R Cooney</td>
</tr>
<tr>
<td>263</td>
<td>Stepping into the breach</td>
<td>R Cooney</td>
</tr>
<tr>
<td>264</td>
<td>A drop in the bucket</td>
<td>R Cooney</td>
</tr>
<tr>
<td>265</td>
<td>Bad props</td>
<td>R Cooney</td>
</tr>
<tr>
<td>266</td>
<td>Keeping a lid on medical marijuana</td>
<td>R Cooney</td>
</tr>
<tr>
<td>267</td>
<td>Death knell for the death penalty?</td>
<td>R Cooney</td>
</tr>
<tr>
<td>268</td>
<td>IUDs and IUDon’ts</td>
<td>R Cooney</td>
</tr>
<tr>
<td>269</td>
<td>Reborn on the Fourth of July</td>
<td>R Cooney</td>
</tr>
<tr>
<td>270</td>
<td>Cheesed off at the FDA</td>
<td>R Cooney</td>
</tr>
<tr>
<td>271</td>
<td>All sound, no fury</td>
<td>R Cooney</td>
</tr>
<tr>
<td>272</td>
<td>Welcome to The Lancet USA</td>
<td>R Cooney</td>
</tr>
</tbody>
</table>
The underappreciated difficulty of the family caregiver for hospice patients

Larry Beresford

Hospice is a specialized service and a professional team mobilized to make the last stages of life as peaceful, comfortable and pain-free as possible for patients who have a terminal prognosis of six months or less to live. Most often this service is provided in the patient’s own home and in most cases the major provider of day-to-day, hands-on care is a family member or friend, who is designated as the primary caregiver. Hospice can provide skilled and compassionate support at a difficult time of life, but sometimes what gets lost is the burden on the caregiver.

“If people knew what it was really like, they’d be scared,” Parker Oliver says. The courage required, the physical burdens of moving a bedbound patient, providing sophisticated medical treatments such as injections, making decisions under duress, the whole emotional rollercoaster—these things often aren’t fully imagined when a family member takes on the role and responsibility of being a primary caregiver for a dying loved one, she says.

Hospice staff visit the home one or more times a week for one to two hours at a time, longer during times of medical crisis and with after-hours availability for emergencies. But the patient may need attention around the clock. Family caregivers are asked to do things that their doctor or nurse calls simple, yet they have no training in—skills that might have taken the professional years to master, such as giving an injection into the stomach. Meanwhile, the home is turned into a mini-hospital, with an electric hospital bed and varieties of other equipment.

Documenting caregivers’ experience

Parker Oliver has studied this issue by interviewing numerous family caregivers of hospice patients. Her work has documented the challenges of hospice caregiving, high rates of depression and anxiety, gender differences in caregiving, and variable access to support and support groups, including those offered online. A significant proportion of caregivers have negative health outcomes—including higher mortality rates—focusing on helping hospice teams do a better job of helping family caregivers, she says. “What we haven’t studied enough is how people in these circumstances find ways to cope.”

She also had first-hand experience caring for her husband David, who died at home in 2014, 3·5 years after a diagnosis of nasopharyngeal cancer and six months after he enrolled in hospice care. “It’s such a profound experience. It clouds your grief; it impacts your health. There is such intensity of involvement and then, poof, it’s done and you’re left with the images of the final days, whether they were peaceful or horrifying.”

In a 2016 first-person account published in the Journal of Palliative Medicine, “Bearing Witness to the Exit: Depriving Death of Its Strangeness,” she calls her experience “both the greatest challenge and the greatest honor of my life.” Her husband’s efforts to dispel the strangeness of his dying experience are also archived online.

Parker Oliver and her two daughters made plans to care for David. “We took shifts. Even so, I kept wondering whether I would be able to manage at the end. I can’t imagine being a caregiver all alone for a patient in the final hours.” Who ever thought a wheelchair could be so heavy, or an oxygen tank? she says. “I had to make hard decisions, such as: is it time to go to the emergency room? I understand the panic some families must feel, but nobody tells them how difficult it will be. I learned all about agonal breathing. They said it didn’t mean he was in pain, but that didn’t make the terrible breathing sounds go away.”

Because hospice professionals see dying so often, they can forget what it feels and sounds and smells like the first time it is confronted, she says. “They know how to say goodbyes, and they like to say to families: Tell your loved one that it’s okay to go. Well, we don’t want our loved ones to go. We’re just not doing a good job of schooling people in how to say goodbye.”
End-of-life doula helps with planning for the end

“In my experience, most people have absolutely no idea of what’s about to happen when they agree to care for a terminally ill loved one at home,” says Nada Frazier, who is trained as a spiritual caregiver, death educator and certified end-of-life doula with the Sacred Servant, collaborating with hospices in the Jacksonville, FL area and elsewhere. Like doulas for birth, end-of-life doulas supplement professional services with personalized attention.

“A lot of what I do as an end-of-life doula is planning and training—helping people to understand what’s coming so they’re not making crucial decisions in hot moments of crisis. For caregivers, it’s not only demanding and draining, but often very expensive,” she says, especially before hospice comes in to help.

Frazier believes that we need a conversation as a culture about end-of-life care. “Americans don’t like to talk about death. We as a society have not planned for it. We’re not structured for family caregiving as in past generations,” she says, when extended families often lived under one roof. The majority of Americans say they would want to die at home, and yet the majority doesn’t get to.

Parker Oliver encourages families confronting a life-threatening illness to get hospice care into the picture. It can provide a lot of help and it gives the patient an opportunity to talk to someone other than family. David was home-bound for three months, but his caregiving only got really hard in the last seven days. “You’d think I would have been prepared, with everything I know. But it’s so different when it’s your own life,” she relates.

“Those last seven days were also the most intimate for us,” she now says. “I’d never wish the experience away, but I wouldn’t have wanted it to go on for one more hour. It’s such a loving thing to do for someone you love, and I don’t think that’s recognized enough,” she says. “Don’t lose sight of the fact that these are precious moments. The difficult and challenging aspects of the caregiving will fall away in time, but you wouldn’t want to lose the beautiful aspects.”
Congressman Tom Reed serves as a hospice patient care volunteer

Larry Beresford

“She taught me how to live and how to die with grace,” he recalls. “I fought it. I said, ‘Mom, we’re going to fly all over the country to fight this.’ But she sat me down and said: ‘Tom, this is how it is. I want to spend the time I have left with you and your brothers and sisters and your new daughter,’” he tells *The Lancet*.

“Hospice is an issue that strikes closest to my heart. I went from wanting to fight my mother’s cancer to becoming an advocate for hospice.” And for the past four years, he has gone a step farther, serving occasional shifts as a hospice patient care volunteer for the Washington Home & Community Hospices, which operates a hospice inpatient unit in the nation’s capital.

Reed went through the customary hospice volunteer training. He often drives himself over to the inpatient facility from Capitol Hill, or gets a ride from a staffer. Then he spends time sitting and talking with hospice patients in the facility. Reed’s schedule as a Member of Congress requires some accommodation by the hospice, unlike volunteers who might serve a regular weekly shift. But otherwise, he says, he is treated like other volunteers, and he enjoys the same privilege of hearing patients share their life stories. The patients come from all over the world, he says, and many have amazing stories they want to tell.

“These are just precious moments. I am so humbled by it. Sometimes they ask what I do for a living, but I don’t lead with that. More often we talk about their family and their kids. Whatever they want, I try to do it, reading to them, sitting in silence, holding their hands, giving respite to their families, trying to bring comfort. One woman wanted her hair combed.”

Reed’s hospice training emphasized that patient care volunteers don’t provide medical services. The hospice team, comprised of nurses, physicians, social workers and chaplains, brings its professional skills to bear on coordinating and managing the patient’s care and medical needs in order to make the last stages of life as comfortable and peaceful as possible. While the professionals focus on solving problems that come up for terminally ill patients and their families, the volunteer provides an intangible extra layer of humanizing support. Volunteers come to the patient’s bedside without an agenda beyond being present in a spirit of compassion. Most importantly, they bring themselves.

In 2015 the National Hospice and Palliative Care Organization calculated, based on its 2014 National Data Set and Member Database, that 430,000 hospice volunteers in the United States provided 19 million hours of service, with three-fifths of that service “direct support” to patients and families. Most hospice patients are cared for in their own homes, where volunteers might offer rides to appointments, yard work, light housekeeping and respite for families, along with companionship. Others are cared for in the long-term care facilities where they reside, and some who can’t remain safely at home may end up in a hospice facility, where they might meet a volunteer like Reed.

A special kind of care

He is a conservative who, like most House Republicans, voted in 2017 for health care bills that would have repealed the Affordable Care Act. But he was a major advocate for the Palliative Care and Hospice Education and Training Act (PCHETA), a bill that passed the House of Representatives in late July and now is up for consideration in the Senate, where it has 33 cosponsors. PCHETA would fund the training of physicians and other health professionals in a variety of settings about hospice and palliative care.

Palliative care offers a similar kind of support to hospice for patients who have serious illnesses but are not yet terminally ill or hospice eligible. For both hospice and palliative care, workforce shortages can be an issue, which is why advocates have proposed training physicians across specialties in primary or basic palliative care, so that palliative care specialists could concentrate on the more challenging cases. PCHETA would also create education centers, academic career awards, research on improving the delivery of
hospice and palliative care and a national campaign to better inform the public about their benefits. Hospice in America has grown from its volunteer roots in the 1970s to a $17 billion industry with nearly 4400 hospices, two-thirds of them for-profit companies. It now cares for 1.4 million Medicare beneficiaries per year.

A new report from the federal Office of Inspector General has concluded that the US hospice industry is vulnerable to fraud, and that some patients have received poor and/or unnecessary care. Recent newspaper accounts have detailed instances where hospices failed to deliver promised services. Others are accused of enrolling patients too soon—or more precisely, without adequate clinical documentation in the medical record to justify a hospice-qualifying terminal diagnosis, even though the patient may still be very sick. OIG recommends strengthening the government's hospice survey process and giving it more authority to address poor performing hospice providers.

Reed says he is aware of these stories but reminds his colleagues on The Hill to keep them in perspective. “My experience in hospice has been that the positives far outweigh the negatives.” He points to studies showing cost savings and increased quality of life resulting from hospice and palliative care and says PCHETA could help drive improvements by building a better workforce and providing more professional training. He says he has been in contact with NHPCO and other groups about the need for more standards for hospice care. “I highlight the need for reform, but let’s not throw the baby out with the bathwater.”

An exhilarating opportunity
Reed says his colleagues sometimes ask him how he can handle the emotions of volunteering with dying patients. “I tell them I am exhilarated by the opportunity. I finish my shift reminded that the things we usually worry about in our day-to-day lives are minute by comparison to what people sometimes face. Another reason why I do this work is because some of these patients are alone and have no one to be with them at the end of their lives,” he says.

“So many people don’t understand what hospice is all about. Too often, we live in denial. As we face the looming demographic bubble [of aging Baby Boomers], it’s important to make sure that people are aware of hospice care and the need for advance care planning.” He would like to see a national conversation about the importance of not putting off end-of-life decisions until a crisis occurs. “I would encourage people to embrace this conversation with open arms.”
Bad batch: synthetic marijuana overdoses on the rise

Rebecca Cooney and Aaron van Dorn

As they attempted to intervene in the mass overdosing, some individuals were treated and then returned to park, where they needed to be treated after consuming K2 again. At least one individual was treated in three separate visits to the emergency room.

K2, also known as “spice” and “kush” is often referred to as a synthetic marijuana. It’s a human-engineered chemical compound similar to THC, the psychoactive ingredient in marijuana. However, K2 is often as much as fifty to one hundred times stronger than naturally occurring marijuana. Overdoses tend to cause increased heart rates, respiratory distress, severe bleeding and vomiting, and unconsciousness. The drug is often sprayed onto plant material and smoked, or it can be in a liquid form and inhaled through e-cigarettes or other vaporizers.

Given the swift and dramatic reactions, first had responders suspected that the K2 in the New Haven outbreak might have been adulterated with an opioid, likely fentanyl, leading them to apply more than fifty doses of naloxone, a drug that can reverse opioid overdoses. Three people were taken into custody as “persons of interest” and at least three arrests were made for possession of a controlled substance in connection to the overdoses. Although some of the victims treated tested positive for fentanyl, New Haven police ultimately determined that the K2 consumed in the park contained fubinaca, a potent cannabinoid agonist Fubinaca, which was abandoned by Pfizer in early development as an analgesic was designated as a Schedule 1 controlled substance in the USA in 2014.

A large spike in overdoses has occurred since 2015, including over fifty overdoses in Chicago in April (which lead to four deaths), and over fifty people in one Brooklyn, New York neighborhood. The US Food and Drug Administration made a statement last month underscoring the imminent public health threat and continued monitoring for contaminated synthetic marijuana products.
A layover in the land of The Lancet

Catarina Sacristán

With the current Editor on maternity leave in London, I landed a secondment gig as Acting Editor-In-Chief of The Lancet Haematology—a six-month experiment that was agreed upon by two of Elsevier’s premium brands: Cell Press and the Lancet group. As Editor-in-Chief of Trends in Molecular Medicine—a reviews journal—I welcomed this extreme change in handling manuscripts from basic biomedical and translational research, to those from pure clinical research, the Lancet group’s area of expertise. This task was fascinating, but also challenging. For instance, I had to heavily rev up my skills and knowledge of statistics. But in addition, I also needed to know and recognize, the various reporting guidelines that are required to publish different clinical trials and other clinical studies. Accordingly, the importance of flawless and accurate human clinical trial reporting—legal ramifications aside—was foremost on my mind.

Another aspect of the job that represented a new experience for me, was wearing the hat of social advocacy. Indeed, the drive with which the Lancet group of journals exerts its voice in terms of social awareness, politics and their relationship to clinical and scientific research, is unparalleled. As such, I thoroughly enjoyed writing various editorials for the journal, expressing, uninhibited, The Lancet Haematology’s voice on pressing questions such as new cancer immunotherapy advances, the tragedy of contaminated blood samples in transfusions, the high cost of drug treatments for hemophiliacs, the associations between sedentary lifestyles and risks of blood clotting, and other interesting topics. I am eager to apply some of the lessons learned, and experiment with expressing my editorial voice when ‘coming back’ to Cell Press.

From another angle, I was based in Cambridge, MA, and as such, working remotely and across time-zones with colleagues from the Lancet group proved to be logistically challenging, based on the existing workflow at The Lancet—an obstacle that may need to be reassessed in the future. Nevertheless, I pleasantly benefited from the degree of generosity and collaborative work that exists among editors of the Lancet journals. In this particular editorial model, being able to collectively discuss and decide on manuscript paths among all editors of the Lancet journals is a privilege: an editor’s dream for being able to maintain an overall sense of clinical relevance and ‘big picture’ scientific overview for published articles of this kind. The camaraderie at The Lancet, and the new connections made, endowed me with a sense of belonging, amidst a close family of editors, publishers, and staff, reminiscent of the ambience at Cell Press. Moving forward, by working with and learning from each other, I am certain that the ongoing collaboration between Cell Press and the Lancet group will solidify and fortify our competitive edge and expertise in publishing.

Check out Helen Brooks’ account of working at Trends in Molecular Medicine here.
Trump administration’s Medicaid work rules hit a snag

Susan Jaffe

The victory may expose a major flaw in the Trump Administration’s effort to reshape the Medicaid program, advocates say. But others claim the flaw is in the court decision.

Sixteen Kentucky residents who depend on Medicaid for medical care filed a class action lawsuit against Health and Human Services (HHS) Secretary Alex Azar who approved the state’s request to add work rules and make other changes to the insurance program. Medicaid, funded by both the state and federal governments, provides medical care for about 72 million low-income families and single adults, including millions of Americans who enrolled after the Affordable Care Act (ACA) expanded criteria for coverage.

US District Court Judge James Boasberg ruled June 29 the Kentuckians were rightly concerned that they could be among the 95,000 Medicaid recipients the state estimated would lose coverage due to the changes.

HHS “paid no attention” to such consequences, according to Boasberg, and instead focused on how work and community service along with other changes would improve health and well-being. HHS “never adequately considered whether [Kentucky’s plan] would in fact help the state furnish medical assistance to its citizens, a central objective of Medicaid,” he wrote in his decision. As a result, the HHS approval was “arbitrary and capricious.”

He invalidated the approval and ordered HHS to revise it. The agency could do so or file an appeal.

Although Kentucky’s Cabinet for Health & Family Services (CHFS) Secretary Adam Meier said the decision was wrong, the state will work with federal health officials “to quickly resolve the single issue raised by the court,” concerning the impact of work requirements.

“Able-bodied Kentuckians deserve to have a stake in their health and will benefit from the dignity that comes from career training, education, and volunteer opportunities that are available as part of Kentucky [Medicaid] community engagement program,” he said in a statement following the court ruling. “We will fight to preserve these opportunities for our citizens so that we can proceed with the only viable path forward for expanded Medicaid in Kentucky.”

The ruling came just two days before the work rules would have taken effect on July 1, as part of a federally approved pilot project intended to test how to improve the state’s Medicaid program by promoting overall health and wellness. Medicaid provides medical care for about 72 million low-income families and single adults, including millions of Americans who enrolled after the Affordable Care Act expanded criteria for coverage. The project was created under a provision of the Medicaid law that allows HHS to waive some legal requirements of the Medicaid program. It affected only those patients in the expanded Medicaid program.

Kentucky was among the first of nearly a dozen states to respond to the Trump Administration’s appeal to governors and state Medicaid directors to propose changes in the program to encourage those who gained coverage under the ACA to enter the workforce and improve their quality of life. Ultimately, work and other requirements added to Medicaid would create incentives for beneficiaries to move out of poverty and out of Medicaid, returning the program to its pre-ACA mission serving children, people with disabilities, pregnant women and impoverished elderly Americans. (For more details, see The Lancet’s March 24, 2018 World Report, “Trump Administration’s new direction for Medicaid.”)

A majority of beneficiaries in the Medicaid expansion already work, according to an analysis by the Kaiser Family Foundation. Most of those who do not work report that they are unable to do so because of illness, disability or caregiving responsibilities.
Although the court decision affects only Kentucky, it reveals a potential vulnerability in similar state Medicaid pilot projects that would impose work requirements and other changes, said Catherine McKee, a senior attorney at the National Health Law Program, which represented the Kentucky Medicaid patients in the lawsuit along with the Kentucky Equal Justice Center and Southern Poverty Law Center.

“The court was very clear here that the secretary has to consider how the project will advance the central purpose of Medicaid which is to provide medical assistance,” said McKee. A waiver or pilot project that takes away coverage for some beneficiaries would be contrary to what Congress intended when it created Medicaid in 1965 to provide medical treatment to those who could not afford it.

But Angela Rachidi, a research fellow in poverty studies at the American Enterprise Institute, said the judge’s conclusion that the project would harm beneficiaries is premature. The results of the pilot can’t be known before it starts, she said.

“The law allows waivers if they are going to increase the well-being of children and families,” said Rachidi. “The judge is presupposing something that there really isn’t any evidence for, which is why Kentucky proposed this demonstration project.”

In Kentucky, Medicaid beneficiaries could satisfy the 80-hour monthly requirements for what officials call “community engagement activities” by performing a combination of paid work, volunteer service, attending job training, or caring for an elderly parent, among other things. Whether those alternatives have similar health benefits as working have never been tested in the Medicaid context, said Rachidi.

The judge also assumed that if people lost Medicaid coverage, they also lost health insurance, said Rachidi. But after finding a job that includes insurance, for example, they would no longer be eligible for Medicaid.

Arkansas, Indiana and New Hampshire have received HHS approval to add work requirements in pilot projects aimed at improving health and well-being that resemble the one the federal court stopped in Kentucky. In those states as well as in Kentucky, people can lose Medicaid coverage if they do not document the required number of hours of work or volunteer time per month or do not submit the necessary paperwork proving they qualify for an exemption. They can also be locked out of the program temporarily or dropped from the program if they don’t pay premiums or report a change in eligibility.

Even if such rules are intended to improve overall health and well-being, the judge in the Kentucky case wrote that goal is not Medicaid’s primary objective. “This focus on health is no substitute for considering Medicaid’s central concern: covering health costs,” he wrote.

HHS is reviewing similar requests to modify Medicaid from Arizona, Kansas, Maine, Mississippi, Ohio, Utah and Wisconsin. And officials in Virginia and Michigan are preparing to submit requests.

For updates, check the Kaiser Family Foundation’s Medicaid waiver tracker.
An advance directive designed for living with dementia

Larry Beresford

But what if the future circumstance involved Alzheimer’s disease or another form of dementia—a terrifying but common diagnosis for older people? Some 5.7 million Americans are living today with Alzheimer’s disease and worldwide the number is expected to grow from 47 million in 2015 to 132 million by 2050.

The need to know patients’ values and preferences for medical care is greater with dementia—but so is the intimidation factor. “On the one hand, it’s something nobody wants to think about or talk about,” says Dr Barak Gaster, a primary care physician and medical educator in Seattle, Wash. “But it’s on many people’s minds, especially if they’ve had first-hand experience with a loved one with dementia and know what they wouldn’t want for themselves.”

Dr Gaster has developed a new process for expressing wishes and preferences about possible treatments for such a future state of progressive loss of brain function—a kind of living will for dementia. He says that his patients, to whom he recommends it, and those who have downloaded his Advance Directive for Dementia, express gratitude for its help in getting a handle on something that they already worry about—even though actual need may be far in the future.

“About four years ago, I realized that dementia was really the hardest issue we as primary care physicians face, and that our patients face. So I developed a program to train primary care doctors to do a better job of identifying dementia and helping their patients and families navigate through it.” Even though Alzheimer’s is not curable at this time, important things can be done based on a diagnosis, he explains. For example, “just aligning care and treatment better with what people say they want.” Other opportunities might include retiring from driving, avoiding harmful drug interactions, and doing legal or financial planning.

“As I started thinking about what primary care doctors could do to better engage with this disease, I looked at our existing advance directive approaches and forms and realized that they don’t apply to dementia patients, who might live for years following a diagnosis.” Yet dementia is the leading reason why a person might lose the capacity to make decisions about their own medical care, such as whether they would want to be hospitalized, or have a feeding tube, or even get antibiotics for pneumonia. These could prolong a life that one might not want to prolong after losing the ability to communicate or recognize loved ones.

Gaster’s document might be helpful in saying no to burdensome medical care in situations where many would not want it to continue. But it also offers people the option to specify more medical intervention, not less. This approach does not involve medical aid-in-dying, which is a legal option in seven states but only applies to patients who have the mental capacity to choose it. Patients with advanced dementia don’t qualify for aid-in-dying.

The point of diagnosis may be too late

“In working with his own patients, Gaster discovered that even the earliest possible diagnosis of mild dementia might be too late for wrestling with the complex issues involved in planning for future medical care. His document offers a range of possible treatment options for mild, moderate or severe dementia, encapsulated in the following choices: living as long as possible; receiving life-prolonging care but not cardio-pulmonary resuscitation; receiving care only in one’s current residence, not in a hospital; and receiving comfort-oriented care only. Now he shares the advance directive with his patients at the time of their first annual physical assessment under Medicare when they turn 65 and enter the age bracket where a future diagnosis of dementia might not be far-fetched.
Subhan Schenker, who co-directs a meditation center in Seattle, is a patient of Gaster and downloaded his advance directive form. “When I first heard about advance directives for dementia, I was very interested. I am 72, and I have seen that the aging process has its benefits, if there is a foundation of deeper understanding,” such as through a meditative practice. Schenker was a criminal lawyer in Baltimore before meeting a teacher of active meditation in India in 1979 and discovering his affinity for the practice.

“An incident that brought this issue home to me recently was when I was taking statins for angina and started having short-term memory issues as a consequence of the medication. So I changed to natural alternatives and my short-term memory returned. But when I was losing my short-term memory, I was able to use the experience of just watching it in a meditative state, rather than freaking out.”

Schenker filled out the form developed by Gaster and shared it with his doctor, his wife and his daughter. “I’m not someone who wants life at all costs. I understand clearly that quality of my life would be a factor in what I would want. If I were in a state of mental deterioration, I would be pleased to get comfort-oriented care, but I wouldn’t want to live as long as humanly possible after I lost the ability to communicate,” he explains. “If I were sitting outside of myself at that point, I’d say: You know what? It’s time to move on.”

The legal questions are less important

Gaster’s form is one of several documents developed recently to help people think about and capture what would be important to them were they to develop dementia. The Conversation Project, which promotes advance care planning conversations nationally, has an Alzheimer’s/Dementia Starter kit. End-of-Life Washington has an Alzheimer’s Disease and Dementia Mental Health Advance Directive, and End of Life Choices New York has its Advance Directive for Receiving Oral Food and Fluids in the Event of Dementia.

For Gaster, the legal questions are less pressing than just getting people to think and talk about what would be important to them while they are still able to do that. His directive does not include a place for a witness or notary, which can be a barrier for some people. It could be challenged legally if there were a family conflict. But most legal advance directive forms permit a personal addendum, for which his directive qualifies.

“I am the chair of the Advance Care Planning Committee at the University of Washington, and the reality is that standard advance directives aren’t that useful in most situations,” Gaster says. They are designed to address narrowly defined situations like coma, persistent vegetative state or terminal illness—rather than the more common experience of dementia.”

He urges people of Medicare age to download, carefully review and fill out his form. “Then, absolutely, talk to as many family members and friends as possible. Make copies; give them to your family and your doctor. If you don’t know what kind of medical care you’d want, then who is the person you would want to designate to make these decisions for you? Perhaps the most important thing is to make sure you have a clearly identified health care proxy.”
Sepsis: a prolific but under-recognized mass killer

Ray Cavanaugh

This figure is more than the number of annual US deaths from breast cancer, prostate cancer, and AIDS combined, reports the Sepsis Alliance—an organization founded in 2007 which seeks to “revolutionize public awareness of sepsis and to reinvigorate the sort of healthy respect for bacterial infection that was present before the advent of antibiotics,” relates Steven Q Simpson, MD.

“We are literally in the infancy of educating the general public (and perhaps in the toddler phase of educating most physicians) that sepsis begins much earlier—and that it should be diagnosed much sooner—than when it causes refractory hypotension and multiple organ failure,” says Simpson, who is the Chief Medical Officer of the Sepsis Alliance and Acting Director of the Division of Pulmonary and Critical Care Medicine at the University of Kansas.

Sepsis was identified as the most expensive condition for inpatient hospital stays in 2013, when it costed the US healthcare system about $24 billion. Simpson relates that the current annual cost of sepsis is estimated at more than $27 billion, and that sepsis accounts for the largest percentage of hospital stays, outside of those involved with giving birth.

Despite its prevalence, sepsis can be tricky to diagnose, as it develops quickly and may be confused with other conditions. There is no clear timeframe for how long it takes for sepsis to become critical. Aside from the particular patient’s immune system, sepsis rapidity depends largely on the virulence of the pathogen.

“The so-called ‘flesh-eating’ bacteria produce a toxin that destroys normal cellular structures under the skin and allows the infection and sepsis to progress very rapidly,” says Simpson. He adds that, “meningococcus, a common cause of meningitis, may progress overnight to dire illness.”

Septic mortality can vary significantly within the US, with some states recording several times the rate of others. Such regional differences have been linked to levels of poverty, lack of health insurance, and diminished accessibility to good medical care. Simpson cites another possible factor as the “lack of education around recognizing and seeking treatment for sepsis.”

“The so-called ‘flesh-eating’ bacteria produce a toxin that destroys normal cellular structures under the skin and allows the infection and sepsis to progress very rapidly,” says Simpson. He adds that, “meningococcus, a common cause of meningitis, may progress overnight to dire illness.”

Septic mortality can vary significantly within the US, with some states recording several times the rate of others. Such regional differences have been linked to levels of poverty, lack of health insurance, and diminished accessibility to good medical care. Simpson cites another possible factor as the “lack of education around recognizing and seeking treatment for sepsis.”

Because of the lack of public knowledge about sepsis, a major part of the Sepsis Alliance’s public outreach is its sepsis symptom acronym, which was created to “help everyday people learn and remember the symptoms of sepsis,” says Simpson. “A lot of work went into distilling the primary symptoms and putting them together in an easy to remember and understand form.”

The Alliance reports that incidence of sepsis is rising by 8 percent each year. Part of this increase is actually a good sign, as Simpson points out how improved recognition of sepsis has led to more diagnoses. Another factor is that the population is aging and “with advancing age comes impaired, possibly dysregulated immunity and higher susceptibility to infection.” Simpson cites additional factors as an increase in bone marrow and solid organ transplants, as well as a rise in incidence of diabetes and related complications.

Infections of the gut, lungs, skin, and urinary tract are especially at risk of leading to sepsis. Though the very young, the very old, and those with chronic disease are more susceptible, sepsis can affect anyone regardless of age or health.

And even persons who survive it can be impacted severely: sepsis results in about 14 000 amputations each year. Simpson relates that sepsis survivors have an elevated risk of new cardiovascular events, such as strokes and arrhythmias. “Survivors also face an increased risk of readmission for acute renal failure within 90 days of hospital discharge.” He adds that as many as one-sixth of survivors experience “moderate to severe cognitive dysfunction,” which includes diminished ability to concentrate, decreased memory, and impaired decision making.

In order to improve the septic knowledge of US health providers, the Sepsis Alliance has been hosting monthly
educational webinars. The Alliance has also designated September as Sepsis Awareness Month.

The Alliance is now launching the Sepsis Coordinator Network, which will offer a peer-to-peer forum where professionals can ask questions when facing a challenge. “This will be the first program of its kind dedicated to highlighting evidence-based best-practice resources for managing sepsis in a variety of facility types,” relates Simpson.

In his view, “Every potential patient out there—which is all of us—needs to understand that sepsis is a medical emergency and needs to know some of the cardinal signs that it might be present in them or in a loved one...Public awareness is the number one issue in sepsis care right now.”

The importance of improving such awareness is hard to overstate: Prompt diagnosis and treatment could eliminate as many as 80 percent of sepsis deaths.
Besieged EPA Chief still committed to Trump agenda

Susan Jaffe

But in separate hearings held by the congressional subcommittees that oversee EPA, Pruitt dismissed the investigations as politically motivated.

“Those who attack the EPA and attack me are doing so because they want to attack and derail the president’s agenda and undermine this administration’s priorities,” Pruitt told the congressional panels two weeks ago. “I am simply not going to let that happen.”

The first investigation to be completed found that the $43 000 soundproof booth Pruitt had installed in his office to ensure privacy for classified and confidential telephone conversations violated federal spending rules, according to the General Accountability Office, the independent investigative arm of Congress.

“Even if he could make these scandals magically disappear, there’s no reason to think he would be right for his job,” said Jon Devine, a senior attorney and director of federal water policy at the Natural Resources Defense Council, an environmental advocacy group with three million members. “He has rushed out half-baked and ill-informed rules and proclamations that routinely flout the law.”

But Republicans were eager to praise his achievements during the hearings, and encouraged him to keep at it.

“You’re not the first person to be the victim, for lack of a better term, of Washington politics,” Rep. Joe Barton of Texas told Pruitt at the US House of Representatives’ Energy and Commerce Committee’s environment subcommittee. “You got picked to be the EPA administrator because of the service you provided for the great state of Oklahoma [as attorney general] in fighting some of the Obama administration radical clean-air policies.”

Barton commended Pruitt for successfully urging President Donald Trump to withdraw the US from the Paris climate change agreement, and for proposing an end to what Republicans have called EPA’s reliance on “secret science.” Under this proposal, EPA could base pollution limits only on scientific studies that revealed their methodology and data.

“This is a very troubling proposal because it would either censor science or violate patient confidentiality,” said Paul Billings, vice president for advocacy at the American Lung Association.

It would also block EPA from using studies for rule making that have documented the “dangerous health implications” of air pollution, said Rep. Raul Ruiz, a California Democrat. Among the studies that could be excluded is a Harvard School of Public Health examination of air pollution in six cities that supported fine particulate matter limits issued under the Clean Air Act. Eight state attorneys generals have urged Pruitt to drop the proposal.

The congressional panels were supposed to focus on President Donald Trump’s budget request for EPA, which would cut the agency’s spending by nearly $2 billion—or 30 percent. Such a steep reduction would shrink EPA’s workforce by nearly 4000 employees said Betty McCollum, a Minnesota Democrat. It also raised concerns even among Trump’s fellow Republicans. “While some reductions may be in order, cuts of this magnitude put important programs at risk,” said Rep. Ken Calvert, the California Republican and chairman of the Appropriations subcommittee that oversees the EPA budget.

Pruitt also defended EPA’s a preliminary evaluation that criticized the Obama Administration’s effort to reduce greenhouse gases by improving automobile fuel efficiency. The new emission limits were announced 2012 and take effect in 2022. EPA has determined that the standards “were too ambitious and didn’t meet the facts and data that we currently have at present,” Pruitt explained.

Last week California and 17 other states sued EPA to stop the agency from revising those limits.

Republicans also praised Pruitt’s efforts to relax Obama administration pollution restrictions on water pollution...
issued under the Waters of the United States rule, which he said contradicted the intent of the Clean Water Act.

Responding to the committees’ questions, Pruitt said he did not approve spending $43,000 for the soundproof booth installed in his office. Had he known, he would not have approved it. He also denied responsibility for large pay raises for close aides that the White House opposed, and said he was unaware of retaliation against employees who questioned his spending and management practices. And he reiterated that EPA ethics attorneys found nothing wrong with his $50 a night condo rental.

After criticism of his first-class airfares, Pruitt reminded the committees that he has promised to purchase less expensive coach-class tickets for future travel. But when California Democrat Anna Eshoo asked if he would reimburse the government for the extra cost, Pruitt was reluctant to do so, saying his travel office and security team determine his travel arrangements.

“I’m confident that these investigations will affirm what I have come to believe is true, that you are unfit to hold public office and undeserving of the public trust,” said Pallone. “I just think that every indication we have is that you really should resign.” Pallone is one of 131 House members, along with 39 senators, who support resolutions introduced in both chambers demanding that Pruitt step down.

Although Pruitt has so far resisted calls for his resignation, three close aides announced their departure within a few days after his April 26 congressional testimony. His communications director, the head of his security detail, and the director of the Superfund toxic waste cleanup unit—a former banker who is banned from working in the banking industry—have left the agency.

Pruitt returns to the Capitol next week to testify before the Department of the Interior, Environment and Related Agencies subcommittee of the Senate Appropriations Committee, POLITICO reports. Although the Senate hearing is intended to review the EPA budget request, Pruitt is likely to face another round of ethics and spending questions, and demands for his resignation.
AAN issues new guidelines on disease-modifying therapies in MS, including switching, stopping and pregnancy

John Otrompke

A new practice guideline published by the American Academy of Neurology on April 23 attempted to sort out recommendations among an explosion of drugs for multiple sclerosis which are considered to be disease-modifying therapies (DMTs) which have been approved in recent years. The guideline, which discussed clinical questions such as choice of therapies, as well as strategies including switching or stopping DMTs, was published during the Academy’s annual meeting in Los Angeles.

The guideline discussed 17 FDA-approved medications, and also made a weak recommendation regarding off-label use of six other drugs. (Patients may also have to take other drugs to treat their symptoms, which DMTs are not intended to address).

The cornucopia of new medications, at least seven of which have only been approved since 2010, has its origin in immune strategies.

“If you trace it back to the very first FDA-approved medicine, interferon in 1993, the scientists knew MS had something to do with the immune system,” said Alexander Rae-Grant, MD, professor of medicine at the Cleveland Clinic Lerner College of Medicine, and lead author on the article.

Another older drug, glatiramer acetate, was approved in 1996. “It is like a molecular mimic; it confuses the immune system into attacking the medicine, because it looks like myelin,” the substance that surrounds nerve cells, said Rae-Grant. “We know everything there is to know about that medicine.

“Since then, we’ve become much more targeted in our approach, and we’ve adapted some medications used in cancer populations, as well as rheumatology,” he added.

Head-to-head clinical trials urgently needed

But much less is known about some of the newer medications, leading the members of the guideline committee to make recommendations about the need for clinical trials in areas like comparative effectiveness and pregnancy-related issues. And prior to just last year, with the approval of ocrelizumab, there was no DMT for the primary progressive form of MS. (A classification system for several varieties of MS was revised in 2016).

The uncertainty some clinicians may experience is illustrated by the voluntary withdrawal from the market of one drug, daclizumab, which was initially referred to in the guideline, according to Rae-Grant (daclizumab was first approved in 1997 for transplant patients).

Neurologists are hopeful that the new therapies will be life-changing for some patients. Perhaps the most feared consequences of MS are severe disability and a somewhat reduced life expectancy.

“It used to be that about half of the patients would not be able to walk independently after about 25 years. But we don’t have a lot of long-term data on the MS population,” noted Rae-Grant.

“If we go back to earliest therapies, some cohorts have been followed for 20 years. But some of the new DMTs have only been available for two-to-five years, and disease progression is typically measured by relapses which occur over two to three years,” explained Ruth Ann Marrie, MD, PhD, professor at the University of Manitoba in Winnipeg, and co-author on the article. “So it’s difficult to say what a new therapy is going to do for somebody 20 years from now.”

But neurologists are hopeful that patients will experience some long-term benefits, including a delay of progression. In determining how to do that, the experts debated questions like whether to prescribe the strongest therapies first, or to switch to them if less potent drugs stop working.

“One of the key messages of the guideline was to initiate DMT early, even before a formal diagnosis of MS is made, as long as we’re sure that we’re dealing with someone who has demyelination,” said Rae-Grant.

However, doctors may choose not to start with the most potent therapies first, for reasons like cost issues, as well as side effects, such as a brain infection called progressive multifocal leukoencephalopathy (PML).

“It is certainly a major effect, but we have a sophisticated antibody test. And we know that if they had chemotherapy before, the risk goes up,” said Rae-Grant. The DMT that carries the highest risk for PML is natalizumab, which is associated with a risk of PML of about one in 300, compared to one in 10,000 for those prescribed other DMTs, he said.

Experts also debated whether it is sound medicine to stop treatment with DMTs in patients with some forms of MS who stop getting benefit from therapies and can no longer walk, according to Rae-Grant.
Point of view
Educating physicians won’t solve burnout

Special Guest Blogger

Nearly two thirds of US doctors say that they currently feel burnt out, depressed, or both. In their career, the risk that a physician will experience burnout is almost a certainty. In and of itself, this is a concern—physicians deserve support and well-being as much as anyone. But burnt-out physicians are also expensive for institutions to replace and put patients at risk.

The proverb ‘Physician, heal thyself’ appears to be the strategy of many healthcare institutions looking to solve physician burnout. Institutions often take an informational approach to encouraging behavior change, providing courses and resources about what healthcare professionals should do to “heal themselves”. Recommendations like getting more sleep, taking more breaks throughout the day, going on vacations, exercising more and laughing more are all desirable behaviors, but physicians’ cognitive biases and the environment they work in can make following through almost impossible. Simply knowing and wanting to do the “correct” behavior is rarely enough to change behavior, and fails to acknowledge the systemic barriers to achieving it.

We see the limits of education in inducing behavior change in most industries: When evaluating the efficacy of a financial literacy program, researchers found that any change in financial behavior is effectively eroded 18 months after an information-based intervention, even when the intervention was over 24 hours long. In fact, sometimes giving people more information can backfire: When people concerned about side effects of the flu shot learned that it couldn’t cause the flu, they became less willing to get it.

Leveraging behavioral economics on an institutional level

To encourage positive behavior change in physicians, addressing the institutional barriers that keep them from behaving in the desired way is paramount. Taking the science of how people actually behave into account will help avoid inefficient and costly initiatives. For example, Kaiser estimates that 41% of large companies who offer incentives for wellness spent more than $500 per employee per year. These programs are a huge cost for the institutions that offer them, and most of the time they do not achieve the lofty goals they promise. While financial incentives can help encourage one-off behaviors like screening or vaccinations, they are rarely successful at bringing about the complex and sustained behavior change required to fight burnout.

So, where should institutions who are serious about designing an environment that encourages physician wellness begin?

Make it easy and motivating

The first thing to do is acknowledge that changing behavior is challenging. Organizations need to get very specific about defining the key behaviors they want to encourage, then look at the environment in which they happen and make it as easy and motivating to do the behaviors as possible. Too often, the broad suggestions to combating burnout—get more rest, exercise—are not grounded in the pressured, busy life of a practicing physician. The path of least resistance should be the behavior you want to encourage.

Remember that small changes can have a large impact. Say you want physicians to take more breaks during their shifts. What are the barriers that currently keep them from doing it? If the workload is so high that the care team has to constantly run between patients, you probably need more staff. How can you make it more motivating to take breaks? Benefits that are immediate and hedonic, such as adding a massage chair to a quiet area of the break room, can often be surprisingly effective at motivating behavior.

Stick to goals

While the onus of creating environments that make it easy and motivating for physicians to practice self-care should be on institutions, there are exercises physicians can do to help themselves stick to goals. For example, one of the practices recommended in the Medical Professionalism Project is called implementation intentions. Implementation intentions clarify the when, where, and how of following through on your goals by making specific “if–then” plans ahead of time. When practiced, some argue that they can help close the gap between education and practice through commitment and strategically automating the behaviors you want to do.

There are many approaches health care institutions can take to address barriers that keep physicians from taking sufficient care of their long-term well-being, from education, to nudges to social and financial incentives and disincentives, to stricter rules and policies. When each approach
should be used depends on the specific constraints of a situation, as well as the behavior you are trying to encourage. But if institutions want to help physicians turn their intentions into action, they need to do the same: Actively address the barriers in the system and create opportunities that support behavior change.

Ingrid Melvaer Paulin is a Senior Behavioral Researcher at Duke University’s Center for Advanced Hindsight, where she works on applying insights from behavioral economics to the design of products and services that improve people’s health, wealth and happiness. She is also a Project Manager for the Medical Professionalism Project—@medprofproject.

Clare Marash is a writer and producer. She is part of the team at Salty Features, and independent production company that seeks to create media that is thought-provoking, vital, and enhances the world. She is also a Project Manager for the Medical Professionalism Project.

Rebecca Ortega, MHA, is the Director of Strategic Development for the Center for Interventional Cardiovascular Research and Clinical Trials at the Icahn School of Medicine at Mount Sinai in New York. She was previously the Director of Education at the Duke Clinical Research Institute.
Is emotional intelligence the missing link for medicine at the end of life?

Larry Beresford

Ezekiel Emanuel of the Department of Medical Ethics and Health Policy at the University of Pennsylvania has argued that emotional intelligence has been shortchanged as an essential skill for physicians and as a trait to encourage in selecting future physicians. This is particularly true in palliative and end-of-life care settings, where emotions run rampant and the professional is called to help guide the patient and family’s turbulent journey.

Emanuel says emotional intelligence in medicine is manifested in good listening, problem-solving skills, trust building, helping patients learn how to change their behaviors to improve their health, and leading a multidisciplinary team.

The customary focus only on general intelligence and academic pedigree, defined by GPA and Medical College Admissions Test scores, in choosing the best candidates for medical school is misguided, he adds. It maintains that it can give an incomplete or inaccurate account of the potential for a student to grow into an excellent, caring physician.

Emotional intelligence, one of nine distinct kinds of intelligence identified by psychologists, is defined in terms of the ability to manage emotions and interact effectively with others—using emotions to enhance thought. According to Emanuel, high EQ translates into better sensitivity to the moods and temperaments of others, displaying empathy, and the ability to take perspective.

What does palliative care say?

We asked leaders in the palliative care field about emotional intelligence, and they agree that it is important—and is being taught in settings like palliative medicine fellowship programs. “Clearly, there are people who are more gifted at recognizing emotions in other people and more able to respond to emotional data in their patients. That’s what we’re talking about,” says James Tulsky, chair of psychosocial oncology and palliative care at Dana-Farber Cancer Institute in Boston, Mass. “But these are skills that can be acquired and taught. My own experience training hundreds of doctors would tell me that it’s probably easier to teach how to respond to situations than how to recognize emotions.”

Tulsky is a cofounder of VitalTalk, a nonprofit evidence-based curriculum and communication training program that disseminates skills in having effective, empathetic and honest conversations with patients. The VitalTalk approach starts with observation, he says. “They need to see what good communication looks like—and then, going deeper, to deconstruct how it was done. Then they need to practice these techniques through a structure we have created, first in a protected setting with simulated patients, and then in the real world.”

A VitalTalk course might involve a full day of didactics, observation, simulations working with actors and feedback from trainers, adds cofounder Anthony Back, professor of medicine at the University of Washington. Palliative care has a lot to teach to the rest of medicine, because it has been grappling with these issues and paying attention to communication with patients, he says. “It’s not about being nice, but making better decisions. These are high-stakes, high-impact decisions. The treatments have very significant side effects. Patients need to be informed in a way they can hear,” he says.

“The way we get into situations where someone with a life-limiting illness might say: ‘I want everything done’ is often because the doctor lacked the emotional intelligence to know how to communicate to the patient what’s really going on.”

Can emotional intelligence be taught to doctors?

Other examples of communication skills training for doctors include the Continuum Project at Massachusetts General Hospital (see “Doctors learn how to talk to patients about dying” by Melissa Bailey in Kaiser Health News, February 12, 2018), which trains primary care physicians how to talk to patients with serious illness about their goals and values. Patients who talk to their doctors about their values and goals have better quality of life, fewer hospitalizations, more and earlier hospice care, and higher satisfaction.

The Continuum Project uses the Serious Illness Conversation Guide created by Atul Gawande and Susan Block for Ariadne Labs, with a script in sample language printed on a laminated card. Role-plays with professional actors teach participants to step back from day-to-day problem solving and talk about patients’ understanding of their illness.

Oregon Health and Sciences University (“Oregon medical students face tough test: talking about dying” by JoNel Aleccia in Kaiser Health News, March 13, 2018) is also
working to make sure medical graduates know how to deliver bad news with sensitivity and professionalism. It uses a revamped medical school curriculum with new lessons in communications, videotaped simulations with actors, and testing of fourth-year students on their mastery of these skills.

**How should it be taught?**
The best way to teach emotional intelligence is for the institution to truly value it, says VJ Periyakoil, Director of the Stanford Palliative Care Education & Training Program and Fellowship Program at Stanford University Medical Center in California. “You need attendings and the other influencers of future physicians—the people who evaluate them—to demonstrate it to trainees. It’s best taught on the hospital floor,” she says. “At Stanford, we emphasize didactics, attitudes and skills, and we test on all of those.”

Periyakoil resists an either/or dichotomy for IQ and EQ in medicine. “I’d want both from my doctor if I were a patient.” Palliative care has sometimes been viewed as a countercultural movement in medicine, she says. “But it’s starting to percolate into the larger system. The risk we face is that we don’t want to be thought of as just the doctors with emotional intelligence, where you call other doctors to do the smart medicine and then call palliative care to come and hold the patient’s hands.”

In fact, palliative care practitioners sift through a large amount of data from different realms in order to synthesize recommendations for the most appropriate course of care for a given patient. “Palliative care demonstrates the highest level of IQ and EQ— the ability to listen well, to be patient, kind and compassionate, present in the moment,” she says.

An exemplar of this kind of emotional intelligence is BJ Miller, a palliative care physician at the University of California San Francisco. He went to medical school after a horrific accident in college caused him to lose three of his limbs. That’s when his personal relationship with death began, Miller relates in a powerfully down-to-earth Ted Talks lecture, “What really matters at the end of life” which has been viewed 7 million times.

The world of emotional intelligence has to do with recognizing feelings, he says. “It’s not stuff of algorithms or artificial intelligence, at least not yet.” It’s important to pay attention to intuition, gut feelings, what’s going on inside your body. “I try to protect my students’ emotional intelligence more than actually teaching it. Unless you learn how to protect your impulses toward vulnerability over things you can’t control, medicine can chip away at them,” he says.

“As doctors, we have outsized skill and power to affect people and be deeply, profoundly involved in the lives of strangers. Everything you say and do is woven into a story that is very meaningful to someone else.” A certain degree of self-awareness can help to keep these things in proportion, with awareness of the limits to the professional role.

“Can we teach it? We can call these things out, not just relegating emotional intelligence to ‘bedside manner.’ Just as we reward medical students for differential diagnoses, could we reward them for always sitting down at the patient’s level before talking to them, or for asking open-ended questions in interviews, or for performing acts of kindness to patients?” Miller says. “Whatever it is called, it’s teaching basic humanity—and that is gold.”
Welcome to the second installment of In the Open, a special collaboration with The Lancet United States of Health Blog focusing on transparency and data sharing. As children, we’re taught a lot about sharing and learning to play well with others. What happens when researchers are in this proverbial sandbox? In this episode, we’re going to begin to pick up some of the themes around being quote “good” data sharers? Are there characteristics or conditions that we can identify that lend to positive outcomes in data sharing. And, importantly, how might those translate into incentives for researchers? I’m Rebecca Cooney from The Lancet joined again by my cohosts Casey Greene and, up first, Brian Byrd, and our special guest Fabio Zanini.

Brian Byrd: Thanks, Bek. So, as I mentioned in the last podcast I’ve personally been working through the questions around how one shares data effectively. How to actually implement that in my own work and I found it’s not a trivial question. So to illuminate some of the considerations I’ve asked a guest to join us for this second episode for In the Open. So Fabio Zanini is the inaugural winner of the research symbiont award for excellence in data sharing for an early career health researcher. So let me explain what the Research Symbiont Awards are. Access Zanini’s award-winning data sharing website here.

This is a set of awards I founded with Casey Greene. Casey had already started a different award to recognize people who’ve reused shared data in an exceptional manner (the Research Parasite Awards). And that’s clearly a very important activity to reward. Casey and I ended founding the Research Symbiont Awards so that people who share data beyond what’s typical in their field or what’s expected can be recognized for those efforts as well. I had a chance to chair the awards’ committee and in that role I was incredibly fortunate to work with a diverse and talented group of people in judging the entries including Amanda Haddock who’s a passionate advocate for childhood cancer research, to the extent of founding her own foundation. Rebecca Riggins who’s a researcher at Georgetown University. Leslie Vosshall who’s a researcher at Rockefeller University and Ethan Weiss who’s a researcher and a physician at UCSF. And the entries for the Research Symbiont Awards were incredibly impressive.

It was a competitive competition. We judged the entries on criteria that included how inviting the data are for research. For example, how well annotated were the data, and you can read more on the researchsymbionts.org website if you’d like to read more about the criteria that we used to judge the applications. And so we gave the first annual research symbiont awards in January 2018 and we’re lucky to have the winner with us for the podcast. And what I wanted to start with is just asking Fabio what did you do? Tell us about the work you did that won the award and then I wanted to explore more about what motivated you, what challenges you encountered and how you overcame those challenges.

Fabio Zanini: Brian, first of all thanks for having me here, I am honored that you of course invited me and so the work that for which I was given the award is a web application that shares my research that I’m doing my PhD time about infection by the human immunodeficiency virus or also known as HIV. And the research idea was to get several human subjects infected for a long time with HIV and started the type of viruses that these people inside their bloodstream to understand which strain of the virus are thriving in a person and which other ones instead have a hard time and the analysis resulted in something typical for this type of endeavor, which is several publications and I used it for my Ph.D. thesis but toward the end of grad school it was obvious to me that the audience of who I was targeting with this type of research was composed of two components.

The first one was more computer people who are experts and analysts and those who would understand typically the manuscript that came out and even the raw data, but then there was a broader audience, especially of people with a medical background who were interested because of course these types of problems is important for medical research and in the clinic but had for them, it was not easy to interface or to communicate with people like me who had a background mostly in computer science. So I created this web application and website that you can browse and allows you to see many types of visualization of the data that make them a lot more intuitive whenever you want to understand roughly how these viruses are changing in people’s bloodstream without digging into the nitty gritty details or the details of the computer code, etc.

And so when I created the website for the first time it was very rough, but I was fortunate to collaborate with incredibly helpful and great researcher from Sweden, Jan Albert, who was the medical side of the collaboration and the first
time my advisor, Richard Neher showed the website to him, we were really impressed with how much more we could communicate and we could plan ahead with him compared to before. Because suddenly this more intuitive way of sharing the data with him made it clear, made it a lot easier for us to discuss problems and plan ahead. And that was quite a discovery because I certainly enjoyed putting together some computer code for fun. But I wasn’t expecting that it would turn out to be so important.

And then, that made me think that maybe really this current process of doing a lot of research in your lab and then everything turns into a single paper or publication, there’s only a very partial way of sharing your results with the community. And that maybe websites and this more intuitive and visual ways of sharing the data can become quite crucial, actually, to reach audiences that are relevant but you would totally miss if you were just doing a paper.

Brian: What other motivations did you have, Fabio, beyond wanting to unlock the data for clinicians? Were there other reasons that you wanted to take the time to do the process of making the website and sharing this information?

Fabio: Well, the main motivation, of course, was that I wanted my data to be available to the clinicians. But there is also kind of second level of motivation which is that the technologies for creating this website and these more intuitive visualizations are out there now. And this wasn’t the case 10 years ago, or 15 years ago. But thanks to the enormous progress of the fast internet and the technologies brought by especially big companies, like Google and Facebook, etc. Now we are living in a time in which really the interactive approach towards datasets and scientific data is taking over from the type of manuscript, old school type of reporting.

And so all these technologies for exploiting the web for sharing data are out there and I was curious and thrilled to realize that although they’re mainly used for by companies for marketing purposes, there is an enormous potential that researchers could leverage for making their results more accessible. And so, in a way, mainly I was interested in showing my data but I was also interested secondarily in how much can we use these technologies for...how difficult would it be for anybody like me who has no background in web development to reach a point of being able to actually make a website and share it?

And the answer is that it’s actually quite easy. And so from that experience, I learned that I would like to encourage everybody who has some computer background and a dataset that they really think is important and would like to share, to take the pledge and try and make a web version of the dataset because really by now, this is quite easy and quite powerful.

So, that was, I think the second reason. And then, of course, there was some type of more prosaic thinking, if you wish. Which is that all that type of research was, in the end, supported financially by the European Union, so by a public agency. And so, in a way, after you’ve worked five years using taxpayers money to support your work, I was thinking and I’m still of the same opinion, that it’s just fair to try and reach out the public as much as possible and instead of closing your results into this, in a way, very cryptic manuscripts that are only targeting a very specific niche of the scientific community.

Brian: Thanks. What a great answer. I’m curious to know what Casey’s thinking when he listens to this?

Casey: Yeah, so I think from my point of view, as a sort of re-use person, I think there’s a couple important considerations. So, one is how usable the data are for an individual who wants to come in and poke at the dataset. So I think the types of web interfaces that Fabio is talking about are perfect for that and they can really let you get an intuitive idea of what’s going on there.

And I also think there is value in well structured and shared data from a machine learning point of view. Particularly for people who may want to integrate multiple datasets together. And I think it’s worth bringing up this idea of fair data so data that are findable, accessible, interoperable and reusable. I think the web form of data really makes them findable and accessible and providing them in well-structured ways that are maybe not as usable through the web, but it also helps to make interoperable and reusable.

So I think there’s a lot of complementarity to a web interface and then a really well structured downloadable dataset.

Fabio: Sorry, if I may add to what Casey was saying. I totally agree that, and this was part of the design of the application that I made, one has to try and target those types of audiences when trying to share data with the larger community. And one of the audiences the people like Casey saying, they just want to click through the data and get the right impression. For that type of audience, you have to be very visual and use colors and it has to be attractive.

And then the second type of audience is more data analyst-type people, like analyst researchers who have an expertise in computer science and so that make at the same time the data appealing to them in a way that they can just use their computing and in an automated fashion to download the data fast.

So at the same time you have to target the visual eye of the casual viewer, but then you have to be respectful of people who will use computers screens and computer programs to download en masse and integrate it with other datasets that come from other sources. So these two targets simultaneously is really what one should try to do and what modern web technologies are really enabling.

Bek: Can I jump in here? From a really high-level perspective, what is fascinating about hearing the process behind this kind of data sharing is that it really serves as a kind of a
call for reshaping how creative researchers need to be and
to think ahead in terms multi-disciplinarity means thinking
through who eventually who might touch those data and
how to make it accessible for them.

**Casey:** It’s really almost like distributing data becomes an
exercise in having empathy, right? You have to understand
not just what you were interested in doing with the data,
but what other people might want to do with the data. So
if you’re going to share well, you have to be empathetic in
many fields and understand where they’re coming from.

**Brian:** That’s a great point, Casey. I think one of the things
I want to explore a little bit is that sometimes, when it
comes to discussions of data sharing, there can be a sense
that there are the haves and the have-nots and that the
people who don’t have data are all for data sharing. And the
people who have it, may be more reluctant.

In this instance, to be clear Fabio, you had generated at
lot of data at the lab bench, correct?

**Fabio:** Yeah, that’s correct. The collaboration was with a
group at Karolinska in Sweden and they had access to the
bio bank of the blood samples of the patients who had HIV.
And they did initial parts of the experiments because they
need to be done close to the freezers, etc. and they had a
wonderful technician who was doing all that work.

But then the second half of the experiments were done in
my institute. I would say at least half of them I was doing
myself. Quite reluctantly, I must say, finally. I wasn’t plan-
ning on doing any experimental work and then it turned
out that that was the most efficient way. And so maybe
because I was coming from a computer perspective and
then I was a little bit forced to learn this experimental side
of things that I was kind of maybe lucky enough to be able
to see both sides of the fence.

So both the potential that the computer world and the
web world offers and also the amount of effort you have
to put into the experiment, so that you really don’t want
people to have to go through it again unless there is a good
reason. So maybe going through the pain of the experi-
ment was instructive in the sense that I appreciated how
much work goes into any type of experimental work.

And that really just packing it all together into a manu-
script and then forgetting about anything else may not be
sufficient and may not be fair towards the amount of work
that went into the study, yeah.

**Brian:** Great answer. So it sounds like there were actually
two institutions involved in the generation of the data and
you just tell us a little bit about any interfaces that you
had to have with institutional officials or departments? I
know it’s different perhaps in the EU than in America, but
I’m curious to know, how difficult was it, in fact, to get per-
missions to do the sharing?

**Fabio:** Well, I must say that because I was especially early on
in the collaboration, I was supposed to do mostly the very
downstream parts of the analysis, so only the computer
work. I wasn’t directly involved in all the legal issues that
were set up initially for getting patient consent, etc.

But my experience is that in the collaboration there were
two main institutions, one was the Max Planck Institute for
the Development of Biology in Tubingen and where I was
sitting, and there was the second half of the experiments
and then all the computer work there being done. And the
data was, at that point, was already all anonymized, so I
didn’t have access to any type of patient names or things
like that.

And then the first part of the experimental work was
done at the Karolinska Institute and the main collaborator,
Jan Albert, he had access to both sides. So he had access to
the un-analyzed data and also, if necessary, to the original
names and he was very protective. He was the main person
who was dealing with protocol approvals for dealing with
human subjects, etc.

And then interestingly enough, there was a third layer
which was Goran Bratt and he was the clinician who as
actually meeting the patients who were still alive despite
living with HIV for 15 or more years. And he was meeting
with the patients and so he was seeing these people and
the anonymization process, of course, is crucial to be able
to safely share data without threatening the safety of the
human subjects that provide the source for the material.

And the separation between the original patient identi-
ties and the whole computer work and the whole dataset as
it came out, was so short that Goran and I never even meet.
So, in order to ensure that the downstream researcher
like me, who is involved in sharing the data, can possibly
have a data breach that could compromise the safety of
the human subjects that were the three layers of the cli-
sonian who had to meet with the patients, get consents from
them and then work with their ethics committees in order
to make sure the study was designed properly and safely.

Then there was the medical doctor who was interfacing
between the clinician and was collecting the samples from
the freezers and then there were me and my advisor, who
were mostly computer people and we were involved only in
the unanalyzed data.

And so, I didn’t have a direct role in dealing with the eth-
ics aspect, but my experience was that by layering the sys-
tem through these various chains of people, it allows the
person who is actually sharing the data at the end, which
was me, to enjoy the freedom of being as open as possible
because the ethics concerns had been taken care of earlier
on by the other side of the collaboration.

And personally, the experience was very good. And I
would think that it always good practice to try to physically
separate the two people. The one that has access to all the
patient data in principle and the person who is sharing the
data downstream in the sense that this kind of makes the
This blog post was originally published on The Lancet United States of Health Blog. The blog was closed on December 31, 2018 and all posts are available via the archive at https://www.thelancet.com/journals/lancet/usa-blog

mechanism more fail safe in case any data breaches were to happen.

**Bek:** Fabio, in thinking about imparting advice to others, if you were to do this process over again, do you have anything that you might have done differently?

**Fabio:** That’s a difficult question, I must say, in the sense that my experience overall was quite good and back then I was only a PC student and in retrospect, I think the coordination done by my advisor and from the other side was actually excellent.

Certainly, if one starts the scientific collaboration and already has in mind the goal to share the data to a broader audience and in a more interactive way, then one should probably discuss which parts of the dataset are going to be made public up front. And we didn’t, I don’t remember doing any of this very much. The website really was an accident that happened at the end because I was just playing with various things and it happened to be so successful with the collaboration.

But probably if I were to do a similar collaboration now, I would certainly try to think up front in the early meetings, of which parts of the dataset do we want to make public and broadcast strongly versus which parts we’re going to tell people but maybe they are not so important. And which parts you want to keep secret because they could compromise the safety of the patient.

Yeah, I think an early discussion like that would be recommended for anybody.

**Bek:** So in other words, was there a data sharing plan in advance of this process?

Fabio: Yeah, I think having a data sharing plan from the early meeting, the earliest meetings of such collaborations would really benefit the work downstream because then, when it comes, when one year later it comes to the moment comes of actually starting to work to make the platform and share the data, you don’t have to wait for human input anymore and to set up meetings and people go on holiday, etc.

You have clearly agreed already on what parts you’re going to share and you can just deal with the technical aspects like the computer coding, etc. which are already challenging enough that you don’t want to be dealing with humans and computers at the same time.

**Bek:** And I wonder, too Brian, coming from a really clinical data sharing space, if you did have anything else to say about data sharing plans that might be applicable here.

**Brian:** Good question. Well, we’re going to start doing some very high dimensional assays and those, I think, will have special considerations with respect to de-identification. So I’m very, I think I can contrast that a little bit with what Fabio’s work entailed because, I think, it probably is very difficult to take, for example, an HIV sequence and then try to figure out who that came from. I think that’s difficult. Fabio may be able to talk more about that.

But, I think if you’re actually sequencing tissues from a person, then you really have a big challenge, I think, with respect to de-identification and for someone who was trained as a traditional clinical investigator as I was, those discussions aren’t necessarily part of the training that I’ve had in the past.

So, I am trying actively to get up to speed. Right before our last podcast, I had had a meeting, which this was the topic of discussion. Today, I was sending messages about this as well, trying to understand how does one do this? And as we collect samples and studies going forward, how do we make sure that at the beginning of that collection process, all languages in the ethics applications, do we need to amend things that are already approved so that we can begin to do these things and share.

I think, for me, this is a very rich topic. And it’s a very interesting topic because right now, I think, is the time for the rubber to meet the road and to start doing these things. I’m right in the midst of trying to understand how it’s done.

**Brian:** Well I do have two final thoughts. I have one last question for Fabio. Was there anybody who told you that this was not a good idea? You don’t have to name names, but I’m curious, did you get advice to the effect that this is going to take time away from publishing new things? Or, you shouldn’t do this?

**Fabio:** Yeah, I think I am very grateful to my then PC advisor, Richard Neher, because he was very supportive when I was spending several months of my PhD, developing web technologies that had absolutely nothing to do with anything that would benefit him, right? In science, he wasn’t tenured back then, and so the pressure for publication and manuscripts on him was very high and still he gave me the freedom to pretty much do whatever I wanted just because maybe he had the intuition that something useful may come out.

And certainly at the same time, I was asking around for other students like me, so my peers and also more senior people, whether they thought this would be a good idea or whether I was wasting my time, since the investment of time was quite relevant. And I must say, you find 50/50 opinions. So, half the people were telling me, “Oh, it’s great.” And half the people were not discouraging me, but let’s say puzzled about why on earth I wouldn’t just write a manuscript and leave like everybody else.

And in this type of endeavor in which the benefit is not clear, I think having even a few people encouraging you a lot and giving motivation is essential. So, I don’t think I had anybody who was actively discouraging me, but certainly there were lots of people who were wondering why I’m doing that as opposed to leave and look for a job or something along those lines.

**Bek:** Well, I’m certainly glad that you did and I’m glad that you applied for the Research Symbiont Awards. It was very well deserved.
Bek: Thanks again, Fabio, for sharing your data sharing experience. Both you and Brian have brought up some of the distinctions in different kinds of data that might have different challenges (viruses versus oncology data, for example). But it also serves to highlight that there must be ways to think around these issues—whether it is clearly mapping out a plan in advance, having the contact of those involved somehow layered, but also anticipating accessibility and end users. Casey, do you have some final thoughts here?

Casey: So one thing that I thought was interesting that came up earlier in the conversation is this idea that the conversation has moved so much in the past year where we’re not really talking about data users and data generators separately, or parasites and hosts or parasites and symbionts or whatever terms people want to use for them. And that we’re sort of thinking about things in a more complex and nuanced way.

Sort of thinking about a data eco-system. I think that the advance of the conversation from thinking of participants as having one and only one role all the time to multiple roles in complex ways, I think to me, that’s really exciting and interesting. And I think it reflects reality much more than the potentially simpler view of a data user or a data generator.

So I’m excited to hear that the conversation is moving forward that way.

Bek: And indeed, this conversation is moving forward. And we hope you’ll join us for the next episode of In the Open!
Study presented at AACR and published in The Lancet Respiratory Medicine may set new standard for rare sarcoma

John Otrompke

Crizotinib, a drug which has been approved for the treatment of a certain form of advanced lung cancer since 2011, may be the standard of care for patients with advanced cases of an extremely rare form of sarcoma, according to an oral presentation at this year’s annual meeting of the American Association for Cancer Research (AACR) in Chicago. An article describing the findings was simultaneously published by The Lancet Respiratory Medicine.

“Our study was scientifically and statistically focused on ALK positive tumors,” said Prof Patrick Schöffski, MD, head of the department of general medical oncology at University Hospitals Leuven, in Belgium.

The study was part of a “basket trial” which examined six very rare cancers characterized by rearrangements of the gene ALK, explained Schöffski, lead author on the article. That strategy may be key to effective research in extremely rare tumors like inflammatory myofibroblastic tumor (IMFT), but it is not without controversy.

Promising results in genetically-driven cancers

In the CREATE trial, Schoffski and colleagues enrolled 20 patients with IMFT from 13 study sites in eight European countries. Of the patients who took part in the trial, 12 were ALK-positive and seven were ALK-negative.

Half of the ALK-positive patients achieved an objective response to the drug (meaning partial or complete tumor shrinkage), according to the article, and all patients in both arms achieved disease control (except for one patient in the ALK-negative arm), according to the comment.

Since “only one patient in the total series had previously responded to conventional systemic chemotherapy, these are encouraging results,” the article noted.

Patients with inoperable disease almost invariably die, usually of tumor invasion rather than metastasis.

IMFT is one of 70 different subtypes of soft tissue sarcoma, and occurs in 0.3 per million people, according to Schöffski, who participated in an exclusive interview with The Lancet United States of Health Blog. Sarcoma itself accounts for only 1% of all solid tumors.

The tumor, which is usually found in places like the lung or the abdomen, mostly affects children, at a mean age of 9 or 10. Although the Schoffski trial was conducted primarily in adults, only 30% of cases occur in patients over 20.

Surgery, including amputation, is the usual treatment, but for inoperable cases, there is no standard therapy.

Interestingly, about 50% of IMFTs have translocations involving ALK, a gene which also figures in non-small cell lung cancer (NSCLC). Crizotinib was approved by the FDA to treat ALK-positive NSCLC in 2011.

IMFT is so rare that the US National Comprehensive Cancer Network recommended crizotinib for inoperable IMFT patients based on a single case report published in 2010.

A new way of conducting cancer research

“ALK-negative tumors have a higher risk and also higher rates of metastases than ALK-positive cancer,” noted Victor Villalobos, MD, PhD, assistant professor of medicine at the University of Colorado in Denver. “Those are actually very different tumors, treated with very different drugs. If you look at them in comparison with IMFT, it makes you wonder whether the ALK-positive and ALK-negative forms of IMFT are actually a different tumor,” explained Villalobos, lead author of a comment on the Schloffski study which also appeared in The Lancet Respiratory Medicine.

The discovery of genetically-driven forms of cancer may be changing the face of oncology research, according to Villalobos.

“Before, research was based on a tumor’s histological appearance—for example, did it look like muscle or fat? And most trials were conducted in patient populations composed of all forms of soft tissue sarcoma. But that’s changed over the last several decades, because there could be 40 or closer to 80 molecular abnormalities involved in soft tissue sarcoma,” he said.
That seems to raise the question: if some forms of both sarcoma and lung cancer are driven by ALK and respond to drugs that target ALK (while other forms of the same diseases are ALK-negative, and don’t), then are NSCLC and IMFT actually the same disease, even though they have different appearances under a microscope?

“Given that crizotinib has activity in IMFT similar to to NSCLC, one could argue that it should be approved and used routinely in all tumors that have the genetic abnormality, even though pathologists call one disease NSCLC and the other IMFT,” said Schöffski. “But there might be factors that only a play a role in one or the other. The best example is BRAF inhibitors. When they are used in melanoma cases with the BRAF mutation, we see impressive responses, but if you treat the same mutation in colorectal cancer, you won’t see any efficacy,” he noted.

Orphan trials need orphan strategies

“We designed the trial to give ourselves sufficient time to find patients, but after five years, we realized it would take a lot of time to find our maximum number of 35 ALK-positive IMFT patients. We had 12, and it would have taken us another 10 years, or 15 years in total from the entry of our first patient.

“What we should not forget in this disease is that the pool of existing cases is not unlimited. Over five years time we were able to mobilize patients, but a lot of those were pre-existing patients with this disease. In the early stage, you always have quite good accrual in a rare disease for which nothing else is available, then the pool dries out, because doctors are not diagnosing multiple new cases on a monthly basis,” he explained. “For them to put together this many patients was really quite a feat,” said Villalobos. The trial was additionally complicated by the fact that out of 35 IMFT patients initially recruited, 40% of them were found to have been misdiagnosed, and not actually have IMFT. “That just shows how complicated this set of diseases is: even sarcoma experts don’t agree on the diagnosis,” he explained.

The researchers were aided by ways in which the healthcare infrastructure in Europe differs from the US. “They have specialized sarcoma centers, because they have single payer, and each country is smaller. That’s unlike the US, where every city has its own sarcoma center, so they get volume, and that allows expedient trial accrual,” said Villalobos. “It also allows them to develop expertise,” he added.

It is well-known to be difficult to conduct research into rare diseases, and these developments raise the question: do precision medicine strategies make that easier or harder?

“It makes it harder, because now we’re turning what is rare into even rarer things. If ALK-positive cancer is not restricted to one disease, it’s not quite as rare as we once thought, but they’re still rare. Only a fraction of a percent of the population get some of these tumor types. But the efficacy goes up, so the total number you need to put in may be less,” said Ross Camidge, MD, PhD, professor at the University of Colorado in Aurora, and a co-author on the comment in *The Lancet Respiratory Medicine*.

Global collaboration is needed to enroll sufficient patients for clinical trials in rare diseases, said Schöffski.
The growing threat of antibiotic resistance and the growing need for antibiotic stewardship

Ray Cavanaugh

The 23,000 figure pertains to persons who die as a direct consequence of antibiotic resistance. Many others die from conditions exacerbated by antibiotic-resistant infections.

Aside from the human toll, these infections also place considerable strain on the healthcare system, accounting for as much as $20 billion in extra annual healthcare costs, reports the CDC, which has outlined four primary actions to combat the spread of antibiotic resistance.

The 2017 book Deadliest Enemy: Our War Against Killer Germs tells how the rate of antibiotic resistance "now far exceeds the rate of new antibiotic development" and that the next 10 to 20 years could see us transition into a "post-antibiotic era," where bacteria that previously required little more than a doctor visit could lead to a severe, perhaps fatal, infection.

Deadliest Enemy also points out that pharmaceutical companies have less incentive to design antibiotics, as they are used for shorter periods of time than other medications and are therefore less profitable.

As increasingly resistant pathogens have rendered established antibiotics ineffective, Dr Lance Price has seen clinicians, who, "out of desperation" are "treating more and more infections with colistin." Around since the mid-20th century, colistin is a highly potent (and toxic) antibiotic often used as a last resort. A frightening case in 2016 saw a Pennsylvania woman present with an infection of E.coli that was resistant even to colistin.

As the founding director of the Antibiotic Resistance Action Center at George Washington University’s Milken Institute School of Public Health, Price observes that the US healthcare system is failing to "properly incentivize the use of rapid diagnostics that could dramatically improve antibiotic stewardship." He adds that, "Until payers start reimbursing for diagnostics, companies will not develop the kind of next-generation, point-of-care diagnostics that we need to curb unnecessary antibiotic prescriptions."

Price would also like to see the implementation of an "active, community-based surveillance program to detect the emergence of multidrug-resistant COPs [colonizing opportunistic pathogens]."

He believes that the northern European countries are "doing a much better job at monitoring antibiotic use and drug-resistant infections" than the US. He points out that in Sweden, "basic penicillins and tetracyclines are still effective against many bacterial infections" and that such a situation "says a lot for the power of antibiotic stewardship and infection control."

Some good news for the US, relates Price, is that the CDC and other organizations are seeking to educate healthcare professionals –through infographics, posters, research papers, social media, webinars, etc.—in order to improve antibiotic stewardship.

In 2015, US providers issued 269.4 million antibiotic prescriptions in outpatient settings. This figure is equivalent to 838 antibiotic prescriptions per 1000 persons. The CDC contends that at least 30 percent of these prescriptions were medically unnecessary.

Even persons who cautiously limit their own antibiotic use may consume the meat of animals that are given antibiotics. And even if one avoids such meat, there remains a risk of consuming crops contaminated with animal waste containing antibiotic-resistant bacteria.

The use of antibiotics in food animals persists as a serious factor. Price relates how 70 percent of antibiotics sold in the US are allocated to food animals, largely "to compensate for [their] overcrowded and unhealthy living conditions." Such a situation is highly conducive to generating drug-resistant pathogens.

"The US has implemented some positive policies to curb antibiotic use in food animals. However, it has fallen far short of what is needed," says Price, who co-chaired a commission of antibiotic resistance experts that released
an August 2017 report outlining policy recommendations to lessen the use of antibiotics in livestock.

Even if the US takes extensive measures against antibiotic-resistant bacteria, there remains the ongoing risk of ABR bacteria brought over from other countries. In our interconnected world, bacteria can travel far distances quickly. And “many of the worst superbugs can colonize healthy people without [manifesting] any symptoms,” says Price, who adds that, “Colonized people can unwittingly become vehicles for multidrug-resistant bacteria, bringing them home from countries where they flourish.”

“The good news,” Price says, “is that these resistant bacteria will have a hard time getting established in the US if we significantly reduce unnecessary antibiotic use, implement active surveillance and control programs, and continue to improve hygiene in our hospitals.”

Because bacteria can evolve so rapidly, humans will never win the war by just creating more and more antibiotics. Price says, “We desperately need to change the way we use our antibiotics, so we stop spurring the evolution of bacteria that resist them. Otherwise, any new drugs that are developed will meet the same fate as the older ones.”
No barrier to CDC research on gun violence—except funding

Susan Jaffe

Questions about CDC’s ability to investigate gun violence—as it would other public health threats—have persisted ever since Congress passed the 1996 Dickey Amendment prohibiting the use of research funds to advocate or promote gun control.

“We don’t believe that it gets in the way of our ability to do violence research or firearms violence research at any part of HHS,” Azar told another congressional panel a month later. “I think we’ve now made it quite publicly—and within the administration—clear that we don’t see any barriers around violence or firearm violence research. We’re in the evidence and science-gathering business.”

His assurances were also included in the instructions that accompanied the budget agreement Congress approved and President Donald Trump signed into law last week.

While some observers believe this means CDC has permission from Congress to proceed, some leading experts in firearms research are skeptical. There may be no barriers, but they say there’s no funding either.

“What’s needed is an appropriation so that not just CDC but the National Institutes of Health and the National Institute of Justice can conduct and support research on firearm violence and its prevention,” said Garen Wintemute, a professor of emergency medicine and director of the Violence Prevention Research Program established last year at the University of California in Sacramento with a $5 million state grant.

“Research in this area is important just as research on motor vehicle injuries, opioid and other controlled substance abuse, or for that matter, on cancer and heart disease is important,” Wintemute continued. “If we want to lessen the adverse impact of these problems on the quality of life in the United States, we need to understand them and measure the effectiveness of the interventions we put in place.”

CDC works around the clock to protect “people from diseases, injuries, and disabilities, as well as other health problems associated with natural disasters and bioterrorism attacks,” its website explains. But for at least two decades, the agency’s work on gun violence has focused primarily on collecting data about injuries in the US. The RAND Corporation’s Gun Policy in America initiative unveiled earlier this month is the latest comprehensive study to conclude that gun violence research is lacking.

“Research in this area is generally far behind where it is for most other causes of death that claim similar numbers of lives in the US each year,” said project leader Andrew Morral.

The Dickey Amendment, which is still in effect, has had an intimidating effect on CDC’s gun violence research, said David Hemenway, a professor of health policy at the Harvard TH Chan School of Public Health and director of the Harvard Injury Control Research Center. In 2012, CDC recognized him as one of the “twenty most influential injury and violence professionals over the past twenty years,” according to his biography posted on the school’s website. “The CDC basically stopped doing research 20 some years ago on firearms and is afraid to say the word ‘firearms’ at meetings,” he said, because they fear Congress may retaliate by cutting funding for other CDC programs.

Hemenway said there is still a great deal about gun violence that is not understood. He mentioned some broad questions, including who brings guns into schools and why, does carrying a concealed gun make the owner and the community safer, are penalties for illegal guns effective, how do guns get into the wrong hands, how police decide to use their guns, and why does the strong regulation of machine guns seem to be effective.

Congress could be using information about these and other issues to enact effective deterrents to gun violence, said Hemenway.

“Laws are much better if you have some knowledge of what you’re doing,” he said. They should be “based on science rather than hunches.”
Although Azar told Congress members the Trump Administration’s interpretation of the Dickey Amendment is clear, questions remain about what happens next. “CDC awaits further guidance and direction from Congress and the Department of Health and Human Services,” a CDC spokesperson said Friday. Until then, “CDC has and will continue to support data collection activities and analyses to document the public health burden of firearm injuries in the US.”

But this week, an HHS spokesman said, “As to future actions or research to be done, that will be determined by the scientific processes at the CDC and NIH.”

The Parkland shooting survivors who organized the March 24th massive “March for Our Lives” protest rally in Washington, DC demand stricter gun control laws and have little patience for ambiguities. On a stage with the US Capitol looming in the background, they were joined by friends and relatives of children killed on the streets of Chicago, Los Angeles and New York City. One of the youngest speakers was the nine-year-old granddaughter of Dr Martin Luther King, Jr, Yolanda. Hundreds of local rallies were held across the US, in nearly every congressional district.

Jaclyn Corin, a Parkland student who addressed the DC rally, describes herself to her 135 000 Twitter followers as “just a high school student trying to save the world with her friends.” She told the crowd there is an epidemic of gun violence “that affects communities of all classes—an epidemic that the Centers for Disease Control does not have the funds to research.” She urged protesters to visit their congressional representatives when they are home in their districts this month. “Have them hear you out because they work for us!”
Some children may now receive sex change hormone therapy before 16: ENDO guideline

John Otrompke

The guideline remarked that gender-affirming hormone treatment may sometimes be appropriate for children under 16 years old, among other changes.

For example, social transition in prepubertal youth is no longer categorically recommended against. The guideline’s current recommendation is that, if a social transition takes place in a prepubertal youth, it should be done in consultation with a mental health professional, according to Stephen Rosenthal, MD, medical director at the Child & Adolescent Gender Center at UCSF.

“Both guidelines recommend not treating a patient with any kind of medication prior to the onset of puberty, but the 2009 guideline also suggested that an endocrinologist should not advocate or recommend that a child undergo a social transition prior to onset of puberty,” said Christopher McCartney, MD, associate professor of medicine at the University of Virginia in Charlottesville.

“In 2017, they don’t say you should. They don’t say you don’t do it. They say decisions should be made in consultation with a qualified mental health provider,” added McCartney, chair of the Society’s clinical guidelines subcommittee.

The 2009 guideline relied on “the high rate of remission of gender identity disorder after the onset of puberty,” a reference which was dropped in 2017.

“Earlier studies tried to figure, out of children who appear to have gender incongruence before puberty, how many will continue to have it after puberty?” explained McCartney, who moderated a session on the guideline on Monday.

Some experts feel that the number of remissions was overstated by previous studies, which may have initially misdiagnosed some children with gender dysphoria who did not actually have it.

“As the diagnostic ability continues to improve, the percentage of persisters will go up,” said McCartney.

“The Guideline was changed in this section to acknowledge that categorically not endorsing a social transition for any young transgender child did not seem appropriate,” said UCSF’s Rosenthal, who also spoke at the meeting on Tuesday.

A ‘sea change’ in medical practice

Even if understated, the revisions, which reflect what Rosenthal called “a sea change in how we provide care,” may allow endocrinologists to perform sex change procedures on more children.

The guideline recognizes four aspects to gender affirmation therapy. The first is the social transition. The second is puberty-blocking therapy (usually with gonadotropin-releasing hormone agonist); the 2009 guideline already permitted this at the outset of puberty.

Dysphoric children who must go through puberty in their birth-assigned gender face “significant risks for self harm, suicidal ideation and potentially suicide,” Rosenthal said.

The 2009 guideline recommended against gender affirmation hormone therapy (the third aspect to the procedure) until the age of 16, which is the legal age of consent in some countries. However, it can be onerous for some children taking hormone blockers to delay the onset of any puberty whatsoever until 16, which represents “a real risk for bone and emotional development,” Rosenthal said.

“There was not an age requirement for starting a puberty blocker; it should be at the early stage of puberty, as early as eight or nine years of age,” said Rosenthal. “The blockers are reversible; but once you go on gender affirming sex hormones, it’s going to cause sexual changes you’re going to be stuck with.” (Gender-affirming hormone therapy is off-label in children, he noted).

The revised guideline also adds a new section 5.6, which gives discretion to practitioners to determine when to conduct breast surgery on transmales.


The Vrije University Medical Center in Amsterdam had treated 6793 people since 1972, and the number of people assessed increased twenty-fold, from 34 in 1980 to 686 in 2015.

Treating gender-incongruent children at puberty

Although historically there were more transfemale patients at the clinic, that trend reversed in 2015, mainly due to an increase in transgender boys.

Over time, the percentage of people who started hormone therapy within five years after the first visit decreased...
from almost 90% in 1980 to 65% in 2010. However, the percentage of patients who underwent gonadectomy remained constant, and few of them expressed regret, according to the paper: only 0·6% of transwomen, and 0·3% of transmen.

"Prof Peggy Cohen-Kettenis, one of the co-authors, was working in the University Hospital in Utrecht, where one day a child was referred to her psychiatry outpatient clinic. Professor Cohen-Kettenis counselled this child. From that time on, she was the one who saw children with gender identity issues. So there was not an intention to serve this group and offer care, but it slowly evolved," said Chantal Wiepjes, MD, a PhD student at the university and lead author on the paper.

In 2002, the clinic at Utrecht was folded into VUMC, which to date has seen 548 children 12 and under, of whom 49·1% of transboys and 33·6% of transgirls went on to receive gender-affirming hormone therapy.

At ENDO, Wiepjes and colleagues also presented several substudies from the cohort investigating possible adverse effects in adults, including cancer risk, reduced bone marrow density, and effects on the brain.

However, the 2017 guideline seems to downplay some such risks. "Screening for liver function test abnormalities was removed from the guideline, because our data suggested they were not a problem," said Vin Tangpricha, MD, PHD, professor of medicine at Emory University in Atlanta, and member of the guidelines committee. Additionally, the revision downgraded its position on prolactin screening from recommended to suggested.

However, there is some scientific concern about cardiovascular events among gender affirmation patients. Tangpricha noted. "In the meta-analysis of 20 studies published as a companion to the guideline, the long-term data suggest that transwomen are at increased risk for ischemic stroke and pulmonary embolism. The lifetime risk for embolism is less than 5% in the general population, compared to as high as 10% in transwomen, he added.

In addition to the dangers attendant in any operation, unique risks associated with gender-affirming surgery include perforation or stenosis of the neo-vagina, and inadequate nerve association to the neo-phallic graft.

The authors of the Amsterdam cohort article also investigated the ratio of desistence to persistence. "Worldwide, in about 85% of the children the feelings of gender dysphoria desist, so the persistence rate is 15%," said Thomas Steensma, PhD, psychologist at VUMC and a co-author on the paper. But in the Amsterdam clinic, the persistence rate was 40%, he added.

And while none of the youth treated with gender-affirming hormones reported regret, the dataset might be incomplete, the article acknowledged. Large numbers of patients were lost to follow-up, and 36% did not return after several years of treatment.
A colleague and I have today published a Correspondence piece in The Lancet explaining how “gun control” will always be divisive. Instead, we call for #GunSafetyNow, a movement that everyone can support.

Since Valentine’s Day, I have had an ongoing, attention-seeking, visceral sensation which I have never before experienced. Some of the ingredients in the emotional cocktail responsible are recognizable: anger, sadness, fear, shock, more anger; others I’m simply not familiar with.

Like millions of Americans, the Parkland massacre affected me deeply. However, I’m not American. This has nothing to do with me. I’m a foreigner, a legal alien, venturing out of the quintessentially English liberal-academic bubble of Oxford where I work as a preventive medicine physician to spend a year in America.

I’m used to reading about the carnage that guns reap on American communities while reassuringly insulated from it by nearly 4,000 miles of ocean. “Again?! How do you still let this happen??” Turn page.

This time it is different and I’m trying to work out why. Perhaps it’s because one of my daughters is at school here? Or maybe it’s because I have friends here? Or perhaps it’s because I’m beginning to understand the hypocrisy of so many US politicians. Elected law makers can ignore the overwhelming evidence screaming at them that there are safer ways to live with guns, accept thousands of dollars from pro-gun lobbyists, and—whilst knowing all this—still unblinkingly offer thoughts and prayers to grieving families.

Gun violence in America is an epidemic. It is a public health crisis. And it is a safety issue.

In the 45 days up until the day of the Parkland shooting, 1818 Americans are reported to have been killed and 3129 injured by gun violence. And between 2015 and 2016, guns were responsible for 74,910 American deaths, more than the total number of US military casualties during the 11 years of the Vietnam war and the eight years of conflict in Iraq combined. This figure includes 60% of deaths from suicide and represents an average of eight American children and young adults under the age of 20 killed a day by guns. Every day.

Much has been made of terror attacks in the UK, but the numbers simply don’t warrant comparison. Between 2000 and October 2017, 126 people had been killed in UK terrorist attacks. And the latest data from England and Waleson domestic gun violence show 26 deaths between April 2015 and March 2016, with the numbers of suicides from guns being too small to be separately reported. Yet you can still own a gun, you can be part of a gun club, you can still hunt. You’re just in a much safer environment.

When it comes to gun homicides, among highly educated and high-income countries the US is in a league of its own.

And incidentally no, in the UK we don’t make up for it with stabbings instead.

People generally don’t choose to get shot. Children definitely don’t choose to get shot. They can’t even vote. They, along with all the other innocent lives wrecked by gun violence, are the collateral damage of an ideological interpretation of a Second Amendment that says you shouldn’t limit access to semi-automatic weapons, shouldn’t have mandatory licensing, shouldn’t have universal background checks, shouldn’t require guns to be stored separately from ammunition.

Furthermore, the pattern of conflating every act of domestic terrorism with mental health is not only stigmatizing but deeply disingenuous. Those with mental illness are far more likely to be victims of violence than perpetrators. And these political assertions are made whilst increasing barriers to Medicaid, proposing scant funding for the opioid crisis, and presiding over a health care system where over 20% of those with mental illness can’t get the
treatment they need. Any discussion about mental health following a mass shooting must focus on the needs of victims far more than the medical history of assailants.

So, what to do?

This isn’t about whether or not you should be able to use guns, it’s about using guns safely.

There are no excuses for maintaining the status quo. I’m aware it is politically contentious. I know that up until April last year, despite Columbine, despite Sandy Hook, the US electorate remained split on gun control. What would the response be if the question were about whether or not they support gun safety instead? A 2017 Pew Research Center survey found the majority of gun owners reported having taken a safety course, favored introducing background checks for private sales and at gun shows, and were supportive of a federal database to track sales.

Following Parkland, the student-led response of survivors like Emma Gonzalez calling out politicians’ empty words and initiating the March For Our Lives on 24th March gives me hope that things could change. But recent noises from Washington suggest that little will be done to improve gun safety.

Stopping this epidemic isn’t about votes, it’s about blunting the National Rifle Association’s arguments against gun control and doing the right thing. It’s about children not needing active-shooter training just to get an education. It’s about parents not having to worry next time the phone rings. It’s about people’s, children’s, lives.

Such change requires political strength and leadership. Whether you are choosing to march or not, as Americans you can help law makers by changing the narrative to something everyone can support: gun safety. And if your current law makers still won’t act, then for the sake of your children’s unheard voices, please elect ones that will.

#GunSafetyNow

With thanks to Elliott Fisher for his ideas about how to change the narrative of gun safety in America, and also to Adam Castaño, Sarah Briggs, Ellen Meara, and Amber Barnato for their advice on early drafts of this article.
Hospices respond to community grief caused by opioid overdoses

Larry Beresford

Hospices are mandated by Medicare to provide bereavement support services to family survivors of the terminally ill patients in their programs for a year after the patient’s death. But many also offer grief support to the wider community and to others who have experienced losses, through individual counseling, support groups, children’s grief camps and the like. The new specialized groups offer survivors of overdose deaths peer support from others who have gone through the same experience, and a chance to explore issues specific to this socially stigmatized loss.

Non-profit Mountain Valley Hospice and Palliative Care, based in Mount Airy, North Carolina, now offers two open-ended grief support groups for overdose survivors, one that meets twice a month in Winston-Salem, and the other in Stokes County. “We serve 17 counties in North Carolina and Virginia and we’re exploring the need for groups in the other counties, as well,” says the hospice’s Outreach Provider Representative and medical social worker, Selene Teague. She points out that the current opioid crisis has shredded traditional stereotypes about drug abusers—urban versus rural, socio-economic, age, racial/ethnic profile, etc. For many of the families she sees, the drug problem started with a legal prescription for an opioid pain reliever.

Mountain Valley Hospice offers grief support, including one-on-one counseling, to anyone in the community who has experienced a loss, free of charge and supported by donations. “We have long offered a support group for parents who lost a child. But we realized that the dynamics of overdose deaths were very different than for the other parents. With drug abuse comes social stigma, a lot of guilt and shame, and the tendency to blame themselves for what happened,” Teague says. Also a lot of questions about what they might have done to prevent the death, and other feelings that don’t conform to social expectations about grief.

In the face of rising overdose deaths, the hospice launched the specialized group. To get the word out, Teague used her contacts in the community and participation on a community-wide opioid task force representing multiple agencies including mental health, emergency services and law enforcement.

In rural Stokes County, overdoses often present more of a stigma than in urban Winston-Salem. “Because it’s a smaller community, people are still afraid that a neighbor might see them coming to the group, even though we’ve explained that this is a safe place, and we follow HIPAA privacy guidelines.” Teague herself lost an ex-partner to an overdose ten years ago, and more recently two friends. She remembers asking herself many of the same questions that she hears in the support groups.

The groups combine education and an open forum for sharing participants’ concerns. “I provide information on other resources in the community and expertise on grief and loss and all of the emotions that come up. At the beginning of each group I read the guidelines: We’re not here to judge. Don’t take other people’s problems home with you,” she says.

Understanding addiction

“Mostly what I’m seeing in these groups is that folks are still trying to find an understanding of addiction—what it is, how it took over their loved one’s life. Often they have lived with the consequences of addiction for many years, but never understood why the addict could not stop the self-destructive behavior,” Teague says. “My co-facilitator, who works for a drug rehabilitation agency, brings expertise on addiction and explains what drugs do to the brain over time.”

In Norwich, Connecticut, which has also seen dramatic spikes in the rates of overdose deaths, the Center for Hospice Care Southeast Connecticut has co-sponsored an overdose community bereavement group with Norwich Human Services. The group is facilitated by Angela Duhaime, an adjunct professor of child psychology at
Eastern Connecticut State University. The group has met monthly since last July.

“I give participants an opportunity to focus on expressing their grief. In this community, the average overdose is a white male in his 40s, who may have children left behind. I bring a toolkit of resources on what to talk about, focusing on a specific emotion for group members to process—like guilt or shame. We’re slowly getting around to anger,” she says.

The group was inspired by a public talk the hospice sponsored about loss of a loved one from addiction, given by Kenneth Doka, PhD, a professor of gerontology at the College of New Rochelle and prolific author on grief. “Losses like this can easily be disenfranchised by others’ judgmental attitudes. Often the best support is by others dealing with similar situations as they are unlikely to jump to judgment,” Doka says.

A group started at Hospice of Frederick County in Frederick, Maryland, a year ago. “Just opening the Frederick newspaper, it was not hard to figure out the need,” says bereavement coordinator Linda Beckman. “No one came to the group at first, until we started publicizing it on local TV and radio.”

A closed group ran for eight weeks, followed by an open-ended, ongoing monthly group, addressing many of the same issues as other grief support groups. “What’s different is this idea of a preventable death—and the loved one’s feeling that it was their fault. I also see a lot of anger—toward drug dealers, toward the police for not stopping it,” Beckman says. Her job is to help them see the reality of the situation—and that they were not able to control the outcome. We try to help people understand the concept that addiction is a disease. I can also help to normalize what they are going through,” Beckman says. Duhaime says she has been astounded to see people who come to the group very early in their grief, 30 or 60 days after the loss. “It’s very empowering to feel that they have some control over pulling themselves together by coming to a public setting to talk about it.” Group members are very good at supporting each other, and the group highlights differences in the way women and men grieve. “We also get siblings of the overdose victim. Interesting conversations happen in the group when siblings talk to parents, who may have other children dealing with these issues.”

In Ohio, which has been an epicenter for the opioid crisis, Hospice of the Western Reserve was approached by one of its local county substance abuse recovery programs to present an open forum for the community to come together and talk about overdose grief. “We determined that a number of people were interested in a specific grief program, so we developed a five-week series,” says the hospice’s bereavement coordinator, Diane Snyder-Cowan.

“We’ve had employees here who lost a sibling or an adult child.” And don’t forget the professionals, first responders, doctors, pharmacists, she says. “A lot of people are grieving these issues. It touches us in so many ways, that we just needed to respond. We also do groups in the schools.”

Snyder-Cowan, who is the Bereavement Section Leader for the National Council of Hospice and Palliative Professionals and has led webinars on the subject for professionals, says hospices need to be part of the communities where they live. “You have to look at other available resources. Don’t work in isolation. Be aware of what’s happening in your community.”
Onco-cardiology—targeting the double heart break

John Otrompke

To measure cardiotoxic risk associated with exposure to a class of decades-old chemotherapy drugs called anthracyclines, researchers at the Mayo Clinic reviewed data from the Rochester Epidemiology Project to identify 900 residents of Olmstead County, Minnesota diagnosed with breast cancer or lymphoma between 1985 and 2010, as well as 1550 controls who did not have cancer.

During the first year, those treated with anthracyclines, which are still commonly prescribed, had more than three times the risk of congestive heart failure compared with the controls, and the risk persisted up to 20 years later, detailed in the poster, “Short and Long Term Risk of Congestive Heart Failure in Breast Cancer and Lymphoma Patients Compared to Controls: An Epidemiologic Study,” presented Saturday at the scientific sessions of the American College of Cardiology in Orlando (ACC.18).

“We’re trying to raise awareness amongst patients and physicians that they need to be carefully monitored for symptoms of heart damage after therapy, so that once cancer patients become cancer survivors, they don’t go on to suffer from heart disease,” said Carolyn Larson, MD, assistant professor of medicine at Mayo Clinic Arizona, who presented the study, which won a “Best Poster” award at the meeting.

“Decades of data have established that cancer patients who receive radiation therapy for lymphomas and left-side breast cancer are at increased risk for cardiovascular events, myocardial infarction, and valvular heart disease,” said Tomas Neilan, MD, associate professor of medicine at Harvard and director of the cardio-oncology program at Massachusetts General Hospital in Boston.

“But what’s different about the new checkpoint-blocker immune therapies for cancer is that the presentation is dramatically hyperactive, and death will occur in 30% of those 0.3 to 1% of patients who have adverse events,” added Neilan, who co-presented the poster, “Myocarditis in Patients Treated With Immune Checkpoint Inhibitors.” The poster found a myocarditis incidence rate of 1.9%.

A cardiotoxic wave?

“There are currently over 900 immune agents in more than 3000 clinical trials in the US, enrolling 600,000 patients. These immunotherapies are a paradigm shift for cancer care, but when you unblock the immune system, you not just allow it to attack cancer cells, but you also turn off its ability to distinguish between natural and unnatural cells, and the immune system sometimes goes after the heart,” said Neilan.

The first checkpoint inhibitor was approved in 2013, and there are six currently on the market. While some newer-generation cancer drugs are the last resort for some cancer patients, who untreated have a life expectancy of only eight months, they are expected to move into the adjuvant setting, and earlier-stage cancer patients will receive them.

“With newer drugs we are only seeing the tip of the iceberg of the different type of cardio-toxic events that can occur,” said Melissa Moey, MD, resident physician at East Carolina University in Greenville, North Carolina.

“With understanding a little better how cancer works, and with more targeted therapies, we’re seeing an increase in survivorship in cancer patients, but cardio-toxicity can be as high as 10–13%, and we saw it occurring even within three months of treatment,” explained Moey, who presented the poster, “Retrospective Analysis of Cardiac Medications in the Prevention of Cardiotoxicity in Trastuzumab-Treated Her2 Positive Breast Cancer Patients.”

Cancer patients who develop cardiovascular complications may face an interruption in their therapy, although it can sometimes be re-initiated later, said Moey.

A number of factors can help doctors identify cancer patients who may be experiencing cardio-toxicity. Over 80% of patients with myocarditis present within three months of starting immune therapies, and the vast majority had abnormal EKG or elevated troponin. The third thing is that 44% had preserved ejection fraction, which is a relatively large proportion,” said Harvard’s Neilan.

Fixing bugs in a rapidly-evolving field

The adverse effects of anthracyclines have been well known for decades and scientists have developed newer, alternative forms such as doxorubicin, which when given in a formulation encapsulated on lipids, has reduced cardiac toxicity. (“But then it has its own non-cardiac toxicities,” noted Larsen of the Mayo Clinic).

Cardiovascular side effects occur more commonly in patients with liquid malignancies, according to Monica Avila, MD, assistant doctor at the Clinical Hospital of the Medical School of São Paulo.

“When patients are being treated for liquid lymphomas, generally the tetracycline doses are higher,” explained
Avila, who presented late-breaking clinical trial “Carvedilol for Prevention of Chemotherapy-Induced Cardiotoxicity—Results of the Prospective, Randomized, Double Blind, Placebo-Controlled Ceccy Trial.”

In that trial, researchers randomized 200 breast cancers receiving low-dose, modified format anthracycline to receive either adjuvant carvedilol (a heart failure drug), or a placebo.

In one respect, the experiment didn’t work; those patients who received adjuvant beta blockers didn’t have a reduction in adverse events. Both groups experienced about the same frequency of cardio-toxicity, which was actually higher in the arm that received the beta blocker (15%) compared with the group that did not (14%).

“Our prediction that the ejection fraction would be very low was correct; only 0·9% of patients in the carevdilol group experienced a reduction in ejection fraction, which is very low compared to the literature,” said Avila. “However, we saw injury during the chemotherapy, which was characterized by elevated troponin,” she added.

Other researchers have tried administering ACE inhibitors, beta blockers, and statins to reduce cardiovascular side effects, said Avila. In the context of biological treatment, Moey and colleagues from East Carolina University found that patients prescribed a renin–angiotensin–aldosterone system inhibitor were roughly four times as likely to have preserved ejection fraction. And when patients were detected early and prescribed high dose steroids, that could dramatically reduce adverse cardiovascular events in this population, according to Harvard’s Neilan.

A new science is born

“A substantial portion of patients will get therapy in a community setting without access to a cardio-oncologist, so they may not get access to protective medications because it’s a novel field,” noted Syed Mahmood, MD, MPH, a fellow in cardiology at New York-Presbyterian Hospital who was the lead author of Neilan’s poster.

“This very new science is less than five years old,” said Avila. “In the beginning of my study, it was very difficult to enter an oncology hospital and say, ‘Please help me give the patient a medicine to protect their heart.’ They would say that it doesn’t exist, but now they believe us and ask for our opinion. We are convincing oncologists that cardio-oncology does exist.”

Onco-cardiology programs have increased in recent years, with the Cancer Institute of Sao Paolo created a fellowship; the ACC itself has created a subsection.

“Some different definitions from clinical trials are really not designed to study cardio-toxicity,” said East Carolina’s Moey. “For example, why didn’t you count those patients with preserved ejection fraction? In our study, they all had trastuzumab, but the other medications are not the same—some had tetracycline, and in some it was docetaxel versus carboplatin, for example. It’s not standardized, so we couldn’t compare one to the other.” To conduct an effective study would require researchers from more than institution, and more than 200 patients, Moey estimated.

However, the entire scientific community may be getting involved, according to Harvard’s Neilan, who attended a round-table workshop called the “irAE Myocarditis Workshop” sponsored on December 15 sponsored by a company called Project Datasphere which operates a database containing information on 200 000 cancer patients.

“In the room were the US FDA, the Chinese FDA, and the European Medical Association, immune oncology scientists from pharmaceutical companies and academia, who all came together to discuss myocarditis,” he said. The group will try to standardize definitions and collaborate to address the problem of myocarditis and immune checkpoint inhibitors.
Single payer healthcare debate takes the stage in managed care

John Otrompe

Two of the advocates in the eloquent and occasionally fiery debate cited recent surveys: Douglas Holtz-Eakin, PhD, president of the American Action Forum said that a survey of 1100 likely voters his organization had commissioned in February found that 51% of respondents opposed single payer healthcare, while 41% were in favor of it. To the contrary, said Larry Levitt, senior vice president for special projects at the Henry J Kaiser Family Foundation in Menlo Park, California, his organization had been conducting surveys on the topic which found that 54% of adults favor single payer, while 43% oppose it. “The number has been growing modestly over time” since 1998, added Levitt.

“If you present people with the kinds of arguments that opponents would use, those arguments do resonate and diminish support; whereas if you present them with arguments in favor of it, that blunts the opposition as well,” he noted.

“If you ask them if they like the Sanders plan which would make private insurance illegal, the outcome goes even more negative,” said Holtz-Eakin. “But single payer is in the eye of the beholder. You could also imagine Medicare Advantage for all, with private ownership of hospitals and contracting of providers, but government funding, and that certainly makes a difference whether single payer is acceptable.”

“I don’t know that single payer is a panacea,” said Donald Berwick, MD, president emeritus at the Institution for Healthcare Improvement in Boston. Berwick was also administrator at CMS in 2010 and 2011, where he drew controversy over his advocacy. “There are widely differing definitions of it, but there is no moral virtue in single payer in itself; that depends on if it achieves its aim,” added Berwick, who was knighted in 2005 for his work creating new care models in five trusts in the UK’s National Health Service (acute care hospitals, multi-specialty groups, accident emergency rooms, mental health, and nursing homes).

Significant social advances (like LGBTQ rights, and other constitutional changes) often take place at the state level before becoming nationwide. For example, Vermont enacted legislation creating single payer universal health care in 2011, but abandoned the effort in 2014. “It’s difficult for a state, particularly a small state, which doesn’t have leverage over the drug industry, to create a single payer system,” explained Levitt, who testified in January before the California legislature, where the strategy has been put on hold in the Assembly after having passed the Senate.

For a state to create its own single payer program would require three federal waivers: one to fold Medicare into the program, a second for Medicaid, and another under the ACA, noted Levitt.

“States can provide an example that shows that an approach can be done, and also create momentum. It’s hard, but I wouldn’t say it’s impossible. That was the experience in part in the drive for healthcare reform. Massachusetts implemented a system very similar to the one that ultimately became the ACA,” he added.

Daniel Tsai, Medicaid Director for Massachusetts, who also spoke at a separate session at the AHIP conference, explained that Massachusetts, which has the lowest uninsured rate in the country, rolled out its first Medicaid ACO plans last week.

“My premise when I was at CMS was that our policies and payment designs should be driven by two purposes,” said the IMI’s Berwick. “First, that healthcare is a human right, and it should be available, without any exception whatever, to every American, and second, that American healthcare today is remarkably defective, and cannot achieve the triple aim of better care for individuals, better health for populations, at a continually decreasing cost. If that is not the business you are in, it is not in this country’s interest, and you are in the wrong business.”

“We are so overfunded for care, we are just spending it the wrong way. Some of it is your waste—stop it,” Berwick told the audience later. “Why are you tolerating quarterly increases in insulin costs? Where are you? I’d back off, but it’s not happening right now. The market’s failing.”

Managed care has proven right in some controversies, including, perhaps, the litigation over coverage for bone marrow transplants for breast cancer in the 1990s. Outcomes have improved a great deal, yet bone marrow transplants are rarely prescribed nowadays.

“There are elements and important pieces we’ve improved, such as cardiovascular outcomes, which have improved in all countries,” admitted Berwick. “But overall, the combination of the triple aim is very elusive under our current healthcare system,” said Berwick in an interview with The Lancet United States of Health Blog.

Given these considerations, one is left with a question: if science has become convinced that managed care was right about bone marrow transplants, has the electorate become convinced that single payer advocates are right about managed care?
Dismantling institutional discrimination in healthcare by empowering minority women professionals

Special Guest Blogger

"The most common way people give up their power is by thinking they don’t have any."

—Alice Walker

Although the numbers of underrepresented minorities (URM) and women have increased overall in medicine, they remain short of societal expectations and demographic shifts, and URM faculty growth has been almost stagnant for years according to the 2017 Association of American Medical Colleges report on US faculty. Black and Hispanic faculty comprise only 3·1% and 2·7% of US medical school faculty respectively, including the four medical schools in Puerto Rico. Women make up 38% of academic faculty in medicine and biomedical sciences, but only 16% of deans and department chairs (Lautenberger 2014, Wehner 2015). Even in senior faculty roles, women are not accorded the same respect and professionalism as their male peers (Files 2017). Of these women in departmental chair roles, a mere 1·3% are URM, and of all female full professors, 2·5% are Black and 1·9% are Hispanic. While minority physicians continue to provide the majority of care for underserved and non-English speaking populations, there are no specialties in which the percentages of black or Hispanic trainees are comparable with the representation of these groups in the US population (Riley 2015).

This under-representation of physicians of color creates a perfect storm for the well-described “minority tax” or cultural tax, which includes extra responsibilities placed on minority faculty in the name of efforts to achieve diversity in many institutions. Rodríguez and colleagues found that this responsibility “tax” includes disparities in the following categories: responsibility for achieving diversity efforts, racism, isolation, mentorship, clinical, and promotion inequities (Rodríguez 2015). For many minority women, there is also the unfortunate “double jeopardy,” in which minority women or women of color in science fields experience gender biases and suffer from racial/ethnic stereotypes (Williams 2014).

Solutions to these issues have often been directed at the institutions that harbor and perpetuate institutionalized discrimination, racism, sexism, homophobia, Islamophobia, ableism and xenophobia. Although these solutions are incredibly important, such solutions empower the institutions themselves to explore and implement new policies and procedures, diversity and inclusion programs, action plans, training programs and retention strategies if they are so inclined (Rodríguez 2014, Bates 2016, Griffith 2007). As one deconstructs power into two sociological forms, coercive power and power by choice (Rosado 1996), influencing the behavior of others against their wishes or influencing the behavior of others without violating their wishes, one must be concerned about giving healthcare institutions too much power over the narrative for minority and other disadvantaged women.

What if, instead, we gave the power to women, instead of the institutions, to create their own narrative and harness the power they did not realize they had?

That’s exactly what we did.

In January 2017, Inspire Health Solutions, LLC, parent company of the Association of Minority Women Professionals (AMWP), launched a national conference series and professional development program for Minority Women Professionals (MWPs), through partnerships and support from multiple academic medical institutions across the nation, including the Albert Einstein College of Medicine Office of Diversity Enhancement, University of California, Irvine School of Medicine Office of Diversity and Inclusion, the Ohio State University Office of Diversity and Inclusion and the University of Pittsburgh Office of Health Sciences Diversity.

This initiative, called Minority Women Professionals (MWPs) are MVPs, served to empower minority women in healthcare and other professions to celebrate themselves as MVPs (Most Valuable Players), and to equip them with tools, strategies, resources and networks to survive, thrive and advance in their professional careers. Powered by a book of the same name, the program articulated and breathed life into Ten Essential Ingredients for MWP success, including:

- embrace your roots and your differences
- find ladder sisters and sister circles
- seek and utilize mentors effectively
- bring others up
- mastering the juggling act
- enjoy your life
- learn when to say yes, no or maybe
We reached hundreds of women in the academic medical environments in five major US cities in 2017 through conferences and workshops. In the process, we challenged them to be purposeful and intentional in their goals after leaving the events, setting action plans and specific objectives around professional and personal development, networking, and career advancement. The overwhelming majority of women faculty, professionals, students or trainees were in medicine or other healthcare fields. 46% of participants were between the ages of 26–40, 26% between 19–25, 21% between 41–65, and 7% over the age of 65. Nearly half of the participants identified as early to mid-career. The majority of participants self-identified (on a multiple possible selection question) as racial/ethnic minorities, followed by age-related minorities, socioeconomic minorities, religious minorities, and minorities based on immigration status or disability. 100% of women left the conferences with new professional goals and nearly 100% described the experience as “excellent” and “empowering.” Many women voiced a new sense of excitement from tapping into unknown or unrealized power. One of the most important themes that emerged in the qualitative feedback was that the MWPs are MVPs program provided women with a network of support that they desperately needed, and often found it hard or time-consuming to create on their own or in their institutions. In short, we filled an important vacuum for women across the career lifespan and of diverse backgrounds.

Going forward, we plan to create more spaces that provide women with this level of unfiltered confidence and shared accountability. We are preparing for a range of ongoing professional development programs for MWPs in various academic medical settings and healthcare institutions with which we have partnered. It is our hope that by using a grassroots approach to empowering MWPs across the nation, we can begin to dismantle the institutional discrimination against them. As their synapses and nodes of influence grow stronger, and as MWPs organize, they can realize the power not in losing themselves, but by embracing who they really are. The time has come to change the narrative and give these women, who bear heavy loads but persevere, the strength and conviction to reach for their own power.

“Here’s to strong women. May we know them. May we be them. May we raise them.”

—Unknown

Inspire Health Solutions and Association of Minority Women Professionals
www.minoritywomenprofessionals.org
Twitter and IG: @HIS_LLC
Facebook: @InspireHealthLLC

J Nwando Olayiwola, MD, MPH, FAAFP
CEO & Founder, Inspire Health Solutions, LLC
Founder, Association of Minority Women Professionals
Associate Clinical Professor, University of California, San Francisco
Department of Family & Community Medicine
Chief Clinical Transformation Officer, RubiconMD
2120 University Avenue
Berkeley, CA 94704
Phone: (510) 296-8868
Email: jancorny@gmail.com
Twitter and Instagram: @DrNwando

• dream big
• be excellent—be extra.
• fail!

Each of five conference programs (Oakland, CA, New York, NY, Columbus, OH, Irvine, CA & Pittsburgh, PA) featured a diverse cadre of local women faculty, leaders, deans, clinicians, and administrators in healthcare, as well as women with other professional backgrounds, students, and trainees. A range of minority groups was represented in the speakers, facilitators and attendees in all conferences. We utilized a number of strategies that appeal to adult learners, such as didactics, motivational talks, fireside chats, panels, role plays, storytelling, case studies, active planning, movement, music, workshops, hands on experience and teach back. Our premise was that if we could create a safe and welcoming space for MWPs to unpack their fears, professional concerns and insecurities, challenges and barriers, we could then fill them with tools and resources to combat oppression, discrimination, “otherhood,” isolation, mentorship vacuums, minority taxes, self-doubt, and stagnation, all while maintaining a strong sense of self-identity. Barreto and colleagues assert that it is important to maintain subgroup identities for positive and healthy self-image and work relationships, so claiming identity is imperative (Barreto 2009). With the women we reached, we sought to energize them through their identities, and transition them from feelings of powerlessness and loneliness to recognizing their own power. We trusted the value of networks and “strength in numbers.” These MWPs in healthcare and academic institutions are often one of just a few people that “look like them” at work. What if they could draw power from another source, a sisterhood of women who understood them and shared some of their experiences across their region and the nation? We created the environment for that power source.

And it worked!

We reached hundreds of women in the academic medical environments in five major US cities in 2017 through conferences and workshops. In the process, we challenged them to be purposeful and intentional in their goals after leaving the events, setting action plans and specific
Point of view
A whole-system approach to improving cardiovascular health in women

Women’s Heart Alliance

These inequities are more pronounced among low-income women and women of color, who face even higher risks of cardiovascular disease (CVD) with high rates of high blood pressure, obesity, and diabetes, compared to other women. Today, nearly half (48.3%) of black women 20 years and older have CVD.

In addition to the individual-level factors (eg, diet, exercise, smoking, adherence to prescribed medications) that influence disparities in CVD outcomes, broader systemic factors exert influence as well. For example, living in a food desert or socioeconomically depressed neighborhood is associated with a higher burden of CVD and its risk factors. Maternal morbidity and mortality—an outcome that, in the USA, is driven predominately by CVD and CVD risk factors—also can be mapped to neighborhoods that are predominantly black, Latino, and socioeconomically depressed.

These examples illustrate the primacy of place as an incubator for and driver of health and disease and the critical importance of neighborhood- or community-level interventions. Unless place-based factors are changed, efforts to change individual behaviors (eg, eat more vegetables and less fried foods) or to address patient-provider communication (eg, around adherence to blood pressure medication), while important, will be insufficient.

Because the social, environmental, and policy environment have a strong influence on women’s CVD outcomes, we need whole-system approaches. This means going beyond the traditional focus on getting individual women to change their behavior (eg, stop smoking, eat “healthy”, get adequate exercise, take prescribed medications). We also must address broader contextual factors that drive individual-level behaviors and individual-level cardiovascular health outcomes. Physician knowledge and food deserts are two examples of these factors. Many cardiologists and primary care physicians do not know about the differences between men’s and women’s heart physiology, women’s symptoms of heart attacks, and their response to treatment. Women will not receive the quality preventive, diagnostic, and therapeutic care they deserve until this changes. Similarly, numerous studies have documented that food deserts are more common in neighborhoods that are predominantly black, compared to those that are predominantly white. Health education messages to “eat healthy” will have limited impact among women whose access to healthy food is restricted by where they live. To overcome these access barriers, public health interventions seeking to change women’s eating behaviors will need to engage a broad set of stakeholders, such as local government, the private sector, and neighborhood faith-based and community organizations. Individual behavior change is not enough. Collective action by stakeholders with vested interest in their communities also is critical.

Women’s Heart Health: the Cities and Communities with Heart Initiative

Recognizing the need for a whole-system approach, in 2017 the Women’s Heart Alliance (WHA) launched its signature program, The Cities and Communities with Heart Initiative (CCHI). This initiative focuses on the cardiovascular health of women in mid-sized US cities where the CVD burden is high and where a broad range of stakeholders are ready to engage in interventions where women live and work.

These stakeholders will help to identify gaps, not only in health services, but in each step in the continuum of care, from prevention through treatment. They also will implement interventions that address gaps across the whole system. This collective action approach should yield greater impact than approaches focused on individual behavior change.

Through the actions and partnerships catalyzed through CCHI, WHA aims to provide a blueprint for action on women’s CVD, for use in communities across the USA.

In Nashville—the first city to implement CCHI—partners include more than two dozen stakeholders from multiple sectors: hospitals, health clinics, health care providers, insurance plans, academic institutions, private companies, community- and faith-based organizations, the media, policymakers, local government, and local celebrities. Through CCHI, the WHA provides a platform to bring these groups together for collaboration and collective action using five strategies:

1. help women (especially the most vulnerable and underserved) engage in prevention, care and treatment of and for CVD;
2 increase CVD care availability;
3 improve the quality of CVD-related care;
4 improve the scientific knowledge base for women’s CVD; and
5 promote policies that support and sustain health equity and improve CVD outcomes among women.

Following a review of epidemiologic, health system, and other data, as well as numerous stakeholder meetings, WHA and its partners selected five strategies for CCHI-Nashville, designed to strengthen health systems and inform clinical and public health practice, policy, and scale-up to other cities. Three strategies involve CVD risk screening and linkage to care and treatment for different populations. These are: The Mayor’s Workforce Initiative (for female municipal employees), an initiative with Tennessee State University (for young, primarily black, women), and Caring for the Caregiver (a health-system based intervention for nurses and other care providers). Caring for the Caregiver, for example, screened 530 nurses in a two-week period, with follow-up support given to those deemed “at risk.” One nurse credits the program with saving her life. She recognized that she was having a heart attack because, through Caring for the Caregiver, she had just learned to identify the signs and symptoms of heart attacks in women. And she got help in time. The fourth strategy is a comprehensive community intervention that builds on the other activities and that focuses on black women and may expand to focus on refugees and recent immigrants. The fifth strategy—a biomedical research and clinical training effort—aims to improve the identification and management of maternal risk factors for CVD. The Women’s Heart Alliance will conduct a process and impact evaluation to assess program fidelity, quality, and results.

Moving forward
Communities serve as a vessel and auger both of disease and of wellness. By applying a whole-system approach to community-level interventions, CCHI seeks to address deep inequities that produce the unacceptably high rates of CVD risk factors and CVD in low-income communities and communities of color.

The time has come to see women’s cardiovascular health as the public health crisis that it is and to address the gross inequities that fuel the unacceptable morbidity and mortality rates for women from CVD. With one in every three women dying of heart disease or stroke in the United States, we need coordinated action, involving multiple stakeholders from multiple sectors, working collaboratively at the community level. We need this different approach.
Equality, parity, and visibility

Rebecca Cooney

In observance of the event, a two-day forum was held at the UN Headquarters in New York, February 8–9, 2018, in collaboration with the Permanent Mission to Malta and the Royal Academy of Science International Trust (RASIT).

The connections to the SDGs may not be obvious when we think about concerns like eradicating poverty and hunger, but strengthening the participation and inclusion of women in science and technology is likely one of the most important foundational steps in making progress in gender equality and social justice more broadly. It is impossible then not to discuss the role of women in science without highlighting the greater context and the deep gaps that must be narrowed. Only two thirds of countries, for example, have gender parity in access to elementary education. The road to receiving an advanced education is far more elusive and harrowing for many girls because of myriad deterrents, including lack of resources, safety concerns, domestic demands, and early marriage and motherhood.

In high-income countries where conditions are more conducive to education access for girls, there are still major deterrents. Even though girls tend to scholastically outperform boys early in life, powerful forces of stereotyping undermine performance and perception in middle and high school and prevent many girls from selecting science and math-oriented college majors. For those women who have gone against cultural expectations and discouragement and attained advanced education in science and technology, career prospects are staggeringly inequitable. Women comprise less than 30% of the world’s researchers and fewer still occupy leadership roles. When they do, they are not remunerated equitably. In the US, women in technology, engineering, and science occupations are paid less than 80% of their male counterparts’ earnings.

In the most recent issue of The Lancet, we editorialized the movements in addressing some of these fundamental inequities, calling 2018 a “year of reckoning for women in science”. Indeed, potent campaigns like #MeToo have shifted attention and conversation to acknowledging the systemic abuse and oppression women experience—and the world of science is by no means immune from such harmful occurrences. Ask any woman scientist whether, at some turn in her career, she has experienced bias or harassment and she will undoubtedly answer in the affirmative. The Lancet has also taken our next step by issuing a call for papers that unpack the issues, the systematic barriers for women in the sciences, as well as where measurable improvement has been made.

There is a great power in acknowledgment that even after decades of progress, inequity is steep, harmful standards persist, and issues of personal safety and unwanted contact or advances are not being adequately addressed or prevented. The UN agenda and the work being done by many academic-facing communities of women in science are absolutely necessary. But there also exists the need to simultaneously pledge ourselves—as individuals—to correcting and improving the outlook for all women in science.

It is often through very simple means that we can make a difference for a new generation of women scientists. When I was in finishing my senior year of college, right after I had been accepted to graduate school, the chair of the department asked me to coffee. She had a reason to do so: to talk with me about how difficult it had been for the women who had gone before me to make the transition and to finish their graduate degrees. It was then that I first learned about the leaky pipeline, the slow drip of talented, hard-working scientists who had to make difficult life decisions that ultimately took them away from their chosen fields. She told me that she was always a phone call away, that her door was always open. I took that message to heart and it has stayed with me.

Within each of us is a role model and an instrument of change. It doesn’t necessarily need to be a formal or academic capacity that we serve each other. Perhaps in its most essential state, it is about being present and visible—giving girls and young women accessible models and fair representations of who we are as scientists and people.

At the UN event, I was struck by the words of one of this year’s Girls in Science recipients, Maria Jose Solis Rivera from Costa Rica, who asked, “Who dares to stop us?” As the many attendees and I clapped, I considered those sentiments. The sad truth is that it is not just a deeply flawed system that can stop us, but it is often ourselves. Whether feeling the toll of imposter syndrome, engaging in unproductive comparisons with our peers, trying to balance the demands of parenting and caregiving, worrying about being too “gendered” or not gendered enough in our behavior, or failing to challenge privilege and injustice, there are so many ways that our journeys in science can be impeded.

On this International Day of Women and Girls in Science, alongside calls for bringing about equality and parity, let us also make it a call for lifting ourselves up by being visible.
Advance care directives: making plans for future medical care

Larry Beresford

Advance care planning is part of a process for clarifying and specifying the kind of medical care people might want if they were to become a lot sicker or even lose the ability to speak for themselves. Advance directives are legal documents designed to capture the sentiments generated through advance care planning for use in a future medical crisis when that information might be helpful.

But despite fears about the medical juggernaut of unnecessary, unbefitting or futile invasive treatments at the end of life, most people don’t bother to complete these documents. The subject is off-putting, the legal language can be intimidating, and it’s just hard to imagine what kind of medical care one might want in some unspecified, distant future scenario.

Even when people fill out the form (easily downloadable from a variety of online sites), there’s no guarantee that their expressed wishes will be honored by medical providers when the time comes. They may not share their thinking about these issues with loved ones, so the family isn’t on board with the plan. And if there is a document, it may not be readily accessible when it is needed most—perhaps because it’s stored in a safe deposit box or because the crisis occurs when the patient is a long way from home or something unexpected happens, like a car accident.

Iris Plans is an Austin, Texas-based advance care planning service that applies a remote videoconferencing app to these problems, using trained health professionals to facilitate meaningful conversations with the patient and as many loved ones as care to log onto a video conference call. The end result of this process typically includes a legally valid advance directive and an online archive of the patient’s wishes and fears, preserved on video for future reference.

“But we’re a discussion company, not a document company,” says Iris co-founder and chief medical officer Stephen Bekanich, MD. “Our value is in bringing patients and families together to talk about these difficult subjects.”

The power of Iris’s goals of care video conference is for people to see and hear each other and the words and language and emotions that are expressed, rather than reading what’s on a piece of paper.

The heart of the Iris approach is the HIPAA-compliant teleconference itself, usually two to three sessions of 40 to 60 minutes each. The facilitator asks leading questions appropriate to the patient’s age, medical condition and other personal factors. Family members want to be included in these discussions, Dr Bekanich says, and sometimes there may be seven, eight or nine participants on the call. Everyone gets to ask their questions and hear the information at the same time.

Disagreements and misunderstandings often arise, but it’s the facilitator’s job to help resolve them. “It’s not that conflict is a bad thing; it usually arises out of love,” he says. At the end of the conversation, documents are auto-generated using the Iris technology for reviewing, signing online, and sharing with whomever the patient designates. And the whole process can be updated as needed when goals change.

Bringing the family together

Bekanich is a palliative care specialist who is used to having these kinds of conversations in his office with patients, talking about what they can expect from their medical condition and what is most important to them in the face of serious illness. But that’s hard to do with all of the other people in a patient’s life who have an investment in what happens. Some have day jobs; others live across the country.

“We realized that by using technology we could bring all these people together,” he explains. The company started out bootstrapping in 2013, marketing to consumers while building its technology platform. “Now we’ve gotten to enterprise-level partners, which generally are groups interested in value-based health care.”

Iris Plans’ service typically is paid by the health plans and health systems responsible for health benefits or covered services. Clients include Humana, Innovista, Aledade, the University of Utah Health Care, and Brookdale, a senior living company. But health plans don’t get a copy of the patient’s document. It might go to the patient’s doctor, hospital or anyone else the patient specifies, and it’s stored in a protected hub online.

The service is billed to the client, not the patient, after the family has completed its advance care planning. “We are not incentivized in any way to steer people to a specific outcome. They don’t even have to sign a document if they’re not ready. Our job is to educate and help people navigate these complex issues,” Bekanich says. He estimates that Iris Plans has facilitated about a thousand such advance care planning conversations in the past year, and it has received venture capital to scale up for expansion in 2018.
Other technology
A number of other firms and organizations have launched products designed to overcome the identified problems of advance directives, trying to make them easier to execute and easier to access when needed. That is important because of the huge variability, regionally and otherwise, in whether terminally ill patients get to die at home or with hospice—rather than in an ICU, hooked up to high tech medical equipment, says Susan Tolle, MD, director of the Center for Ethics in Health Care at Oregon Health Sciences University.

OHSU was an incubator for a new kind of legal document called physician orders for life-sustaining treatment (POLST), which patients use to specify end-of-life treatment options when they have advanced illnesses, and it has partnered with the California tech firm Vynca to enable health care providers in the state to quickly access the 172,000 active POLST forms in Oregon’s electronic POLST registry. But prompts for accessing POLST and advance directives also need to be built into hospital electronic health records, Dr Tolle says. Ideally, they would also be accessible to emergency medical technicians in ambulances. “How do we help the medical system take every little thing, including what’s on video, that patients have said they would want? All of these kinds of programs can increase the chances of their wishes being honored.

A/D Vault’s MyDirectives.com of Richardson, Texas, which started in 2007 and went live in 2012, is the country’s largest digital advance care planning service. It allows people to create, update and share their own digital advance care plan online, reflecting their values and treatment goals and incorporating messages, video posts and photos. These are then available to any authorized medical providers anywhere in the world, says CEO Jeff Zucker. “We believe every consumer needs to live with the confidence that their voice will be heard. They will get better health care because it’s the medical care that they would want.”

MyDirectives is part information system and part technology with an emphasis on work flow and on desensitizing advance care planning. People should do it while they’re still healthy, just as with life insurance, Zucker says. “We want everyone over the age of 18 to create an advance care plan. They can own it, manage it and keep it current with their evolving values through their MyDirectives account.”

For a real-life flavor of the kinds of conversations facilitated by Iris Plans conversations, see this brief clip from an actual advance care planning teleconference session.
CDC director resigns over financial conflict of interest

Aaron van Dorn

According to the report, Fitzgerald was already under congressional investigation for not divesting herself of other financial holdings that could have caused a conflict of interest. Fitzgerald’s departure leaves the CDC under interim leadership during a pressing time for the organization, with a major flu season currently underway, with every state except Hawaii currently experiencing widespread flu activity, and with as many as 50 000 Americans expected to die before the season’s end.

Fitzgerald is the latest in a series of high profile Trump Administration figures to leave government abruptly, including former Health and Human Services Secretary Tom Price, who was forced to resign after a series of scandals involving misuse of government resources. Price selected Fitzgerald for the role of CDC Director. Price was replaced last week by Alex Azar, a former pharmaceutical executive.
After a weekend of negotiations and demonstrations, shutdown disrupts health agencies and services

Susan Jaffe

Update 2. Congress approved legislation to fund government operations through February 8, which President Trump signed late on January 22. The budget agreement ended the shutdown and also provides funding for the Children’s Health Insurance Program for six years.

Update. The shutdown is expected to end Tuesday, January 23, after the House of Representatives approves legislation that passed the Senate this afternoon providing temporary funding to continue operations through February 8. The president is also expected to sign the bill.

This morning, many federal agencies began the third day of the shutdown and the first workday without thousands of their usual employees, who are considered “non-essential” and have an unscheduled, unpaid day off. Nearly 41 000 employees at the Department of Health and Human Services (HHS) stayed home, including 42 percent of the Food and Drug Administration, 63 percent of the Centers for Disease Control and Prevention (CDC), 77 percent of the National Institutes of Health (NIH), 64 percent of the Centers for Medicare and Medicaid Services, and 93 percent of the Substance Abuse and Mental Health Services Administration.

On Friday, the CDC updated details of this year’s unusually intense flu season, in which 8900 people have been hospitalized and 30 children have died. Although the HHS contingency plan stated otherwise, a CDC spokeswoman told The Washington Post late Friday that the agency had decided to continue its response to influenza and other urgent disease outbreaks in the event of a government shutdown, including analysis of influenza data from state health departments.

Nearly 95 percent of the Environmental Protection Agency (EPA) would be missing, under its Contingency Plan for the Shutdown of the Agency Due to a Funding Hiatus, leaving in charge an estimated 781 employees “considered necessary to protect life and property.” However, EPA Administrator Scott Pruitt sent a memo to his 14 449 staff members Friday assuring them that the agency had enough funding to remain open for a short time if there was a government shutdown, including analysis of influenza data from state health departments.

Active military personnel and about half of the defense department’s civilian workforce will be on duty, although they may not be paid until after the shutdown. Air traffic controllers, the postal service and Social Security disability and retirement payments, veterans’ hospitals, the Federal Bureau of Investigation, Central Intelligence Agency, and other essential services are not affected by the partial government shutdown.

Although the federal government will be running with a skeleton staff in many agencies, the shutdown doesn’t save money in the long run. In 2013, a 16-day shutdown cost $24 billion in lost services and wages, according to an analysis by the financial services company Standard & Poors.

Senate Republican majority leader Mitch McConnell of Kentucky blamed the shutdown on Democrats who insisted on addressing the problem of 800 000 undocumented young adults who were illegally brought to this country as children. Under the Deferred Action for Childhood Arrivals (DACA) program, they were allowed to stay and were eligible for work permits. President Trump has said he would end the program if Congress did not fund a wall along the US–Mexico border.

“So who pays the price for that?” McConnell said last night on the Senate floor. “Health care for needy children, training and resources for our men and women in uniform, care for our veterans who came home and survivor benefits for families of heroes who did not. Full funding for the CDC, for the NIH and for routine safety inspections of food and medicine.”

He accused the Democrats of treating continued funding for the Children’s Health Insurance Program (CHIP) and
other “fundamental responsibilities” as “hostages ripe for the taking.”

Senate Democratic minority leader Charles Schumer of New York responded by blaming the president, “who has driven our government into dysfunction.” Speaking on the Senate floor last night, he said both parties had reached tentative agreements twice but Trump objected. “It all really stems from the president whose inability to clinch a deal has created the Trump shutdown.”

Schumer also doubted the Republicans’ commitment to fund CHIP, which ran out of money in September. State officials have been operating the program on temporary short-term funds that may be depleted as early as the end of this month.

“The Republican leader also accuses Democrats of blocking CHIP when he knows full well every Democrat here supports extending CHIP. It’s four months [since it] elapsed—who let that happen? The Republican majority.”

The shutdown also loomed over the second annual “Women’s March” held on Saturday. In Washington, DC, protesters gathered at the Lincoln Memorial before marching to the White House.

First-year medical student Madhuri Rao attended the march with a group of other students from the George Washington University School of Medicine. She is concerned about gender inequality, funding for children’s health care, and Republican efforts to dismantle the Affordable Care Act.

“My hope is that people like us can change the healthcare system and make it more accessible to a lot of people and make insurance more affordable,” she said. “Health care is a human right to me.”
One-hundred years after influenza catastrophe, is the US pandemic-ready?

Ray Cavanaugh

We are also approaching the centenary of the onset of the influenza pandemic of 1918–19—likely the deadliest outbreak in human history—which infected about one-fifth of the world’s population and claimed tens of millions of lives, including an estimated 675,000 Americans.

In the US, the influenza first surfaced at Camp Funston, Kansas, in early March 2018. In fact, some contend that Kansas was the origin of the worldwide pandemic; others point to a European or Asian origin. Wherever it began, the influenza in 1918–19 was uncommon not just for its deadliness but for the high rates of healthy young adults that it killed. By causing a cytokine storm, the virus induced immune systems to work against themselves, so those with the strongest immune system were most vulnerable.

One-hundred years later, the planet has four times as many people, and far more of these people have access to quick transportation around the world. Additionally, the frequency of outbreaks has tripled since 1980. Pandemic talk isn’t scaremongering. In fact, scientists say we are overdue for the next big one. So, how prepared is the US this time around?

The good news is that, “the US is the world’s best prepared country,” says William Schaffner, MD, Chairman of the Department of Preventive Medicine at Vanderbilt University School of Medicine. “The scientific capacity at the NIH and the public health expertise at the CDC are second to none. We have shown that both resources can be directed at new threats swiftly.”

But Schaffner also relates how the past decade has seen cuts in budgets for local and state health departments. “You can’t fight fires if you do not have skilled firefighters,” he says, before adding that “the CDC Director needs to have an emergency fund available. During Zika, money had to be scavenged from other budgets to fight this new virus. That is inefficient and not sustainable. [Congress] should appropriate such a fund that can be used in emergencies.”

Aside from the 1918–19 catastrophe, an influenza pandemic in 1957–58 killed about 2 million worldwide, and a 1968–69 pandemic claimed about 1 million worldwide. “Influenza’s capacity to create major global pandemics assures a place on the scientific radar,” says Schaffner. “Much research is ongoing in an attempt to create a ‘universal’ influenza vaccine that would provide protection against virtually all genetic variants of influenza.”

As for other viral outbreaks, Schaffner relates how “no scientist predicted the sudden surge” of AIDS, MERS, SARS, or Zika. “Science has to be ready to respond to the unexpected…it is fortunate that our capacity to respond to new outbreaks has improved greatly because of scientific advances.”

Because of all these scientific advances, though, much of the general public has lulled itself into a false sense of security, assuming that modern science will have everything covered. Schaffner points out how many people “are stunned to learn that epidemics caused by new viruses can still occur in the 21st century.”

Schaffner—who previously served as president of the National Foundation for Infectious Diseases—agrees that the next outbreak will most likely reach the US by airplane. “New viruses emerge in the developing world, where people live closely with their domestic animals. The animal viruses mutate and become adapted to living in humans. Humans can travel in airplanes around the world, spreading the new viruses, introducing them into other countries.”

The internet and social media were beyond even science-fiction in 1918. Now, they’re a ubiquitous, constant reality and “vehicles for both good and bad,” says Schaffner. “Both can transmit accurate information quickly to many, but they...
also can transmit gossip and false information. The potential is there, but we have not yet exploited them optimally."

Though names like Ebola tend to elicit more terror, Schaffner contends that our greatest threat for a massively fatal epidemic comes from new influenza viruses, “because they spread so readily and quickly and because influenza can cause such serious life-threatening illness.”

One-hundred years on, we’re locked into an extremely high-stakes cat-and-mouse game, with viruses forever mutating and scientists trying to neutralize them. About this predicament, Schaffner says: “We can predict that it will be unpredictable, except that there will be new infectious disease threats.”
Temporary CHIP funding falls short

Susan Jaffe

Despite wide bipartisan support for the Children’s Health Insurance Program (CHIP), Congress agreed last week to continue coverage for 8·9 million children only through the end of March. But several of the program’s state directors say the $2·85 billion rescue plan won’t even last that long, and federal health officials are not offering much reassurance.

“Due to a number of variables relating to state expenditure rates and reporting we are unable to say with certainty whether there is enough funding for every state to continue its CHIP program through March 31, 2018,” said Johnathan Monroe, a spokesman for the federal Centers for Medicare and Medicaid Services (CMS), which oversees the program.

The aid was part of the budget legislation President Donald Trump signed into law December 22 that will keep the federal government running until January 19. CMS officials believe the $2·85 billion for CHIP should be enough to keep the program running in all states at least until then. At that point, Congress will have to approve another funding bill to prevent a federal government shutdown.

CHIP covers children up to age 19 in families with incomes too low to afford private health insurance and too high to qualify for Medicaid. It cost the federal government $14·4 billion last year, with states contributing just $1·2 billion. But this year, Congress failed to renew funding, which expired September 30. CHIP has been running on diminishing funds since then.

Alabama’s share of the $2·85 billion infusion averted a planned January 1 enrollment freeze and a February 1 CHIP shutdown that would have been “a huge hardship for families,” said Cathy Caldwell, director of the Bureau of Children’s Health Insurance at the Alabama Department of Public Health. But now she fears that plan may take effect just a month later.

“We need Congress to continue funding in January because it looks like this new money might only be equivalent to three to four weeks’ worth of funding,” she said.

During conversations with congressional staffers and others in Washington, Caldwell was frequently reassured that “everybody’s in support of this program,” she said. “I am absolutely baffled and never thought it would come down to the wire like this.”

In Virginia, the new aid will be enough to continue coverage for 68 000 beneficiaries only through January. Officials there are counting on another source funds to buy more time when CMS redistributes CHIP money that some states didn’t use.

“We are waiting to learn from CMS how much additional funding we can expect to see if that gets us through February. At this point, we are still looking at shutting down at the end of January,” said Linda Nablo, chief deputy director at Virginia’s Department of Medical Assistance Services.

“We are relieved but it is not really sufficient funding to keep all states going for three months,” said Nablo, who also who also managed CHIP programs nationwide during the Obama administration. “The money is available until March but that does not mean it is enough to get through March.”

In Colorado, Gov. John Hickenlooper requested emergency state funding to supplement its new federal money for the state’s CHIP program, which covers about 75 000 children. But the combined aid is still only enough to keep CHIP operating until February 28, said Marc Williams, a spokesman at the Colorado Department of Health Care Policy and Financing. At least that’s the plan, unless the department’s budget analysts say otherwise.

After Alabama’s CHIP program posted a warning on its website last week about shutting down, “our phones were ringing off the hook,” she said. Calls from families and CHIP advocates expressed shock and disbelief, with some promising to contact their congressional representatives. On December 12, Alabama voters surprised the nation by electing Doug Jones to the US Senate, the first Democrat to represent the state in Congress in 25 years. During his victory speech on election night, Jones called on his future Senate colleagues in Washington to fund CHIP.

Like other CHIP families across the country, Alabama beneficiaries have few good alternatives if the program closes. Some children will qualify for Medicaid, while others may
be able to get coverage through the Affordable Care Act’s insurance marketplaces and may receive premium subsidies, said Caldwell. Another small portion may be able to get coverage through a parent’s employer-sponsored insurance.

But subsidized ACA or job-based coverage will cost substantially more than CHIP, she said, where monthly premiums range from $52 to $104 per child, depending on family income. Federal law limits CHIP premiums to no more than 5 percent of family income and most states charge no premium.

Since CHIP began two decades ago, the number of American children without health insurance has dropped from 10 million in 1997 to 3·3 million in 2015.

“CHIP came about on the federal level to address the issue of the millions of uninsured children in middle-income families who could not afford private insurance,” said Caldwell. Before CHIP, 20 percent of Alabama’s children had no health insurance coverage. “Now it is 2·4 percent, a huge improvement, and if CHIP goes away there will be many children who become uninsured in Alabama.”
Alex Azar’s controversial qualifications

Susan Jaffe

When President Donald Trump nominated Alex Azar last month to lead the Department of Health and Human Services (HHS), supporters said his experience working in government and the pharmaceutical industry more than qualified him for the job.

HHS is the largest civilian agency in the federal government, with a budget of $1·15 trillion. It includes the Food and Drug Administration, Centers for Disease Control and Prevention, and the National Institutes of Health. It also operates health insurance programs for the more than 100 million Americans in Medicare, Medicaid, the Indian Health Service, and the Affordable Care Act’s marketplaces.

But critics say Azar has the wrong kind of experience. When he appeared before Senate Committee on Health, Education, Labor and Pensions (HELP) last month, the committee’s senior Democrat Patty Murray of Washington said if Azar runs HHS then “the fox is guarding the hen house.”

Azar joined Eli Lilly, the Indianapolis-based pharmaceutical firm, as a senior vice president in 2007 to oversee the company’s effort to lobby federal and state governments. He later became president of Lilly operations in the United States until he left earlier this year to establish a pharmaceutical and health insurance consulting firm.

Azar’s industry experience is “a plus,” said Sen. Lamar Alexander, a Tennessee Republican and the committee’s chairman.

“My own view is that, that’s a big help, because having some familiarity with—drug pricing is such a Byzantine situation that someone who did not know anything about that, or much about it, by the time they came in—they’d be gone before they even figured out 5 percent of how we might lower drug prices,” he said.

But while Azar was at Lilly, the company increased its price for its insulin drugs by 20·8 percent in 2014, 16·9 percent in 2015, 7·5 percent in 2016, and another 7·8 percent in the first quarter of 2017. These price hikes attracted the attention earlier this year of the attorneys general of California, Florida, Minnesota, New Mexico, and Washington which have asked Lilly for information “relating to the pricing of our insulin products,” the company stated in financial documents filed with the Securities and Exchange Commission. (A spokeswoman for the Washington state attorney general said she could not comment on pending investigations, including confirming whether they exist.)

“Alex Azar’s role and Eli Lilly’s involvement in price gouging must be fully investigated and revealed before he is put in charge of America’s health needs,” according to Congressional Progressive Caucus leaders Arizona Democrat Rep. Raúl M Grijalva, Wisconsin Democrat Mark Pocan and Illinois Democrat Jan Schakowsky. In a letter to members of the Senate finance and HELP committees, the group asked for a delay in Azar’s nomination until the drug pricing investigations have concluded.

Questioned about Lilly’s price increases, Azar agreed there was a problem.

“The current system of pricing insulins and other medicines may meet the needs of many stakeholders, but that system is not working for the patients who have to pay out-of-pocket,” he said. “That’s why the president, so many members of this committee on a bipartisan basis, and I have talked about the need to fix this system.”

Azar will also testify before the Senate Committee on Finance, which is responsible for deciding whether to approve his appointment as HHS secretary. The committee is expected to vote on the matter in January.

Before working at Lilly, Azar, an attorney who graduated from Yale Law School, held the number two post at HHS as deputy secretary during the George W Bush administration. He managed a budget of $698 billion and had “more than 66 000 employees reporting up to him,” according to his LinkedIn profile. While at HHS, he was part of the response team handling the anthrax attacks following 9/11 and the SARS and monkey pox threats. He also helped roll out the
addition of prescription drug coverage to Medicare, the government’s health insurance program for older adults and people with disabilities.

Among those groups backing Azar are the American Hospital Association, the Association of American Medical Colleges, American Medical Association, America’s Health Insurance Plans, and the Pharmaceutical Research and Manufacturers of America (PhRMA).

AMA president David Barbe called Azar “a capable and proven administrator who has a deep understanding of the HHS portfolio based on his prior work as Deputy Secretary and General Counsel.”

Organizations opposing the Azar nomination include the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO), National Nurses United, National Physicians Alliance, Alliance of Retired Americans, the National Committee to Preserve Social Security and Medicare, and Public Citizen.

“Public Citizen opposes the nomination of a top pharma lobbyist and longtime pharma executive to lead the people’s health agency,” said Peter Maybarduk, the consumer advocacy group’s Access to Medicines program director. “Affordable healthcare requires standing up to precisely the interests Alex Azar has represented for much of his career.”

Azar would replace Tom Price, a physician and former Georgia congressman. He resigned in September after Politico revealed that he billed the government more than $1 million for the use of private and government aircraft instead of taking less expensive commercial flights.
The recent rise of cannabinoid hyperemesis syndrome

Ray Cavanaugh

In a sense, CHS is a paradoxical condition: Marijuana has been used to mitigate vomiting in persons with cancer and other conditions. However, consistent and extended use of marijuana can beget a hyperemetic reaction.

Aside from severe nausea and vomiting, other CHS symptoms can include abdominal discomfort, bloating, excessive sweating, and weight loss. Some patients may present with diarrhea, but it’s by no means a requirement for diagnosis. Patients often seek relief by taking hot baths or showers, and such immersion in hot water may become a compulsion.

Many healthcare workers, let alone the general public, are unaware of the potential hyperemetic effects of long-term cannabis use. But as potency and availability increase, emergency room doctors across the country are more likely to encounter at least a few cases of CHS.

“I think it’s fair to say that dose matters,” says Eric Lavonas, MD. “Marijuana use has been around a long time, but the highly potent clonal strains grown under precise indoor conditions are relatively new, and their widespread availability preceded the uptick in CHS cases by a few years.”

In 1993, the average marijuana potency was 3.4 percent THC. By contrast, Colorado’s legal marijuana has an average potency of 18.7 percent THC, and some brands contain has much as 30 percent.

CHS made it into medical literature in 2004 with a paper involving cases in southern Australia. Specific numbers of CHS’s prevalence in the US are difficult, if not impossible, to ascertain. Lavonas—a medical toxicologist at Denver Health Medical Center, where he is serving as Interim Director of the Emergency Department—remarks that “we definitely have been seeing more of this in the past 2–3 years.”

Lavonas has seen “a few cases in older teenagers, but for the most part it’s people in their twenties to fifties.” Though “anecdotally, [CHS] seems to be more common in women,” he adds that, “men are certainly susceptible as well.”

A significant concern with CHS is that the hyperemetic patient becomes so dehydrated that the kidneys shut down. Lavonas urges persons who “can’t keep fluids down at home” to come to the hospital for proper hydration to prevent permanent damage. “The temporary kidney damage caused by dehydration almost always goes away when we fix the dehydration,” he adds.

Many CHS cases are resolved within a day or two, while others might take a week or up to a month before resolution of symptoms. In some instances, patients have contended with the syndrome on a cyclical basis for years before receiving a diagnosis.

Though the majority of persons with CHS have used marijuana consistently for more than a year, one study reported that nearly one-third of persons experienced symptoms after less than one year of consistent use. And though persons with CHS tend use marijuana daily, some can get the syndrome with less-than-daily use, and a few cases involved persons who used marijuana less than once per week.

“Here in Colorado, we see enough CHS to recognize it pretty readily,” says Lavonas. However, doctors in states that are less marijuana-friendly may not be so attuned to the condition. Increased knowledge of CHS in the medical community could save a lot of costs pertaining to unnecessary diagnostic tests, such as endoscopies.

Hospitals typically treat CHS in the short term with haloperidol. For now, the only way to cure CHS long-term is to stop using marijuana. “The huge challenge for patients is that long-term abstinence is needed to reset the body,” Lavonas points out. “That’s very hard for people to do. I’m hopeful that with better understanding of the disease will come a solution that works faster.”

One doesn’t need to smoke the marijuana in order to suffer from CHS. “Most of our heavy users tend to smoke or vape,” says Lavonas. But one can get the syndrome...
“from any form of marijuana exposure.” That said, most heavy marijuana users never get CHS. It’s been speculated that those users who get the condition may have a slower cannabinoid metabolism, which can lead to toxic accumulation.

When told that marijuana is very possibly the cause of their ailment, “Patients are typically very surprised, and for many of them their reflex response is to assume that their doctor is just being anti-marijuana,” says Lavonas. “Honestly, I’m not for or against marijuana use by adults—I’m anti-vomiting!”

For persons who have recovered from CHS, the symptoms will most likely return if they resume using marijuana. “In my experience, it’s very difficult for people with CHS to agree to stop using marijuana,” says Lavonas. “People have been told for so long that marijuana helps with nausea, and they feel temporarily better when they smoke it. It’s definitely an uphill battle.”

Lavonas expects this condition to become more prevalent in the coming years. “I’m afraid this is the tip of the iceberg.”
Coordinated care is taking on opioid abuse in one rural community

Mary Beth Nierengarten

Little Falls, MN may best be known as the boyhood home of aviator Charles Lindbergh, but talk to people working in the trenches on the current opioid abuse epidemic and another name may come to mind when hearing of this small town of roughly 8500 people in central Minnesota. CHI St Gabriel’s Health, a healthcare system founded in 1892 by Franciscan nuns, is emerging as an innovator in tackling the rampant opioid abuse and addiction plaguing its community and in doing so is catching the eye of state and federal policymakers.

A program initiated by CHI St Gabriel’s Health to grapple with the growing opioid abuse and addiction problem in Little Falls, and the surrounding rural towns of Morrison County, is showing that reducing the number of opioid prescriptions dispensed in a community is a critical component to interrupting the vicious cycle of misuse of and addiction to these narcotics.

In 2015, CHI St Gabriel’s Health formed a controlled substance care team, comprised of two family practice physicians, a pharmacist, nurse navigator, social worker, and mental health coordinator, to help physicians identify and monitor patients on pain medications, the reasons they are on them, when to modify or taper patients off narcotics when appropriate, and focus on individualizing care of patients dealing with chronic pain.

The program was initiated after healthcare providers in 2014 became aware of how ubiquitous opioids were in Morrison County. Prescribed narcotics were being found at and reported by law enforcement at drug-related crime scenes and in cases of overdose, and people seeking additional pain medication for chronic pain was the number one reason for people seeking treatment at the hospital emergency room.

When tracking the number of narcotics dispensed in 2014, the data showed an average of about 100,000 doses of narcotics dispensed per month from the three local pharmacies.

Since implementation of the program in 2015, the number of narcotics dispensed has dropped appreciably. Currently, 329 patients have been weaned off their prescribed opioids. “This equals 370,000 doses or pills of opioids prescribed annually,” said Kathy Lange, Director of CHI St Gabriel’s Health Foundation, who added that these numbers continue to increase weekly.

According to Lange, most of these patients did not need opioids but were prescribed them regardless. One reason for their misuse of the opioids, she said, was the lack of a coordinated care management system of prescribing narcotics that led to patients getting multiple prescriptions from multiple prescribers. “This is why when the controlled substance care team is in action, they are looking at one provider,” she said, adding that the implementation of an electronic medical record system made a big difference in the ability to track opioid prescribing practices.

By using a coordinated care approach, the program at CHI St Gabriel’s Health is not only helping patients wean off of unneeded opioids but also reducing the number of opioids that enter the community. This is a boon for the community at large in terms of reducing the number of people who overdose and those jailed for narcotic use and drug-related crimes.

And in terms that often influence policy most, the program at CHI St Gabriel’s Health is saving money. According to Kathy Lange, the cost savings of weaning 324 patients off opioids was 1.3 million dollars for just the reductions in opioids used by the group. This is based on estimates of reimbursement dollars from their lowest payer—Medical Assistance.

These numbers are getting on the radar of both state and federal policymakers. In May, legislation passed in Minnesota that included a bill to establish opioid abuse prevention pilot projects modeled after the CHI St Gabriel’s Health program. In September, Lange and members of the controlled substance care team met for the second time with congressional lawmakers in Washington, DC who expressed strong interest in the program.
Among the comments Lange heard was someone who said the program “is the best opioid solution we’ve heard.”

But personally, Lange said the comment that struck home the most was from a person who approached her while she and Dr Kurt DeVine, one of the physicians on the controlled substance care team, sat at a DC café after the congressional hearing. A young man walked up to their table and thanked them for what they are doing. “That was a pivotal moment,” she said. “It validated why we are doing this work.”

Sustaining the work is obviously crucial, and at least for the next two years is ensured through recent state monies of just over $1 million recently approved by the Minnesota legislature. However, Lange regretted that the amount of monies approved fell short of their requested goal of $4 million that would have helped to replicate the model in other rural communities.

Despite the lack of funding, educating clinicians in other communities about their program and opioid abuse and addiction will soon be made available through an innovative project called ECHO (Extension for Community Healthcare Outcomes) based at the University of New Mexico. According to Lange, CHI St Gabriel’s Health is one of four Minnesota hubs recently chosen to offer education on opioids through ECHO.
Bursting superpower: obesity in the United States

Ray Cavanaugh

The NCHS Data Brief Report

The truth is that not only are we still in crisis mode, but “it is likely to get worse,” says James O. Hill, PhD, who serves as Director of the Center for Human Nutrition at the University of Colorado Health Sciences Center.

The significant implications of obesity are no secret among the public: the majority of US persons view obesity being “tied with cancer” as the nation’s most serious health issue. But despite all the publicity on the issue, a huge and growing proportion of the population remains obese.

This suggests that “we are not on the right path to solve the problem,” says Hill, who has worked on obesity-related issues for more than 35 years. “This does not mean that everything we are doing is wrong but rather that it is not sufficient to reverse the trend. It may be time to take a breath and consider what we know and what we don’t know—and how to do things differently in the future. If we keep doing what we are doing, I think we can predict the results. It may be time to admit that we do not know how to reduce obesity and bring the best experts together to develop a better strategy.”

Annual US healthcare costs due to obesity are estimated to exceed $190 billion, and many billions more are lost due to diminished workplace productivity.

“It is hard to get excited about the positive impact of anything we have done. We need innovation and new thinking.” Hill says. “We have to stop thinking about a single solution to the problem of obesity. It is extremely complex and we need to better understand the complexity if we have any hope of addressing it. Everyone thinks they know how to reduce obesity … and yet rates continue to increase.”

Adults aged 40-59 have the highest obesity rate at 42.8 percent, followed by adults aged 60 and over at 41 percent, and adults aged 20-39 at 35.7 percent.

Obesity rates can vary significantly according to race: Hispanic adults had a rate of 47 percent, followed by non-Hispanic blacks at 46.8 percent, non-Hispanic whites at 37.9 percent, and non-Hispanic Asians at 12.7 percent.

More than 20 percent of adolescents aged 12-19 are obese, along with 18.4 percent of children aged 6-11 and just below 14 percent of children aged 2-5.

Among youths aged 2-19, Hispanics had an obesity rate at 25.8 percent, followed by non-Hispanic blacks at 22 percent, non-Hispanic whites at 14.1 percent, and non-Hispanic Asians at 11 percent.

Instead of policy changes, Hill “would like to see us trying more things at the community level and then scaling those that show promise,” adding that, “We cannot just focus on food; we have to increase movement as well.”

According to the US obesity prevalence map, every state had an adult obesity rate higher than 20 percent. Though it may seem confusing to some that the national adult obesity rate of 39.8 percent is higher than any of the state rates, Hill explains that, “The state obesity rates come from self-reports and are always lower than measured values.”

Craig M. Hales, MD, who works as a Medical Epidemiologist for the Centers for Disease Control and Prevention, adds that: “Among adults and teens, self-reported height tends to be over reported and weight is underreported.” As BMI, the criterion for obesity, is calculated by one’s weight in kilograms divided by one’s height in meters squared, “it leads to underestimates of obesity prevalence.”

Obesity has long been linked to heart disease and stroke, but its link to cancer has become more evident in recent times. Two-fifths of US cancer diagnoses are related to people being overweight or obese. Especially startling is that these factors account for 55 percent of cancer diagnoses among females.

Based on results from the 2013–2014 National Health and Nutrition Examination Survey (NHANES), 7.7 percent of adults were considered extremely obese (BMI of 40+), and more than 70 percent of all adults were either overweight or obese. Though men were more likely to be either overweight or obese than women, women had higher rates of obesity and extreme obesity. Men were significantly more likely than women to be overweight without being obese.

As for where the national obesity rates will be in ten years, Hill says: “It depends on whether we are willing to do what it takes to better understand obesity and how to impact it. If we are not successful, rates will likely continue to rise. At some point, everyone not genetically protected could be obese.”
Does government quality website capture what matters to hospice patients?

Larry Beresford

Needless to say, there were some kinks in rolling out the government’s computerized system for reporting the data, and lots of complaints from hospices that felt they were not represented in the best light. The performance data on which hospices were scored is self-reported and covers care provided one to two years ago (October 1, 2015 to September 30, 2016).

Hospices were allowed to preview the government’s report of their data for accuracy before it went live, but there is a lag between identifying an error and having it updated or “refreshed” on the webpage. Hospices also report mistakes in the demographic data—their address, phone number, even whether they are non-profit or for-profit companies.

Some of the current measures don’t discriminate very well between providers, because most get equivalently high scores. Experts also say the quality measures currently on display, pulled from the seven-question “Hospice Item Set” questionnaire hospices are supposed to fill out for each of their Medicare patients, are only process measures of whether the hospice is taking the right steps such as asking patients about their pain and documenting it in the medical record—not measures of actual outcomes experienced by the patient and family.

The government plans to add additional quality reporting data each quarter, including results from family satisfaction surveys in the first quarter of 2018. Future measures will quantify, for example, how many professional visits were made to the hospice patient’s home in the last seven days of life.

How to validate and document quality

The concerns expressed to date about Hospice Compare thus are largely technical. They reflect the long and arduous journey to develop valid and methodologically sound measures that meaningfully capture the quality of hospice care—which is highly subjective and nuanced—yet can be used the same way every time by every hospice.

How do you quantify compassion? How do you score clinical competence, effective care coordination, use of an individualized patient-centered approach, or honoring the patient’s values? How confident caregivers say they feel in the support they received from the hospice—and in their own ability to care for their dying loved ones—starts to get closer to something that could actually be counted.

But the methodological and technical challenges remain huge.

Can Hospice Compare (even with the expanded measure set the government has promised for next year) actually measure true quality of care—as it is experienced by very vulnerable people in the middle of perhaps the greatest crisis of their lives? How close can we get to quantifying what you would want for the care of your own mother during her terminal illness?

Hospice Compare is far from a perfect system, says Michelle Webb, Chief Clinical Officer for Four Seasons, an innovative, research-oriented hospice and palliative care program in Flat Rock, NC. Four Seasons’ initial Hospice Compare ratings were less than stellar. “We’ve had some of the same concerns about the data not being very current and about the process measures not giving the whole picture of a hospice’s performance,” she says.

“Our internal outcomes measures are really great, but our process measures now reported on Hospice Compare primarily reflect problems with documenting assessments in our electronic health record, not the actual care we provide,” Webb says. For example, five of the seven elements in assessing patients’ pain must be included in the record for the assessment to be credited as complete. This can be particularly challenging for non-verbal patients—but the hospice is still responsible for assessing their pain.

“I have worked in hospice for 13 years, and if we haven’t truly defined what represents quality in hospice care and communicated that to the public and to our other stakeholders, well shame on us,” she says. “There is an assumption by some providers that because we have enjoyed this reputation for being very caring people, then we can rest on our laurels. But now that Hospice Compare is out there, we need to check the accuracy of our data on the website while working to elevate our scores. It’s a real challenge.”

Word of mouth is critical

Word of mouth is probably the best way to choose a hospice, says Dr Todd Cote, medical director of Bluegrass Care Navigators, a venerable hospice in Lexington, KY. He thinks consumers should be prepared to dig for information about their hospice. In some communities there are dozens to choose from, so it’s not unreasonable to interview several and ask them a lot of questions. “What is the distance
between what the hospice promises and what it delivers—and how do you ascertain that up front?”

Dr Ira Byock, veteran hospice physician, chief medical officer for the Providence Institute for Human Caring in Los Angeles, and author of several books about the travails and opportunities inherent in the end of life, says he hears a lot about hospice experiences from the public. “I remain an ardent supporter of hospice care and want to see people get it sooner. It ought to be the standard of care in the American health care system for patients with advanced disease,” Byock asserts.

“But people write me stories all the time, and I am aware of some deeply disturbing, chillingly bad hospice care out there. That should not be tolerated.” Some of that shockingly bad care has also been documented in an article series in The Washington Post and Huffington Post.

Byock believes that hospice industry leaders and organizations including the National Hospice and Palliative Care Organization have been slow to tackle the problem of bad hospice care, seeming to defend the provider community at the expense of vulnerable dying patients. “Hospice care is hugely variable, ranging from absolutely superb to clearly deficient in key aspects. It’s a fact that the hospice field and industry and their leaders have never stepped up to the plate and developed truly meaningful measures of quality.” The government already has data reported on hospices’ claims forms about, for example, staffing ratios, professional visits within 48 hours of death or live discharges from hospice, he says. These should be reported to the public as well.

In most cases, consumers of hospice care and their hospice providers will only have one chance to get it right. And the consequences—for loved ones whose memories are either of a peaceful passing and meaningful goodbyes or of a disaster defined by chaos and suffering—could last for years.

What kind of story do you want at life’s end, and how can the hospice help you? Webb poses. “What is most important to you at this time of your life? I had to select a hospice for my own parents. How willing were the hospices to learn the life story of my father, who had lived 85 full years?”

Questions to ask about your hospice provider

- Does the patient really have a choice? Or is the hospice provider determined by geography or the policies of the patient’s physician, hospital or health plan?
- Who owns the hospice? Is it a non-profit agency, a privately owned for-profit company or a big, investor-owned national chain? There is evidence that for-profit hospices in general perform less well on certain quality parameters.
- How does the hospice respond to the very first call for help? Does it answer promptly? Does it roll up its sleeves and work with the patient and family to try to figure out the best approach to care—within the limits imposed by Medicare regulations—or does it say: “We’re not sure you are eligible for hospice?”
- Does the hospice have special services like an inpatient unit, music therapy, accessible volunteer services, or a crisis medication kit placed in the patient’s home?
- What are its staffing ratios? How often do professionals visit the patient? How accessible is the after-hours response, or inpatient or continuous care when these are needed?
Patents, licenses and drug prices

Aaron van Dorn

Editor’s note. The following is an edited transcript of a podcast.

Rebecca Cooney: Welcome to the United States of Health Blog Podcast. I’m Rebecca Cooney, North American Executive Editor of The Lancet. The rising cost of drugs are one of those issues that many Americans feel is, simply put, unacceptable. But the factors that underpin pharmaceutical pricing are decidedly complex. In this podcast, we’re going to delve into one of the more specific, although more distal determinants of pricing, patents, the holy grail of pharmaceutical innovation.

You may have heard in September of this year, the pharmaceutical company Allergan gave six patents for its popular dry eye drug Restasis to the St Regis Mohawk tribe in northern New York. It’s a controversial move that hasn’t gone unnoticed by the industry or lawmakers who suggest that the arrangement might exploit an unforeseen loophole that would protect patents from being reviewed and, in essence, hinder competition from generics.

We spoke with Tahir Amin from I-MAK, the Initiative for Medicines, Access, and Knowledge, about this rather unusual story, and what this means more broadly for patent protection, and a bit about how the Patent Trial and Appeal Board or PTAB works, as well as the potential effects on prices and the global market.

Tahir Amin: The transfer, as we know it and has been reported...Obviously, we’re not privy to access to the materials, the license, the agreement that has been struck between the tribe and Allergan. But what we understand it to be is that the patents on the drug Restasis has been transferred over to the Mohawk tribe and, then, they will license it back to Allergan and, essentially, Allergan will be able to use it and protect the marketplace using those patents as it wishes.

So, obviously, there must be certain terms and conditions that will allow Allergan to use those patents in a way as if it was the owner, even though the owner, technically, would be the Mohawk tribe. But that’s based on the reports. As I said, we’re not privy to seeing those particular legal agreements and contracts.

Cooney: A couple things come to mind. I think that, from the perspective of not wanting to impugn the tribe because, obviously, there is a financial motivation and, I think, at least from media reports they’ve been described as being somewhat assertive in trying to lay the groundwork for this sort of arrangement. But what really struck me was the fact that for Restasis, the profits from Restasis are well over a billion dollars, I think, for Allergan. Yet it sounds like the tribe itself has negotiated a lump sum and, then, 15 million dollars or so per year to host these patents, I guess, would be one way of saying it, which seems like an awfully small amount of money for doing that. And, so, it really begs a question, are they still somehow being exploited in
Amin: Well, I obviously cannot speak to their intentions. And I understand that they are trying to diversify their business and ability to bring in income. So from that perspective, I have to respect that. I can’t speak to those issues and their intentions but, certainly, it does raise the issue of exploitation or, certainly, whereby...I think it’s important that the bigger issues at play here are discussed. And, obviously, the St Regis Mohawk tribe has certainly come out and defended this, and I think we just learned the other day that they filed a submission at the Patent File and Repeal Board because that’s where, again, the patents are being challenged, stressing why those patents are now immune because they’re now the holder of them. So, obviously, they’re taking this very seriously. Obviously, whoever’s advising them has really got them fully involved.

We have heard from other people that we’ve been speaking to, people connected with other Mohawk tribes, were a bit disturbed by this, in particular, given recent events in the Dakota Pipeline and all these other issues about how corporate interests are playing into the lives of certain Mohawk communities. I think there isn’t a straightforward answer there as to how did that community or how these different tribes are actually appreciating this. I certainly do take your point, though, that it does raise the question that there is definitely something here that benefits Allergan more than it does the tribe.

Cooney: Because the piece that you’ve written really gets into this, and I think it’s a really useful way of describing the practice and kind of opening some light on the process of how the creation of PTAB...So I thought maybe we could get into that a little bit. If you could give us the layperson’s review of what PTAB is and why it’s important and, then, how that connects up with the story and with Allergan.

Amin: The back story to the creation of the Patent Trial and Appeal Board, depending on how you pronounce the word patent and patent, basically, it came about as a result of the America Invents Act in 2011, as passed by President Obama. The reason why this act came about was because there was concern, particularly coming from the tech industry, that there were a number of what we call patent trolls, or patent trolls, who basically request money and make a litigation. They don’t have any product of their own. And in a lot of cases some spurious patent right, which they use against the people who are trying to get businesses off the ground and products off the ground, in order to extract royalties and licenses. And, so, the act was designed to try and...How can we improve the patent system? How can we improve the quality of patents? And, so, as a result, the PTAB was formed. Congress passed this act and, then, created this process under the US Patents and Trademark Office, and that’s how it was born.

There used to be a similar process in the Patent Office. It used to be called a reexamination process. So, for example, after a patent has been granted, any person could file evidence to say why a patent should not be granted. It was a less robust mechanism. It had its limitations, whereas the PTAB process is much more thorough and, I think, much more well-thought-out in terms of trying to, we believe, actually make the patent system much better and robust because a lot of studies show that the number of patents being granted in a lot of different sectors are actually not valid in one way or another.

Cooney: I’ve also read, and correct me if I’m wrong here, but that IPR is a much less expensive process, too, than previous. Is that correct?

Amin: Right. If we go the way that this issue is usually dealt with, agents have usually dealt with it in the district courts or going up to the federal circuit courts or the appeal courts. Litigation is very expensive, we’re talking well into the millions, whereas at least...And we still think the PTAB process, the IPR process, is still very expensive in the sense that it’s not accessible by all. So, for example, really if you look at the data, most of the people who are using it are actually still corporations or medium-sized businesses. It’s not something that, for example, if you’re a public interest group or if you’re an individual, even an individual inventor, it’s still going to cost you a sum to actually see through an IPR process. I think we’re looking at regions of up to anywhere between 390 to 500,000 dollars, so it’s not cheap. But still, it’s a little bit more accessible.

And the other beauty of it is, and I think this is one of the things that’s causing the pro-patent lobby to get upset, is it actually allows anybody to bring a matter before the PTAB, whereas in the current court system, you must have what we call legal standing. Particularly when it comes to pharmaceutical patents, it’s very hard to have legal standing unless you’re actually another manufacture, maybe allegedly infringing the granted company’s product that’s on the market. So if you’re a patient organization, somebody who suffers from a particular problem, and you want to challenge some of the drug pricing issues, you will not get standing in court. So if you have some grievance you want to take because the patent is actually, maybe, blocking generics going into market, at least you might be able to get some traction in the PTAB.

So this is one of the crux of the issues as to why particularly the pharmaceutical industry is very much anti-PTAB.

Cooney: Well, and I was thinking, just to sort of make this a little bit clearer, too, for listeners who might have a hard time understanding in the broader scope, if a patent for Restasis goes off patent, say, in 2024 I think is what the original date was, how would this process impede that sort of natural kind of coming off patent and, then, having generics come into the market? How does it sort of suppress that unnaturally?
Amin: So what it could do, for example, a typical process, you file your petition against the relevant patents that you are seeking to challenge at the PTAB. If the PTAB decides that you have a reasonable likelihood of success, that’s the sort of standard, they will then what they call institute the petition. And, then, the process then is the parties will go back and forth. So the company who owns the patents will respond to the petition. The petitioner who filed the challenge will respond back with further evidence. And, then, within 18 months, you get a decision.

So if the patents are not found to be valid, what you’ve done then, you’ve created a situation where the company, let’s say, Allergan in this case, would not have any patent rights to prevent generics coming into the market. But given the complexity of the regulation around allowing generics into the market space, just because you’ve removed the patents at the PTAB level does not automatically allow a generic to come into the market. It has to get FDA approval, which is called a...they file a abbreviated new drug application or A, N, D, A, or ANDA as it’s called. And that has to be approved by the FDA. And the FDA will only approve a ANDA if a court has found the patents to be invalid. So therein lies a bit of a problem, in a sense. And I think this is actually a gap in the legislation. It hasn’t brought up to date with the way that PTAB is working in conjunction with our courts and, also, dealing with these issues.

There was an earlier act called the Hatch Waxman Act, enacted in 1984, which was designed to actually balance innovation with increasing access to generics. And it has been able to do that. More generics are coming to the marketplace. They have a bigger share of the market. But what has happened as a result of that is that pharmaceutical companies, the branded companies, started filing more patents because they realized that the Hatch Waxman Act was going to create new challenges. And, so, we have now is a situation where the PTAB has come into play and it needs to be merged into this Hatch Waxman Act, which is still the sort of parent act that governs how pharmaceutical patents are really dealt with in terms of allowing generics into the market.

It’s a very complex and complicated environment. And I think this is one of the fundamental problems as to why we are seeing drug prices so high is because the pharmaceutical companies and their army of lawyers can use this mass complex maze of legal frameworks that work in their favor. And they’ve got all these toolboxes that allow them to do some of the things they’re doing. This in case, giving the patent rights to a Mohawk tribe. And this is just a whole new level.

Cooney: Where does this fit into the scope of this constant dialogue that we have about drug prices and pharma-governments’ inability to negotiate drug prices versus international laws that have a very different situation for governing what are acceptable prices and what the market will bear? So I’m very curious to see what you think the impact of this would be.

Amin: There’s a much broader debate going on. And one of the things that happens in this area, and we’ve been working...I’ve actually been working in this space for over 12 years, and we’ve worked in a lot of different countries. And one of the issues that we see is that there’s a big debate about how does R&D happen? That’s research and development, how much does it cost? Is the patent system the only way to incentivize this kind of drug discovery? And, actually, how much is actually being really discovered? And how much of the patent system is being used, really, as a defense mechanism to keep corporate profits high, to allow shareholders to get the return they want?

I mean, we’ve also seen very much a financialization of the drug industry where there are basically a number of companies now that’s making huge dividend buybacks and share buybacks in order to get to their shareholders. And yet, they’re complaining, “Oh, well, we spent so much on drug developments, and so forth.”

And then, also, the discussion has now shifted from even, well, how much does the R&D cost to, basically, well, if you look at the cases of sofosbuvir, Sovaldi, the Hepatitis C drugs, it’s not a question of how much it costs to develop, it’s a question of “Oh, well, we think this is the value of the drug in the marketplace, and we can price it any price we want.” There’s been various investigations into that particular drug by Wyden-Grassley.

And, so, I think the entire debate has to be re-looked at in terms of how do we create the protective mechanisms? And is the patent system actually reached a point in time where it does not reflect, necessarily...We’re giving patents for science and innovations, which are actually not new. And, therefore, it becomes a game, and it becomes really just about profitability and maintaining market strongholds rather than, actually, how are we going to tackle the drug pricing problem in a really honest and transparent manner?

So I think this is happening all across the globe. And some countries have fared better than others because maybe they’re a lower economic status, and they get away with it a little bit better. But I think if you look at Europe, Europe’s got the same problem, and everybody’s trying to tackle this issue. But the thing they’re not tackling is how much power we are giving pharmaceutical corporations through the Intellectual Property system. Now, I get it that one needs to be incentivized, one needs to be rewarded for one’s investment, but none of that is transparent. And the monopoly powers that are being given, actually don’t reflect, in a lot of ways, the usefulness of some of the drugs.
Cooney: Most recently, Allergan issued a statement about the patent transfer, saying that it urged the judiciary committee to review the IPR process and, in their words, “rectify its infirmities and protect the innovation that is the lifeblood of the bio-pharmaceutical industry and the US economy.” However, it may depend on where you are or who you are in relation to the issues to determine just where those infirmities actually lie.

Thanks for listening. Until next time.

The United States of Health Blog Podcast is written and produced by Rebecca Cooney, and Aaron van Dorn, and the New York office of The Lancet. To listen to more podcasts, log on to usa.thelancet.com.
DACA, a dream deferred?

Rebecca Cooney

Editor’s note. The following is an edited transcript of a podcast.

[Clip of Attorney General Jeff Sessions] Good morning. I’m here today to announce that the program known as DACA that was effectuated under the Obama Administration is being rescinded.

Welcome to the United States of Health Blog podcast. I’m Rebecca Cooney, North American Executive Editor of The Lancet. On September 5, 2017, Attorney General Jeff Sessions, on the part of the Trump Administration, announced that the Deferred Action for Childhood Arrivals, or DACA Program, was being rescinded, saying further that “We cannot admit everyone who would like to come here. It’s just that simple.” But in fact, that doesn’t accurately describe at all the immigrants protected by DACA. They’re already here. They grew up here. They live next door.

Recipients of DACA protection are often called “Dreamers” because of the DREAM Act, short for Development Relief and Education for Alien Minors Act that the Obama Administration had hoped to pass, as well as a riff on the notion of the American Dream. DACA was a program that was instituted by Barack Obama in 2012 that allowed the children who were brought to the US illegally the right to live and study and work here, albeit on a temporary basis. Once Dreamers pass vetting, they’re able to defer action, or deportation, for two years, and with that comes the opportunity to obtain a driver’s license, or attend a college, or get a job. About 1.9 million young people are eligible for DACA, and about 800,000 have participated in the DACA program.

So who are the dreamers? Here is Tomás Jiménez, an associate professor in Sociology at Stanford University, a faculty affiliate at the Center for Comparative Studies in Race and Ethnicity, and author of The Other Side of Assimilation: How Immigrants Are Changing American Life.

Tomás Jiménez: The Dreamers are a group of people so named for a bill that has been introduced in just about every Congress for the better part of the last two decades. They’re a group of people who were brought by their parents to the United States without legal authorization at a very young age, some of them as young as just a few days old, and some of them in their early teens. So these are folks who have effectively grown up in the United States. For many of them, their lives look a lot like the lives of any other child of immigrants. Now there are lots of children growing up in the United States who have an unauthorized parent. But what makes the Dreamers distinctive is that they are themselves also unauthorized. DACA and indeed the Dream Act, which is a kind of broader bill that would create a pathway to legal residency, not just the kind of temporary protective status that is DACA, and potentially also a pathway to citizenship that is the Dream Act, has a lot of support among Americans, tons of support.

And in fact, there’s wide support for legalization programs not just for the Dreamers, but for all unauthorized immigrants provided that they agree to learn English, go through a criminal background check, and that they can prove that they’ve worked. If you give Americans those three provisions, 90% say that they would support the pathway to legal residency and even citizenship.

Rebecca Cooney: By most indications, Dreamers are highly integrated in American culture. They go to school, they go to work, and the majority are in their 20s or even 30s now. And they’re also parents. Parents of children who were born in the US and who are American citizens themselves. Jens Hainmueller, Professor of Political Science and Business at Stanford University, and founder and faculty co-director of the Stanford Immigration Policy Lab, and his colleagues, including Tomás Jiménez, recently published a very intriguing study in Science that investigated the...
effects of the implementation of DACA on unauthorized immigrant mothers. We spoke with Dr Hainmueller about the study and its implications for the health of the children of Dreamers, and for public health more generally.

Jens Hainmueller: As part of our research at the Stanford Immigration Policy Lab, we’re really trying to gather sort of rigorous evidence on the impact of policies that are erected towards immigrants in places like United States, but also in Europe or the Middle East. So we focused on long-term immigrants, but also refugees, and undocumented immigrants. I think the motivation for this broadly is that policy-makers just don’t have a lot of evidence, concrete evidence to go by when it comes to the impact of these types of policies. Immigration is one of the areas where there’s a lot of ideology, there’s a lot of heated debate, people have strong opinions on the issue. But there’s not really a lot of rigorous evidence as to what actually happens as a result of these immigration policies. It’s kind of like what works, what doesn’t. What backfires, what really helps facilitate the successful integration of refugees into those countries, we just don’t really know that much about it. DACA has policies obviously created heated debates.

There’s been a bit of research of the effect of DACA on the recipients themselves, but one aspect that is often overlooked in those debates is really that a lot of the Dreamers now also have become parents. There’s an estimated 200 000 children of undocumented immigrants who were eligible for DACA at the time when the policy was announced. We wanted to look at what happens to these kids if the parents become eligible for DACA, looking at the generational effects of DACA protection, which is obviously kind of an important topic, given that these kids are typically US citizens.

When you are trying to do a study like this, trying to look at the intergenerational impact of a policy like DACA, there’s basically two main problems. The first one is the sampling problem, so as I alluded to earlier you need a reasonably large sample of undocumented immigrant mothers, and then you need access to the health outcomes of their kids in order to kind of say something about the effects of the policy. The second problem is really the one about trying to separate out correlation from causation, because obviously DACA recipients are a specific subset of the undocumented population.

So just comparing DACA recipients with non-DACA recipients is not really going to get at the causative effect of DACA, because the recipients tend to be younger, they tend to be better educated. There’s a lot of differences between families where one parent might have DACA with families that don’t have DACA, and so it’s kind of an apples to oranges comparison. It doesn’t really isolate the cause and effect of DACA. So in the study we basically were able to address both of these issues.

What we recognized early on was that there is this federal program called Emergency Medicaid, that basically in the United States covers labor and delivery, regardless of documentation status. If a mother delivers under Emergency Medicaid, there’s a very high probability that that mother would be undocumented. Given that we had this health data that the Emergency Medicaid claims data that the Oregon Health Authority shared with us, we were able to identify mothers that basically gave birth under this program between 2003 and 2015. So using those birth claims then, we could basically link to the kids. And because the kids are born in Oregon, they’re US citizens by birth, and therefore they are eligible for standard Medicaid. Typically these families are low-income. And so then we were able to use the Medicaid claims, the billing codes, in order to track the health outcomes of the kids from the time of the birth until basically as they’re kind of growing up in Oregon.

So this was basically how we solved the sampling problem, using Emergency Medicaid to identify the undocumented mothers, and then using the Medicaid records to track the health outcomes of the kids. The second issue was the causal identification problem, trying to separate correlation from causation. There we recognized that one of the criteria in order for mothers to be eligible for DACA was an age eligibility criteria. The policy had this arbitrary age cut-point, that basically mothers had to be born after June 15, 1981 in order to be eligible for the policy. It’s a totally arbitrary cut-point, and so if you compare their characteristics they are very, very similar.

And this then gives us a chance to kind of an experiment to isolate the causal effect of DACA eligibility, by looking at what happens to the health outcomes of these kids in the post-DACA period as the mothers who meet the eligibility criteria become eligible for DACA. What we find is that basically in the pre-DACA period, as you look at the rates of mental health diagnosis of those kids, they’re basically very similar. There’s no difference between the children of mothers who are born right before or right after the cut-point. But if you look in the post-DACA period between 2013 and 2015 as the mothers who meet the eligibility criteria become eligible for DACA protection, we see this very considerable, sizeable, and immediate improvement in the mental health of the children.

So basically the rate of adjustment anxiety disorders, which is the core outcome that we focused on, they basically drop in half compared to the group of children of mothers who just missed this eligibility cut-point, and therefore the mothers cannot benefit from the DACA protection. There’s really a quite sort of strong evidence that DACA eligibility for the mothers causally improved the mental health of these children. In some sense, what we’re seeing here is probably only the tip of the iceberg, and if now DACA is rescinded, and the parents potentially face the risk of being deported, or
maybe they are deported, I think the evidence seems to be pretty clear that these effects are going to be reversed, and they’re probably going to end up being much, much worse. I think if policymakers are debating this policy now, that it’s sort of in the hands of Congress.

I think the study pretty clearly shows that if you want...I mean, you can think of DACA whatever you want, but you have to take into account that there’s these broader sets of benefits that come from a policy like this that are not limited to the recipients themselves. But this really affects like the whole family. This affects sort of the next generation of these American citizen kids that these Dreamers have, and so if you think about implications for costs, that is really something that really magnifies the impact of a policy like this.

So we know from a lot of other research that there’s a potentially strong cascading effect of early mental childhood disorder on the outcomes later in life. Children who are diagnosed with early mental health disorders often face challenges later in life, struggles in school, limited job prospects, substance abuse, welfare dependency, and so curbing these kinds of problems in young children, programs like DACA can really have a cascading effect on improving their health across the lifespan. If you look at spending in order to treat early mental childhood disorder, they’re already accounting for the highest share of the nation’s pediatric healthcare spending. This really has significant social costs and consequences that are important for society as a whole, and that’s something that you need to take into account, you can’t just limit it to the recipients themselves. And so our hope is that policymakers are going to start recognizing...Take a broader view on this, and really hope that they can find some sort of solution that will put the recipients and their families on a more secure kind of footing.

Cooney: As with so many areas where the recent political maneuvering has affected the viability of health programs, especially those with similar acronyms, the fate of DACA is far from certain. The legal status of the Dreamers is currently unresolved. And importantly, the fates of their children, American citizens, too, now seem to hang in the balance between the policy, temporary as it may be, but which improved the health and prospects of their parents, and an unknown future. For their part, universities and the medical community in the US have been quick to position themselves in support of the Dreamers. And considering the chronic physician shortages being faced in the US, it is one area where qualified individuals, regardless of documentation, are desperately needed. And from the perspective of protecting the Dreamers from deportation, there are many committed legal professionals actively working to challenge the Trump Administration’s immigration policy.

Jayashri Srikantiah, law professor and director of the Immigrants’ Rights Clinic at Stanford Law School, explains some of the shorter-term and longer-term consequences at stake.

Jayashri Srikantiah: In the very short term, what it means is that certain people who are eligible to renew their deferred action should go ahead and do so. They have one month to do it. The announcement from Attorney General Sessions and the Department of Homeland Security sets forth the people who are eligible to renew. After that one month period, basically nobody can get new deferred action or renewal of their existing deferred action, and instead, they can only have the deferred action for as long as that permission exists. Unfortunately, even somebody who has US citizen children can be deported from the country. So what usually happens is that there’s certain kinds of very limited immigration remedies that are available to people with US citizen children, and those are typically if the children have serious illnesses or other concerns along those lines. There are some remedies that might be available, they’re discretionary and they’re not granted in that many cases.

But beyond that, oftentimes what happens is that the parent has to face a painful decision between staying with their children, and taking their children with them to a country that the child doesn’t know, and maybe even the parent doesn’t know that well, or leaving the child in the United States and being deported to another country and not be able to see their child. So it’s an extremely painful decision and unfortunately one that we encounter too much in our detention and deportation regime in this country.

Cooney: For all those concerned with the fate of the Dreamers, there are miles to go before they sleep. Until next time, thanks for listening.
Smuggling vs trafficking: when words matter

Rebecca Cooney

Editor’s note. The following is an edited transcript of a podcast.

Welcome to the United States of Health blog podcast. I’m Rebecca Cooney, North American Executive Editor of The Lancet.

There’s a line in our instructions to authors that says “Sometimes editors make mistakes. When we do we like to hear about them.”

That applies to decisions on papers, but on occasion it applies to other parts of The Lancet journal, like the editorials we write, which we call leaders in house. Once a week The Lancet editors meet to discuss current events and talk about reports that have been issued and, in general, developments affecting health around the world, and we choose three topics on which we feel that there’s a need to make an editorial comment.

On July 23, 2017, 39 people were transported under brutal conditions across the border from Mexico in a tractor-trailer. Conditions so inhospitable that by the time they were discovered in a parking lot in San Antonio, TX, 10 people had died. In the aftermath of that incident we felt strongly that we should acknowledge the tragedy and underscore the possible role of contact with healthcare as a window of potential intervention in human trafficking. So I wrote the editorial, “Health providers—helping to disrupt human trafficking”. But there was a problem and one of our readers wrote and made the very important point that the term I used, trafficking, wasn’t actually correct. Instead, smuggling was a more accurate term for this instance.

We recently published a letter by that reader, Dr Hanni Stoklosa, an emergency physician at Brigham and Women’s Hospital and the executive director of an organization called HEAL Trafficking. Here’s a conversation that she and I had about the importance of making that distinction.

Rebecca Cooney: I think it would be really helpful to begin by having you talk about, specifically, what the difference is semantically for human trafficking and smuggling and then what that means in the legal framework.

Hanni Stoklosa: Absolutely. Thanks so much, Rebecca. First of all, I was totally thrilled that I was picking up The Lancet and seeing that there was an article focusing on the role that health providers can play in disrupting trafficking. For too long, victims of trafficking have really been hiding in plain sight in our healthcare settings and you just don’t see what you don’t know. And so if healthcare providers don’t know that trafficking victims are going to be coming to their hospitals and their clinics, they’re just not going to see them and identify them. So it’s a huge opportunity for healthcare providers really to intervene and disrupt their cycle of violence. So thank you for writing that piece. And also for being open to this feedback.

The difference between smuggling and trafficking is tricky because someone can actually be both a trafficker and a smuggler. An individual can be both trafficked and smuggled. So there’s definitely in that Venn diagram of the two entities, there’s definitely overlap. To get into the definitions, smuggling is really an individual helping another individual cross the border undetected in exchange for a payment. It’s a crime and the smuggler is the one that is helping the individual cross the border. On the trafficking side of things, there has to be a loss of consent in the process and there has to be an intent for exploitation. Traffickers move people from one place to another without their consent or through some sort of deception or false promises and then there’s an exploitation that happens. Either along the way or at their final destination.

Cooney: Speaking to the San Antonio incident in particular, the feedback that you provided to us was that we don’t have any confirmation that the individuals who died or were harmed in that incident were necessarily being trafficked. But they were indeed being smuggled. Is that a fair encapsulation of what happened there?

Stoklosa: It is fair. What I’d say is we just don’t have enough information. Those individuals could certainly be also victims of trafficking as well as being smuggled into the country. We do see that all the time. Whether it’s in the Mediterranean, whether it’s across the Mexican-US border where someone initially signs up to be smuggled into a country. But then there’s some component of deception or coercion along the way. In fact, the actual cost of paying that smuggler oftentimes ends up being the debt bondage situation that keeps that trafficking victim trapped. It is very possible that those that were smuggled and that unfortunately those that passed away and those were injured could be both smuggled and victims of trafficking. We just don’t have enough information to know.

Just another caveat there, is that if I were the healthcare provider that was treating any of these injured individuals who did survive, knowing that they were smuggled would raise my suspicion that they may be a victim of trafficking. It’s another way of having a problem that is often invisible.
So it would definitely place them in that higher risk category in my mind but I would need to know more.

Cooney: That’s very helpful. I was thinking about the implications of using the language and your initial email to us you made some reference to that, but maybe you could expand a bit about why is it important that we make sure that we are not using these terms synonymously?

Stoklosa: It’s important for a couple of reasons. One is that as healthcare providers are learning what trafficking is and they’re adding to their “differential diagnosis” and putting it on their radars, they are really blank slates right now. What we tell healthcare providers right now about trafficking is what is going to be imprinted in their minds. I see that as a huge responsibility to make sure that we get it right and that they have as accurate information as possible. This is just one example, but the distinction between smuggling and trafficking as well as making sure that healthcare providers know that trafficking is not just sex trafficking, which is what they’ll see in the media, and that it’s not just commercial sexual exploitation of children. If we only train them on those narrow forms of trafficking, then they’re going to miss that labor trafficking victim who comes into their clinic or into their emergency departments.

The way that it’s presented is just really important to be absolutely spot on and completely accurate. Beyond just the training of healthcare providers, getting the labeling right is also important because if you’re using the term trafficking instead of smuggling it’s also important for the public because by using trafficking rather than smuggling you end up ignoring the reasons why people may be migrating and choosing to leave their home countries. Like conflict, human rights abuses, famine, economic destitution by making it “this is something that’s not of their own will and not of their own consent”. By using that trafficking label you ignore all of those other things that are driving them to migrate. That’s the broader lens of why I think it’s important for the public not to conflate those two, but also our responsibility as healthcare providers to get it right.

Cooney: Let’s talk a little bit about advocacy and the work that you do weaving all of these pieces together and let’s talk specifically about the group that you work with.

Stoklosa: HEAL Trafficking was founded in the fall of 2013 by a group of co-founders including myself. It’s been really exciting. We’re now a network of over 1200 individuals that are combating trafficking from a public health lens across the globe. Primarily concentrated in the United States. Our mission is to shift the anti-trafficking paradigm from one that’s just primarily criminal justice-focused to one that’s rooted in public health principles and trauma-informed care. Some real key components to that are expanding the evidence base and the public health response to trafficking, enhancing collaborations among multidisciplinary stakeholders. So we really do believe that together we’re stronger and really try to create that community within the public health response to trafficking as well as to educate the broader anti-trafficking and public health community and advocating for policies and funding streams that enhance the public health response to trafficking and support survivors.

The way that we’re constructed is we have working groups that are working on advocacy, direct services, education and training, media and technology, protocols, and research. It’s been really exciting to see what we’ve been able to accomplish with that mindset of together we’re stronger. So now over 11 health professional societies have policies on trafficking. We have a protocol toolkit that health systems can use when they’re trying to figure out their plan for trafficking victims that are coming in their front doors. We worked both on the state and federal level to improve policies that improve the lives of trafficking survivors. Not just about their healthcare but things like helping to wipe their criminal records clean for crimes that they were forced to commit while they were being trafficked, which is a major barrier for victims getting back on their feet. We have our hands in a lot and it’s really, really exciting to see what we’ve been able to accomplish in such a short period of time.

Cooney: Wow, that’s great. You mentioned protocols and I’m curious too, given your background as an emergency medicine physician, maybe you could bring something like that to life for us. What might a protocol look like in healthcare setting?

Stoklosa: It’s a really good question. A protocol is basically the plan that you’d have in place for any form of interpersonal violence. Having all of your nurses, having all of your doctors ask patients, do you feel safe in your relationship? Something as simple as that actually carries, not only into trafficking but into other forms of interpersonal violence. So there’s the screening component and then as you get those disclosures, it’s also connecting potential victims with resources and having the assigned people that are going to have those conversations with them. So we have social workers that are trained on trafficking and case managers that are trained on trafficking response and they know the community resources so that they can plug trafficking victims in with the care that they need.

We really have such a unique relationship with our patients. I’m speaking as an emergency medicine provider, but I see people on, oftentimes the worst day of their lives and it’s a real opportunity and responsibility and I really take it seriously. And you never know, for that person, that may be the moment that they’re ready to get out of that situation, but if I’m not asking the right questions, they’re just going to walk back out of my emergency department, back into their exploiter’s arms. I really do take it quite seriously.
The other thing just to put out there is that a lot of us imagine that we would know what a victim would look like. One thing that I’ve learned from trafficking victims is that because of the really complex PTSD that many of them experience, they are not the docile, meek victim that a lot of us have in our minds. Trafficking has really caused me to do a lot reflection on what my own unconscious biases are around who is a worthy victim and how does that affect the way that I see whether somebody is a victim at all?

It’s really caused me to do that deep work and those patients that are agitated, those patients that make me feel angry, it’s my process now to stop and reflect and think about what may be underlying and what is driving that as opposed to responding in judgment to them and assuming that they’re coming from a place of strength. But recognizing that there’s probably some underlying trauma there and it may be trafficking, it may not be trafficking but to really pause and reflect and it’s something that’s within the emergency medicine community, I think is really, really important for us to recognize. Not just for the sake for trafficking survivors but for other forms of interpersonal violence.

Cooney: To learn more about the work that Heal Trafficking is doing and to read Dr Stoklosa’s letter to the editor, visit the United States of Health Blog at usa.thelancet.com. Thanks for listening. Until next time.
Hepatitis C in the US—a bigger issue than HIV

Ray Cavanaugh

In 2013, hep C mortality exceeded that of the combined sum of deaths from 60 other infectious diseases, among them HIV, pneumococcal disease, and tuberculosis. Additionally, as death certificates tend to under-report hep C, the number is in all likelihood higher.

From 2003 to 2013, deaths from infectious conditions other than hep C decreased by 28 percent, from 24,745 to 17,915. But during that same ten-year span, deaths related to hep C rose 75 percent, from 11,051 to 19,368. And that number has continued to rise.

After years of declining incidences of new hep C infections, the trend has reversed with a disturbing trajectory. The CDC estimated that 34,000 new cases of hep C infection occurred in 2015, and that the number of new cases almost tripled within a five-year period. The factor fueling this startling rise is the opioid epidemic and the use of shared needles.

Intravenous drug use is now the leading cause of hep C in the US. Though unsanitary medical conditions (such as tainted blood transfusions) are the primary cause of hep C in developing nations, this factor has declined drastically in the US since 1992, with the implementation of more preventative measures, such as the sterilization of medical equipment and enhanced screening of potential blood and organ donors. With current US screening methods, fewer than one in two-million units of donated blood are contaminated with hep C.

About 70–90 percent of older injection drug users (including former users) have hep C. In the 1980s and 1990s, 80–90 percent of intravenous drug users were infected within just one year of initiation to injection drugs, relates Dr Andrew Talal, a Professor of Medicine at the Jacobs School of Medicine and Biomedical Sciences at the University at Buffalo.

Talal, who has worked with hep C for the past 20 years, points out that, “Harm-reduction techniques for HIV were effective in significantly decreasing the risk of transmission of HCV as well.”

Though the perils of sharing needles has become more widely understood in recent decades, sharing does occur, and about one-third of injection drug users between ages 18 and 30 have hep C. In addition to being younger, the persons who now most often contract hep C are “frequently Caucasian, and from suburban or rural areas,” Talal adds.

Aside from opioid use, other causes of hep C include mother-to-child transmission (about six percent of infants born to mothers with hep C contract the virus), hemodialysis, tattoos provided in an unprofessional setting (such as a jail), and hospital accidents (such as needle-stick injuries). Though it rarely occurs, transmission by sexual intercourse is possible.

About 15–25 percent of people who contract hep C manage to eliminate it from their system and avoid chronic infection. However, an estimated 75–85 percent of those infected with the hep C virus will suffer from chronic infection. That said, people can go decades without showing any symptoms, and many have no idea they are infected until confronted with severe liver problems.

“That is why education of potential risk factors, methods of transmission and testing for the infection are so important,” Talal emphasizes. “As we have learned more, we have revised the estimate of the number of individuals who develop cirrhosis upward. It is now thought that if individuals are followed for long enough, for example for 40 years, the vast majority, if not almost everybody, will develop cirrhosis.”

Hep C is the most common reason for a liver transplant, and the virus recurs in 80–90 percent of those who receive a new liver.

Though such recently appearing drugs as Harvoni and Solvadi have proven highly effective at curing the disease, they are extremely expensive, costing about one-thousand dollars per pill. “The ability to obtain these medications...
varies from state to state,” says Talal, who observes that in his state, New York, “most individuals can get hepatitis C treatment.”

Though there are vaccines for hep A and B, no vaccine for hep C exists as of yet. Talal is optimistic, however, about the development of direct acting antivirals, which directly target the hep C virus. “These drugs can cure 95% of individuals, have much shorter treatment duration than the drugs that were used previously, and a much more favorable side effect profile, and don’t require any injection.

Unfortunately, many of those who are infected with HCV are unaware that interferon [which frequently had serious side effects] is no longer required to be part of the mix. Therefore, it is tremendously important that we continue to educate those who might be infected about the new therapeutic developments in hepatitis C.”

Talal is quite confident that hep C mortality will eventually decrease “as long as we get a handle on the opioid epidemic.”
This week in health and medicine

Aaron van Dorn

**Trump Administration cuts ACA outreach programs**
In a move that experts are describing as “being done out of spite,” the Trump Administration is slashing funding for programs used to advertise the Affordable Care Act’s healthcare marketplace open enrollment period, from $100 million for the 2017 season, to only $10 million for 2018. The administration will also cut funding for customer service programs that help people sign up for insurance care, from $62·5 million to $36 million. The funds come from fees paid by insurance companies, so the move doesn’t actually save taxpayers any money. The move also comes the week prior to the deadline for insurers to set their final rates for 2018, a move that could further undermine insurers’ confidence in the marketplace and lead to an increase in premiums. (CNBC)

**FDA approves gene therapy for childhood leukemia**
The Food and Drug Administration has approved a new gene therapy treatment for childhood leukemia. The technique, developed by drug maker Novartis, genetically modifies a patient’s blood T cells to multiply and attack cancerous blood cells. The new treatment comes with potentially severe side effects, although in clinical trials, 83% of the patients receiving the treatment went into remission. However, the length of remission can potentially be short, with some patients’ cancers returning after only a few months. The treatment also comes with a major price tag, as well: $475 000 for one round of treatment. Novartis has said that it will not charge patients who do not see a response within one month. (ABC)

**HPV vaccination rates still lag other childhood vaccinations**
According to a CDC report, rates of vaccination for the human papilloma virus (HPV) in teenagers still lag significantly behind other childhood cancers, with the vaccination rate lagging especially in the South, Mountain West and MidWest. While nationally, an average of 65% of girls and 56% of boys have received the vaccination, the rates can drop significantly in areas of the US, as low as 35% in Arkansas for girls, and 20% in Utah for boys. The HPV vaccine can prevent cervical, vaginal, and oral cancers. Experts say one of the main reasons for the often lagging uptake in providing the vaccine to teens are social taboos surrounding sex among teens. (Technology Review)

**St Kitts investigates herpes clinical trial**
After a professor from Southern Illinois University, with the backing of investment including PayPal founder Peter Thiel, conducted a clinical trial of a herpes vaccine on the island of St Kitts in 2016, without approval of the FDA or an institutional review board. The professor leading the study, and co-founder of Rational Vaccines, the company developing the vaccine, Agustín Fernández III, claims that his partner was supposed to obtain permission from the government of St Kitts. However, the partner, William Halford, died in June, and Fernández claims he doesn’t know who else Halford may have spoken too. (Stat News)

**Harvey evacuees leave medical records behind**
A little appreciated facet of the ongoing disaster in Texas and Louisiana involves patients medical records. Hundreds of thousands of people could be displaced for months if not years, and many patients were forced to flee and often seek treatment wherever they can. What happens when the doctors and nurses treating these patients are unable to access their paper medical records, stuck in Houston doctor’s offices? (Wired)

This blog post was originally published on The Lancet United States of Health Blog.
The blog was closed on December 31, 2018 and all posts are available via the archive at https://www.thelancet.com/journals/lancet/usa-blog
Listen in—the conversations we need to have about racism, health, and medicine

Rebecca Cooney

Editor’s note. The following is an edited transcript of a podcast.

That’s Mary Bassett, Commissioner of the New York City Department of Health and Mental Hygiene, speaking about the events in Charlottesville this August 2017.

Welcome to United States of Health Blog Podcast. I’m Rebecca Cooney North American Executive Editor of The Lancet. When we are confronted with brutal and graphic incidents—like Charlottesville—that hearken to our country’s painful history, they can be potent reminders that what we think of as remnants of injustice and inequality are very much alive, and it’s important for us to take time to reflect and process what lessons need to be learned or re-learned and what needs to change.

The medical profession takes as its primary credo, “First, do no harm.” The public health corollary to that as framed by the American Public Health Association says, “Public health promotes and protects the health of people and the communities where they live, learn, work and play.” Racism and discrimination aren’t vague concepts to be taken into consideration in some contexts of medicine and public health—they literally permeate the fabric of health in our country. And it’s critical that we begin to fundamentally incorporate the effects of racism and discrimination when we discuss health.

Throughout this podcast, we’ll be talking with doctors. Mostly women, mostly physicians, and mostly people of color. And we’ll be talking about racism at different levels of experience. Moving between interpersonal racism that is experienced by individuals to institutional racism to structural racism, that is the historically and culturally reinforced basis that underlies and reinforces belief systems, values, and discriminatory practices all of which produce adverse health outcomes. For some these are new concepts, for others, new names for experiences lived.

Téné T Lewis is an Associate Professor in the Department of Epidemiology at Emory University who studies discrimination and health in African-Americans in the United States.

“I think now what’s happening is the broader public is becoming aware of how many people really hold these sentiments, because I think as people we’re so segregated and isolated from one another that we wind up socializing and interacting with people who are like us. If you’re not a person who discriminates against people who hold those views, you are not socializing, you’re not interacting with people. I think what happened with this last election and some of the rhetoric and a lot of the language that was being used, it kind of pushed it to the forefront and made more people realize like, “You know, this is actually still a problem in 2017, and something we need to start thinking more about.”

Let’s start with the experience of physicians and health care providers of color—what happens when they themselves are confronted with racism or discrimination?

Nwando Olayiwola is the chief clinical transformation officer for Rubicon MD and an associate clinical professor in Family Medicine at the University of California, San Francisco. She’s written poignantly about the firsthand experience of dealing with a racist patient—the dynamics and feelings of being a black woman in a white coat.

“I think the experience that I had with this patient was so jolting because one, it didn’t matter to him...None of that mattered to him. It didn’t matter to him that I was highly accomplished and I had chosen to be where I was and I was really there...All that mattered to him was that he saw a black woman walk in and felt that in no possible way could this person be his doctor and take good care of him. So, on the one hand, it was extremely demoralizing because no matter how much I thought I had achieved and how well I think I had gotten towards my own personal goals, in one moment and in a very short encounter with a patient, all that could just be wiped away.

Esther Choo is an MD, MPH and an associate professor of emergency medicine at Oregon Health & Science University.

“Recently a patient and his wife asked me exactly what my Asian ethnicity was. And the way that it comes about usually is, ‘Where are you from?’ And I said that my background is Korean, and they kind of breathed a sigh of relief and said, ‘Well that’s great because we would never be treated by a Vietnamese citizen.’

And I’ve had that happen before where they say, ‘We really had a bad experience with this type of physician.’ Or, ‘We would never be treated by those people again.’ And sometimes it feels directed against me very specifically or against Asians in general. But it is something that would not happen if you were not a person of color. No one would say, ‘Well I’ve been treated by a white physician before, so we don’t accept white physicians anymore.’ They tend to be
more toned down on the characteristics of that individual person.

So if you’re a person of color, you often don’t get to be an individual. You represent the entire group of those people. And all the assumptions they bring into the room with them.”

For many physicians and healthcare providers of color, encountering racism isn’t confined to interactions with patients. It can extend to colleagues, supervisors.

Jennifer Okwerekwu is a psychiatry resident at Cambridge Health Alliance and columnist for Stat News. She has also written on experiencing racism from patients but how little support there can be in that situation.

“As a woman, as an African American, as an immigrant, and as a medical trainee, my experiences of racism are not unique. They’re certainly not unique to me, but the introduction of a power dynamic in the hierarchy of medical training is what makes a little bit more challenging to deal with. For example, as a medical student, when I had an experience where a patient called me a colored girl in front of an attending physician, from whom I was learning, and the attending physician didn’t say anything to the patient when we were all together, the three of us in the room, nor did she say anything after the patient left when we were alone.

You can imagine the questions that kind of brought up for me. Does the patient respect me? Why are they not calling me by the name I introduced myself by? Why is the attending not introducing themselves? Does the attending think this way? Does the attending think I’m a colored girl? Did she just not notice? This happened multiple times within a clinic visit. I don’t believe that she didn’t notice. Maybe she just didn’t know how to address it. In any case, it left me with a number of questions that I didn’t really have any sort of productive outlet to ask them.”

Often it’s not the individual patients or colleagues that are the issue, but the setting, the institution itself.

As Dr Olayiwola notes:

“Because we all know and I could bring together a room of black women physicians and we would probably all have very similar stories of times where we were looked down upon or we were...People didn’t really necessarily think we were qualified to be there. We were passed over. Maybe we said something that was really intelligent and it was a surprise to people that came from us. We were asked to do things that were not necessarily appropriate maybe on rounds, to bring breakfast or get someone a coffee when we were equal members of the team. I think we could all identify with that experience of that double jeopardy that we have.

For that, it’s a lot harder because do you instill the belief in an institution if there’s institutional racism that’s working against you, that there are policies and procedures that are actually going to not allow you to advance. If there’s not sufficient support to recognize your unique needs as a woman or person of color in the academic institution or the academic hospital or the ranks of the system or professionally, you’re maybe passed over for a promotion. You’re not given the right mentoring to achieve tenure. You’re not considered a leader.”

Dr Choo notes how pervasive that sense may be.

“So people will say things about, ‘We’re relieved you speak the English language so well.’ Or, ‘Do you believe in western as well as eastern medicine.’ I think there’s still just kind of this constant stream of comments and questions and often it’s just that people have never come into contact with anybody from my background or perhaps from a background other than their own. So some of them are just very naïve and it’s hard to take offense. But it’s certainly this background noise at some point of almost every day that I practice.

And so I do think when I talk to my friends who are of different backgrounds, especially right now my friends who are immigrants who are of non-Christian religions who have accents and were born out of the country, I know a lot of my friends are really struggling right now with overt racism. I think in many ways I don’t see that and I don’t encounter it to the extent that they are.

I think it is in general the reality of this country is the darker your skin is, the harder it is for you in healthcare.”

It seems that is a truism that extends beyond healthcare to encompass all of health.

But what do we know about the effects of racism and discrimination on health? Where it concerns black people in the US, actually a fair amount.

Here’s Dr Lewis:

“What about all of these other things that happen in the African-American community, poverty, violence?, et cetera, et cetera, one of the things I think, I don’t often say, but when you talk to African-Americans or black people, they don’t think that it’s an accident that they live in the worst communities or that they’re exposed to the most violence. They don’t think that these things have happened by chance. Studying something that’s actually relevant to the community has mattered a lot for me as a researcher, particularly wanting to do work that’s culturally sensitive.

One of the stressors that was consistently associated with health outcomes was discrimination, and what has been the most surprising thing for me initially was the consistency of the association, independent of again, all these things that we know happen to people, financial stress, negative life events. For whatever reason, discrimination seems to really matter for people, and so for me, that’s the take home.

The outcomes that I’ve looked at are things like atherosclerosis or coronary artery calcification, visceral fat, which
is the fat that surrounds your internal organs, mortality, which is a more obvious outcome, inflammation in the blood, and most of these are things that you don’t know you have, so it’s not as if people are sick and then going back and saying, ‘Oh, I think I got sick because I was discriminated against.’ It’s actually, these are silent, so we can assume that there’s really something going on.”

Epidemiology is an important way for us in a sense to discover and acknowledge the ways in which racism and discrimination have affected people of color in the US. But in addition to the necessity of descriptive data, there is also the strong need for the prescriptive. And targeting a new wave of physicians, researchers, and providers, those who are at the forefront of health may be one of the most substantial levers for change, for addressing racism and discrimination, and improving health.

Barron Lerner, is a physician, historian, and Professor of medicine and population health, as well as the Director of the Bioethics Curriculum at NYU.

“Bioethics is the study of right and wrong, in medicine in particular, so we’re constantly addressing issues within medicine of trying to do the right thing, and issues of race come up not infrequently. There are lots of diseases and lots of situations in which race plays a role in medicine, and so part of what bioethics can add there is to add an ethical analysis to those sorts of issues.

When I read about the current issues surrounding, for example, the statues coming down, and the protests, there are lots of parallels within the world of medicine. I think the one that most people would think about is the Tuskegee study, which was an infamous study in which poor African Americans in the south were experimented on, and basically, their syphilis was let progress by the United States Public Health Service, and so when I teach bioethics, I ask the students to think about those questions historically. What was it that made a group of researchers who were otherwise, actually progressive, very focused on public health, very focused on their patients, what was it that allowed them, that made them do such an experiment that we find so heinous in retrospect? In trying to explore those answers, we understand racism more subtly.

It’s no good, I think, to say, ‘Oh, those people were racist and we’re not. That’s why we don’t do Tuskegee anymore.’ What’s much more interesting is understanding the social factors that led this group of doctors to do an experiment that we would now call racist.

It’s a forceful reminder of how even the well-intentioned within the medical establishment can make harmful decisions. We need to consider our blind spots, what actually constitutes racism, and to confront the biases that lead to decisions that we might not otherwise make if we were thinking from a different perspective or with a different lens. But importantly, we need to be willing to pull our statues down so to speak.

Dr Bassett recalls how even unspoken details embedded in medical training can lead to misplaced assumptions and structural racism:

“When I think back to my own time as a medical student, I don’t believe that there was anything in the curriculum that raised the question of race. There were many passive ways it was conveyed. For example, at DePaul in a class that we had about sexually transmitted infections, all of the photographs were of brown colored genitals and that of course, reasonably, could lead people to the idea that most sexually transmitted infections were occurring among people of color. The issue of structural racism is especially important because a lot of the work that is currently affecting our curriculum has to do with interpersonal racism.”

Here’s Dr Choo on her perspective:

“I think that is just the tip of the iceberg in what we need to offer our trainees. I think we need to support them and make sure they know that they have the resources, but I think ultimately we need to be coaching our residents to expect it when they walk into the clinical setting, it will universally be there, and then know how to respond in the moment and then also know how do you walk away without this chipping away at your confidence and your morale. And your joy of being in medicine. And that’s what I am hoping that we can move toward if this dialogue is to continue.”

Dr Okwerekwu actually attended medical school in Charlottesville at the University of Virginia and after the violent protests there, wrote about her experiences. Not just about the kind of racism that gets on television—the torchlit rallies, chants and violence, but of a different variety, what she calls the ‘quiet racism of every day’ and she has advice for medical training going forward, and the importance of listening—really listening.

“I think this is a particularly salient question for the medical profession, because we train in learning to listen. Every day we listen to our patients. We listen to their hearts. We listen to their lungs. We listen, and we’re able to formulate an understanding of that story, and take action on that story. We’re very good at doing that when it comes to delivering medicine in the form of pharmaceuticals, or surgery, or whatever your intervention is. We need to apply those very same skills to listening to our colleagues, to listening to minorities in this country, because that experience might not be something that a lot of people have firsthand knowledge of.

When people like me are telling that story, people need to listen. People need to be willing to engage to a point of humility. When I do write these stories, I get people who write me back, people in the medical profession, people with medical degrees from all levels of training, telling me
that, ‘Oh maybe it’s not racism, or maybe it’s not sexism, or 80% of people in Charlottesville voted for Hilary Clinton.’ Every time you try and justify the experience, I am telling you that I am having, you’re not pushing the conversation forward, and you’re undermining it.

I think applying those patient skills, those skills that we work so hard to perfect, and to learn to listen, and applying that to the humanity of both our patients and our colleagues, and the people of color, minorities in this country. Those stories are full of truth, and if your knee jerk reaction is to undermine that truth, then you’re not listening.”

Thank you for listening. Until next time.
When the option is the end of life

Larry Beresford

Three-fifths of those requesting the prescription had cancer, with the next highest disease category neuromuscular disorders such as ALS and Parkinson’s, at 18 percent, far out of proportion with their percentages in national death rates. Participation in California has trended toward the white and college-educated. The vast majority (84 percent) were enrolled in a hospice program providing professional end-of-life care and symptom management at the time of their deaths.

Health providers seek solid ground on dilemmas of assisted dying

California’s data suggest that the end-of-life option is being used sparingly. But its regulatory requirements and ethical safeguards, designed to exclude patients who are depressed, pressured or unable to access other care, are viewed by some as too restrictive, preventing some who could qualify from taking advantage of it.

Terminally ill patients can lose their opportunity to obtain the lethal prescription if they wait too long to ask or if they physically decline too quickly. A recent article in the Sacramento News Review asks how many terminally ill Californians are falling through the cracks of the strictest assisted death law in the nation, but that is not a number tallied by the state. In July, a family sued the University of California-San Francisco Medical Center for refusing to help their mother exercise the option, despite previous assurances that it would.

An assisted dying law in Colorado was enacted with 65 percent of the vote on last November’s ballot, making it the sixth state (plus the District of Columbia) to adopt some form of physician aid in dying. While polls consistently show Americans favor making it a legal option, other commentators and clinicians have called it unethical. It has generated strong opposition from right-to-life and Catholic groups, among others. On July 13 the US House Appropriations Committee voted to block implementation of a death with dignity statute passed by the District of Columbia’s District Council. The statute became effective July 17, while the Congressional intervention is not yet resolved.

Meanwhile, a vast middle ground between the two polarizing positions on this controversial subject is occupied by health providers, including physicians and hospice programs, trying to define their own positions and looking for a balance between honoring their personal ethical values and supporting their patients’ autonomy. How can they become more knowledgeable about the law, its provisions and implications? Can they talk openly to their patients about it? Would they write the prescription, confirm a terminal diagnosis, or refer the patient to someone who would?

Experience at the front lines

In Colorado, about ten patients have pursued the option, although one of the first, Kathy Myers, was rebuffed by her hospice and family physician and had to use local news media to find a doctor willing to write her prescription.

Ramp-up for implementation in Colorado was quick–only a month–and most health organizations had not developed a written policy for how they would respond to patient requests even months after the law’s effective date, says Jennifer Moore Ballentine, a California-based palliative care consultant with The Iris Project. Ballentine presented ten day-long educational sessions on the law to more than 500 Colorado health professionals earlier this year.

Two-thirds of the state’s hospitals are Catholic- or Seventh Day Adventist-affiliated and won’t participate under any circumstances, she notes. Some community hospitals are bowing out, too. Hospices tend to be willing to provide information about the law to their patients but not write a prescription, believing that statutory prohibitions against using federal funds such as Medicare for assisted dying could expose them to legal risk. There is a great need for both patient and medical provider education, she says. “What’s lacking is objective training on how the law works and, more importantly, how to answer patients’ requests for information or guidance.”

Ballentine says the topic of assisted dying remains ethically fraught. “We shouldn’t call it a right. The law establishes a narrow legal pathway for physicians to prescribe life-ending drugs to a certain class of patients under certain circumstances,” she says, and that pathway is paved with legal safeguards. Only a tiny fraction of patients will end up going down this path, and those that do need to practice self-advocacy.

But in this uncharted territory of medical ethics and patient self-determination, perhaps the process should be rigorous, requiring thoughtful conversations and soul searching by both patients and providers. “The idea that
there should be a wide open glide path is just not reasonable,” Ballentine says.

Significant legal hurdles for patients to surmount help to ensure that only those who are truly serious will proceed, with fewer opportunities for crossed signals, coercion or a missed chance to address suffering that could have been alleviated—even if that means some terminally ill patients won’t be able to take advantage.

**Impact for physicians**

Health professionals in impacted states are wrestling with the new ethical equations imposed by legalization. Dr Jessica Nutik Zitter in the *New York Times* (“Should I Help My Patients Die?” August 6) details her lack of preparation and emotional discomfort as a palliative care physician in Oakland, California, coming to terms with patients’ requests, although she says she would want the option available for herself or members of her family.

Dr Lynette Cederquist, internist and director of clinical ethics at the University of California-San Diego Health tells *The Lancet* that her institution went through a thorough process of discussion and protocol development for how it would address the issues. “We designated two of our seasoned medical social workers to get training regarding the whole process and become our aid-in-dying coordinators, available by pager to meet with patients and physicians and explain how the law works.”

Most of the patients requesting aid-in-dying have cancer. If their oncologist is unwilling to participate, another oncologist or the patient’s primary physician is asked. A few physicians at UCSD have volunteered to help with other patients, but it’s important to spread the load so they don’t get designated as the aid-in-dying doctors, Cederquist says.

“I think health institutions have to provide sufficient resources for staff to help patients if they intend to allow it. Physicians need the time to have conversations with their patients. I get frustrated when physicians opt out just because they don’t want the hassle.” About 40 patients at UCSD have so far explored the option. Cederquist herself has not yet written a lethal prescription, although she has spoken to several patients who were interested. “But I’m sure, at some point, I will.”
This week in health and medicine

Aaron van Dorn

**Category three hurricane set to make landfall in Texas**
Hurricane Harvey was upgraded from a tropical storm earlier this week, and has since grown to a powerful category three hurricane. It’s expected to make landfall on Texas’ gulf coast this weekend, with winds greater than 115 miles an hour, storm surges up to twelve feet and expected rainfall in the feet. With a coast full of oil refineries and chemical plants, and millions of people living in the area, experts are concerned that the potential damage could be so extensive, it could take months or years to undo. (US News & World Report)

**Ohio fills last insurance marketplace gap**
As of this week, the last county in the United States without an insurer for its Affordable Care Act insurance marketplace—Paulding County in northwestern Ohio, with a population of less than 20,000—has filled the gap, with an Ohio-based insurer, Care Source, moving in to the market. Earlier in the year, more than 40 counties across the US faced the prospect of lacking a single insurer on their individual market. However, insurers, sensing a market opening and encouraged by states, have moved in to take over a captive market. Most of the markets with only one insurer remain rural counties with smaller, older populations and few medical options. (AP)

**Appalachia lags behind rest of nation in health outcomes**
A new report looking at health outcomes for Appalachia, a region stretching from western New York to Mississippi, with a population of 25 million people, found that the region lags significantly behind health outcomes for the rest of the country. According to the report, Appalachia had worse outcomes in seven of the top ten leading causes of death compared to the rest of the country. The study compared outcomes from 1989–1995 and 2008–2014. The report broadly found progress for Appalachia in health outcomes, but the rest of the country often had much greater improvements. Premature deaths rose by 2.6%, compared by a 23.6% drop in the rest of the country, and the rate of cancer deaths fell 11% in Appalachia, compared with a 21% drop in the US as a whole. (Columbus Dispatch)

**Aetna potentially reveals HIV status for 12,000 customers**
Aetna recently mailed information about HIV medication to around 12,000 of their HIV-positive customers. However, the letters were mailed with a large cellophane window that revealed the subject of the receiver to anyone who happens to see the letter, even still sealed in its envelope. Aetna has apologized for the error, stating that the mistake was “unacceptable” and pledging to undertake a review of the mistake. Several legal organizations focused on HIV/AIDS issues are looking at further legal action regarding the situation. (NPR)

**Hospitals surprised by lack of Eye Damage**
Hospitals around the country spent time and resources preparing to treat a massive influx of severe eye injuries related to this week’s total eclipse of the sun, only to find that the hordes of people with burnt retinas failed to appear. While the expected numbers of injuries failed to materialize, the money was hardly wasted—without the prep, the situation could easily have turned out differently, with much more severe results. This time, at least, it seems like the campaigns warning about the dangers of damaging your eyes by looking at the solar eclipse unaided paid off. (Stat News)
Bernard “Bud” Hammes, a medical ethicist who helped to spearhead this county-wide initiative that made advance care planning a routine part of life for the La Crosse community and its health care system, wants to take the program national. Earlier this year the managers of Respecting Choices amicably separated from the Gundersen Health System, which incubated it and which continues to promote advance care planning locally. The independent organization then affiliated with the Coalition to Transform Advanced Care (CTAC), a Washington, DC-based coalition of 140 organizations committed to improving health care for serious illnesses. Nationally, large-scale educational campaigns for advance care planning involve medical societies and associations, health plans, organizations like Aging with Dignity and the Conversation Project, philanthropic foundations, and even tech start-ups.

“Operating as a small, independent, not-for-profit business, we can be much more flexible in promoting our initiatives,” Hammes says. CTAC offers a national platform and contacts with other health care organizations and funders, but Respecting Choices’ national staff of 15 is still mostly based in La Crosse.

The process of planning
Experts have long held that the completed advance directive document, especially the living will, is not as important as the conversation to clarify values and preferences that generates it. Advance care planning is a process of thinking about, talking about and documenting the kinds of general care preferences and personal values that would be important to know in determining a person’s treatments in some future medical crisis—when the individual could not say what kind of care they wanted. These are emotionally laden subjects, but your family needs to hear and share what’s important to you. And the conversation is ongoing—not a one-time event—because people’s values, preferences and experience evolve over time. Advance directives, including living wills and Durable Power of Attorney for Health Care Decisions, are legal documents, slightly different from state to state, that try to capture those values, wishes and desires as well as naming who should speak for you when you can no longer speak for yourself.

Frequently, they are used to voice a desire for end-of-life care that is not overly burdensome, such as avoiding invasive high-tech treatments like cardio-pulmonary resuscitation, mechanical ventilators and feeding tubes at the point where these would only prolong the inevitable. But they can also be used to say the person would want everything done—no matter how grim their prospects.

The courts are clear: patients have the right to refuse medical treatments they don’t want. But in a crisis in the Emergency Room or ICU late at night when decisions need to be made right now, the medical juggernaut and its imperatives to do everything, regardless of benefit, are hard to resist.

When conversation is not enough
“Even though many times people don’t have the document accessible at the time of crisis, the fact that they’ve even had the conversation with their loved ones has an impact. Not all of the time, certainly, but a lot of the time,” says Harriet Warshaw, executive director of the Conversation Project, a national non-profit co-founded by journalist Ellen Goodman to promote advance care planning conversations. “Hospital staff tell us that in the heat of the battle—in the midst of a medical crisis—they don’t look for the advance directive document. They look for the loved ones who have come to the hospital. Where people can get into trouble relative to treatments they might not have wanted is if they never had that conversation, or if their loved ones don’t agree.”

But for Hammes, a great conversation is not enough, nor is storing the advance directive in a place that’s easily accessible in a crisis—although that’s important, too. “The culture of the health care system needs to change to become more truly person-centered, rather than disease- and treatment-centered.” In order to achieve that person-centered system, a lot of things have to happen to embed cultural changes across the system and its various components, so the values and preferences of the individual have a fighting chance against the habits and convenience of the system, Hammes explains. “And that’s what happened in La Crosse.”

In 1991 Hammes was asked to lead a joint task force of the county’s two competing integrated health systems to look at the problem of patients’ values not being known in an end-of-life crisis. Too often, they would receive medical care that offered little benefit but a great amount of suffering, was not aligned with what patients would say was important to them, and would cause lasting moral distress for the caregivers at the bedside.
First the team looked at existing advance directives and then developed and tested its own models. It also surveyed the public about its experiences and attitudes. The Respecting Choices system they created included standardized materials that could be used across all local health care settings, with non-physician facilitators trained to guide patients and families through these difficult conversations to reach a written plan. Standardized policies were adopted for collecting, maintaining, accessing and utilizing these plans in the medical record.

Outcomes were impressive, achieving almost universal penetration for completed advance directives communitywide within the first few years. A follow-up study of 400 consecutive deaths in the county in 2007 and 2008 found that for 96 percent of the patients, a written advance directive capturing their preferences, values and goals was recorded and accessible in the medical record. For those with advance directives, decisions consistent with their wishes were honored by the health care system 98 percent of the time. “I just had cataract eye surgery, and I got asked three times about my advance directive,” Hammes says. “And yes, I have completed one.”

These numbers are vastly different than the rest of the country: an analysis of 150 studies just published in Health Affairs tells us that a third or fewer adult Americans have completed an advance directive, even though the majority say that they would want to have their wishes honored at the end of life. A car accident or stroke could land any of us in the hospital with no warning. But many people put off the conversation because they’d rather not be reminded of their mortality. They also fear that their preferences might change—although these documents can be updated as often as we can get them signed and witnessed.

Going national—and international
The newly independent Respecting Choices organization now offers an array of resources and tools, training, customized curriculums, and strategic thinking to help health systems in other communities implement an integrated strategy for organizational change. Typically this is done through a consulting contract lasting 18 to 36 months.

Respecting Choices projects are being implemented in 287 medical centers—ranging from an 80-bed rural hospital in upstate New York to the Kaiser Permanente HMO giant. Singapore, Australia and Germany have adopted the program, and Respecting Choices also works with state and regional conveners, the largest of which is a collaboration of hospitals and medical associations in Washington State.

“We still haven’t reached the tipping point,” Hammes says. “Respecting Choices has consistently focused on advance care planning as a process—but our real goal has to be transforming health care from an enterprise that treats disease to one that treats people who have a disease. We’re seeing that it isn’t enough to sit down and have a great conversation. You need a plan and it needs to be transmitted to clinicians in the future. And they need to honor it,” he says.

Hammes also thinks we should not be asking people to plan for what is not necessary at this point in their lives. As we get older, he says, it becomes possible to be more specific—especially once we’ve had some first-hand experience with what medical care can offer—or impose. And at that point the POLST form (physician orders for life-sustaining treatment), recognized in many states, can help to spell out that specificity. According to Hammes, “When I ask people what they would want done in those situations, they generally say that if they have lost the ability to know who they are, where they’re at, and who is with them, and if this is unlikely to be temporary, then whatever you call it, they would not want it.”
This week in health and medicine

Aaron van Dorn

Florida uses telephone survey to justify switching kids’ insurance

A group of Florida pediatricians are accusing the Republican-controlled state government of using a duplic- itous telephone survey question to switch over 13 000 children from a children’s Medicaid health insurance program that specializes in children with severe health problems to one that did not cover—or did not have access to doctors who could perform—essential health services that children need. The state asked parents if their children was “limited in his ability to do things other children can do,” and used a no response—whether the child had severe health problems or not—as an excuse to remove children from the Children’s Medical Services, a part of Florida’s Medicaid program that specializes in helping children with severe medical problems, and into other Medicaid programs that were not equipped for that kind of care. (CNN)

Trump to fund ACA CSR for August

After a brutal CBO report this week, the Trump Administration has signaled it will fund cost sharing reduc tion payments for the Affordable Care Act for August. According to the CBO report, ceasing the CSR payments would spike exchange individual market premiums by 20%, and cost $194 billion above baseline by 2026. ACA subsidy rates are calculated by as a factor of the cost of certain plans on the exchanges. While cutting the payments to insurers would ostensibly decrease costs, the costs would be more than offset by the premium spike that would follow, and the automatic increase in subsidies to those eligible. It is unclear, however, if the Trump Administration plans to make a definitive statement on the continuing issuance of CSR payments. Insurers have repeatedly cited ongoing pol icy uncertainty from the Trump Administration as a major component of 2018 premium increases. (Business Insider)

ACS, Cleveland clinic withdraw fundraisers from Trump club

Following last week’s violent conflict in Charlottesville, Virginia, and President Trump’s multiple, equivocal state ments on the white supremacist demonstrations, the American Cancer Society and the Cleveland Clinic have both decided to cancel fundraising events that were scheduled to take place at Trump’s Mar-a-Lago private club in Palm Beach, Florida. The ACS has held their annual fundraiser at the club since 2012, and the Cleveland Clinic has held its annual fundraiser at the resort since 2008. (AP)

Watch out for the solar eclipse

If you’re planning on checking out next Monday’s total solar eclipse, be sure to take care of your eyes when you do so. If you’ve planned ahead, you probably already have a pair of “solar glasses” tha t block out the sun’s dangerous (to your eyes, anyway) ultraviolet radiation. If not, fear not—you can always do what they did back in the day, and make a pinhole projector. Just get a largish sheet of stiff paper and cut a hole in the center of it. Tape some smooth foil tautly over the hole and push a pin through the center of the foil. Et voila! When the eclipse happens, hold out the paper and look at the projected image of the sun on the ground. You’ll be able to see the moon’s encroaching sil houette in the projected image. (Stat News, Wired)

Take care down there

According to a new report, 3% of all emergency room vis its for urinary injuries were due to injuries sustained while grooming pubic hair. Among men and women who groom their pubic hair (67% and 85%, respectively), men and women suffered similar rates of injuries (24% vs 27%). While the injuries are generally mild, they do carry a slight risk of infection, and can increase your chances for contracting a sexually transmitted infection. (CBS)
This week in health and medicine

Aaron van Dorn

**Opioid national emergency roundabout**
The Trump Administration gave people following the ongoing opioid crisis whiplash this week. Earlier in the week, administration officials declined to follow the recommendation of the commission on the opioid epidemic convened earlier this year to declare a national emergency. However, reversing that decision, Trump announced on Thursday that he would be declaring a national emergency. However, while Trump made that announcement, actual paperwork—and more importantly, details about what policy consequences will follow on from that status—have not yet emerged, nor has a timeline for when that would be expected. (Stat News)

**Republicans face constitutes over healthcare vote**
For the long August recess, Republicans in Congress had hoped to step away from healthcare and begin laying the groundwork for a pivot to tax reform in the fall. But attendees at town halls across the country are still concerned about the GOP vote to repeal the Affordable Care Act. Even in districts that have been safely Republican for decades, voters appeared to be concerned and angered about votes to repeal the Medicaid expansion. (Washington Post)

**2018 individual market premiums face double digit hikes**
According to a report from the Kaiser Family Foundation, Republican attempts to repeal the Affordable Care Act and Trump Administration’s refusal to set a clear policy on cost-sharing reductions have led to insurers announcing double digit increases across the nation. Insurers have complained about the uncertainty that the political sphere has imparted in the marketplace, which provides insurance coverage for as many as 17 million people. Rate increases range from a 5% fall in Providence, RI, for a 40-year-old non-smoker making $30,000 a year, to a 49% hike in Wilmington, DE, for the same type of person. (ABC)

**Bipartisan group proposes ACA reform package**
A group of healthcare policy experts from across the political spectrum—from Republicans who have worked for previous Republican campaigns and administrations, to liberals who have argued for the passage and defended the Affordable Care Act—have issued a policy proposal targeted as a bipartisan fix for the ACA that could conceivably pass Congress. The changes are designed to stabilize and hopefully improve the ACA. The proposals are all, in and of themselves, relatively small—from ensuring the stability of CSR payments to expansion of health savings account programs—that have support from various coalitions in Congress. The package would not be a “win” for any one side, and the hope of the drafters is that it gives enough of something to everyone—and not too much to anyone—to enable it to gain majority support in Congress. (Vox)

**New York’s medical marijuana program relaxes some standards**
New York has announced some amendments to its restrictive medical marijuana program. By law, the program can only employ non-smokable forms of marijuana, which have previously been confined to liquids and oral capsules. New forms of delivery will include chewable tablets, ointments, lozenges and patches. Previous regulations which prevented anyone without an existing prescription for medical marijuana from entering dispensaries will also be relaxed, allowing dispensaries to offer information about the program. Chronic pain was added this year as a condition eligible for the program. The changes will also make it easier for doctors to become certified to participate in the program. (New York Daily News)
Research in the lurch—unanticipated funding cuts jeopardize teen pregnancy prevention programs

Rebecca Cooney

In a new podcast, The Lancet United States of Health Blog spoke with Dr Christine Dehlendorf, Jenifer DeAtley, and Representative Barbara Lee (D-CA). The following is an edited transcript.

In the last 25 years, we’ve seen a precipitous decline in teen pregnancy in the US. According to data from the Guttmacher Institute, the teen pregnancy rates peaked in 1990, but has declined since—both at the national level as well as for each state. Importantly, some of the biggest reductions in birth rates have been observed in black and Hispanic girls ages 15-19. The declines in the rates of teen pregnancy can largely be attributed to more widespread use of contraceptives. And driving the greater use of contraception by teens has been access—access to contraceptives and access to information.

Dr Christine Dehlendorf, a family physician at the University of California San Francisco, and Director of The Program in Woman-Centered Contraception, explains why teens are such a unique population to work with.

Christine Dehlendorf: Teens definitely have very active and energetic social networks that are influential on their behavior and their healthcare decision making. And so I think that any interventions designed to optimize their reproductive health needs to take into account the fact that they are part of this social context and can use that social context to benefit them and to help disseminate information that can help them make good quality decisions about their reproductive health.

Sustaining that progress requires concerted efforts. In 2010, the Obama Administration established the Teen Pregnancy Prevention (TPP) Program under the auspices of the Office of Adolescent Health. The TPP program has been dedicated to using evidence-based interventions to prevent teen pregnancy as well as sexually transmitted infections and risky behaviors. In addition to implementing teen pregnancy prevention programs, the TPP also funds training and capacity building, technology, and evaluating these approaches.

Earlier this year, Congress authorized $101 million for the TPP program as part of the FY 2017 funding bill. Yet in mid-July reports surfaced that grantees, the majority of whom have 5-year grant-funded projects, were receiving letters from the Department of Health and Human Services (HHS) notifying them that the project periods were being shortened anywhere from 1-3 years early—effectively pulling the funding for 81 projects to the tune of $214 million.

One of the programs that Dr Dehlendorf is involved in is subject to these cuts.

Dehlendorf: Our project is called Speak Out, and it’s a project designed to help teens get accurate information about long acting reversible contraceptive methods through their social network. We know that teens rely on their social network to get access to information, and often consider information from their peers to be more trustworthy than through conventional medical pathways.

We also know that teens have misconceptions and lack of knowledge about some of the most highly effective contraceptive methods, specifically IUDs and contraceptive implants. The goal of our project Speak Out is to encourage teens who are using one of these highly effective methods to the extent that they feel comfortable, tell their friends about why they chose those methods, and to give their friends information about the methods, and also information about how to access those methods if they want to have them.

The idea is to leverage these social networks and the social communication that we know is already happening to help teens to get good information that allows them to make decisions about their reproductive health and specifically their contraceptive choices in ways that reflect their own needs and don’t reflect misconceptions or lack of knowledge.

We’re in a position now where although we’ve been recruiting participants for many months, we are going to
have to cut our data collection short, and therefore will not be able to get a sample size that will give us information that will have adequate power to provide helpful information about the impact of our project. Essentially what this means is that instead of having a rigorous, evidence-based evaluation of Speak Out, we are going to have nothing more than a feasibility study. This is a huge loss of the invested resources that the federal government has put into our project when we were on track to be able to get important, actionable information about the impact of this on teens’ reproductive health.

Grants administered through research institutions are not the only ones to be affected.

Jenifer DeAtley is the country director for the US programs office of EngenderHealth, a nonprofit focusing on women’s health, sexual and reproductive health, and family planning. She describes how they were notified about the cuts.

**Jenifer DeAtley:** We had been expecting a continuation of our grant funds. Each of our, the projects that fall under the TPP Program out of the Office of Adolescent Health. We have what’s called a cooperative agreement and usually those are a five year agreement. So we have actually in my office, with the EngenderHealth, we have two programs that were currently being funded under the office of adolescent health and were under the impression that those grants would continue into the next fiscal year, which began on July 1 this year. On July 5, we received a letter from the director of Office of Adolescent Health stating that one of our programs in particular, which provides capacity building to youth serving organizations around the country who are running teen pregnancy prevention programs, that that program was going to be cut, effectively immediately.

What was alarming about the letter is that we were already expecting that this funding was going to be continued. We were given indication from our project officers that we were going to be funded. Getting this letter was quite disturbing because it was an effective immediately. There was no close out plan, no wind-down plan. It was just notice that the teen pregnancy prevention program was not a priority at the administration anymore.

What’s behind this decision?

In June, the Trump Administration installed Valerie Huber as the chief of staff to Don Wright, assistant secretary of HHS, whose office oversees the Office of Adolescent Health. Huber is a longtime abstinence advocate. Additionally, HHS secretary Tom Price, opposes federal funding for birth control. So it is not a surprise that the administration is antagonistic to programs like TPP. However, the decision to pull the funding was made without explanation and in the absence of Congressional approval—a fact which is not sitting well with many Congress people.

Representative Barbara Lee, a Democrat from California’s 13th congressional district, is spearheading efforts to get answers from HHS about this controversial decision.

**Rebecca Cooney:** In terms of leading the charge on responding to this decision, you and 148 other members of Congress have sent this letter to Secretary Tom Price requesting an explanation. Can you tell us a little bit about what happens after that? So there’s a public request for information here. What else do you have in store that you and your colleagues plan to help fight this?

**Barbara Lee:** First, we’re waiting on a response from Secretary Price. Sometimes they may or may not respond. Which again, speaks of how horrible this administration is on so many of these issues. When you look at their intention, the present budget’s zeroed out teen pregnancy prevention programs. They zeroed it out, it totally eliminated it.

But this speaks volumes as to why scientists and researchers and people who are working on these programs, get engaged in the political process because we need them to weigh in with their members of Congress. So we’re waiting now for the response to the letter and we’re going to keep fighting to try to get this funding restored. But also to get an understanding of why they would do this so we can have it on the record because it is putting young people’s health at risk and we’ve got to try to stop this every step of the way. But it’s going to take everybody to help us.

In the past, these issues teen pregnancy prevention, comprehensive sex ed, all of these issues have been bipartisan, and I want to thank everyone who continued to work on these issues because they’re very important and these grants are grants that I’m going to keep fighting to preserve. And we just have to make sure that everyone circles the wagons now. And just to speak out. We can’t just sit on the side lines and do our work and not really engage in letting the Congress, the House members and Senate members, know how this is going to affect their work. And so you have got to really get engaged and we’re going to continue to fight in the Congress but people, it’s got be an inside-outside strategy.

In the meantime, organizations like EngenderHealth are looking to find ways to establish continuity, where possible, for programs like Re:MIx, a school-based peer education program that focuses on sexual health and forging healthy relationships.

**DeAtley:** That’s been one of our biggest concerns because while we are working diligently to engage our donors and our communities to continue to reach out and support us and the work that we do. When you’re looking at it, just in the state of Texas we have an $8·6 million dollar loss of funding so that’s a lot of money that needs to be filled.
into those gaps to continue this work. It’s not going to sustain everybody. For one of our programs, the Re:MIX program, we have lost a few staff because we’re now looking at scaling back on the program.

We’ve got to plan for closeout while trying to find some funding to fill the gaps because even if our study does end like you said earlier, the data’s gone. You can’t transition how you’re going to do a program in the middle of a study because it compromises the settings. We might have to pull back from the study component but what we’re really trying to do is rally the community around continuing to serve the youth that we work with.

In addition to obvious consequences like affecting the lives of participants who may depend on studies like these for contraceptive access, the loss of funding to programs mid-project has important implications for the research enterprise in general. It’s a question of research waste. By failing to honor those funding commitments to researchers, we lose data, we lose the trust of participants, and we lose out on knowledge.

Read The Lancet’s Series: Research: increasing value, reducing waste
This week in health and medicine

Aaron van Dorn

Teen suicide rates spike
According to a Centers for Disease Control report, suicide rates in teens have spiked dramatically since 2007. For boys, the increase is still lower than at its peak between the mid '80s and mid '90s, but for girls, that suicide rate reached a 40 year high, doubling between 2007 and 2015. Experts indicate that there likely isn’t a single contributing factor, but issues like mistaking accidental opioid overdoses for suicides and stress factors on families from the economic recession beginning in 2008 probably played a major part in the increase. (CNN)

Shkreli convicted of securities fraud
Martin Shkreli, the hedge fund manager-turned-pharma company CEO was convicted of securities fraud on Friday, and could potentially be sentenced to prison for years. Shkreli, 34, rose to meteoric internet fame and opprobrium after his pharmaceutical company purchased the manufacturing license to an antiparasitic drug that many HIV and AIDS patients relied upon and immediately raised the price from $13 a pill to $750. Often referred to as a “pharma bro,” Shkreli became a touch point for concerns about out of control drug prices, not helped by his uniquely combative and unpleasant public persona. (Stat News)

FCC proposes $82m fine for health insurance telemarketing fraud
According to the Federal Communications Commission, in December, 2016, Phillip Roesel, a health insurance telemarketer from North Carolina, placed over 21 million robocalls targeting the elderly and poor to sell health insurance. FCC investigators confirmed that at least 82,000 of those calls were placed using fraudulent caller ID information, a violation of the Truth in Caller ID Act. The Truth in Caller ID Act calls for a fine of $10,000 per act of “spoofing,” or deliberately falsifying caller ID information in an effort to defraud or trick someone. (ABC)

Minneapolis restricts sale of menthol cigarettes
The City Council of Minneapolis, Minnesota, has passed a new ordinance restricting the sales of menthol cigarettes to liquor stores and tobacco specialty shops, after a campaign by community activists. Menthol provides cigarettes with a minty flavor and a cool sensation, which critics say contributes to younger people starting smoking. Menthol cigarettes have also been marketed to African American communities. The measure, which will take effect in August, 2018, was criticized by convenience store owners, who contend that the restrictions will hurt their business. (Minneapolis Star Tribune)

Legionnaires’ disease increase in Michigan
Public health officials in Michigan are concerned about an outbreak of Legionnaires’ disease, with 73 cases identified in June and July, more than double the average number of cases from the same period between 2014 and 2016. Caused by a bacteria transmitted by moisture and water vapor, Legionnaires’ disease can be difficult to treat and fatal. A common vector hasn’t been discovered in this outbreak, but the disease is commonly associated with poorly maintained air conditioning and heating systems. (US News & World Report)

Gene editing in embryos
For the first time in the United States, the CRISPR gene-editing tool has been used to correct a mutation in human
embryos. The test comes after a relaxing in guidelines for modifying human embryos for any but the most serious medical conditions. The results are promising, with a greater success rate than similar experiments done in China in 2015. The National Institutes of Health still bar funding for research involving genetic manipulation of human embryos, and the study was funded by Oregon Health and Science University and the Institute for Basic Science in South Korea, among others. (New York Times)
ACA repeal fails in Senate (for now)

Aaron van Dorn

Following the House narrowly passing the American Health Care Act in May, the Senate GOP, led by Majority Leader Mitch McConnell (R-KY), began a long series of closed door meetings with a group of only thirteen (all male, all Republican) senators. What they finally produced, the Better Care Reconciliation Act, struggled to find the 50 Republican votes needed to become law, with several more moderate senators from states that would be badly affected by the repeal of the Medicaid expansion, claiming at one point or another they couldn’t support the law. However, as happened with the House bill, one by one the Republican holdouts came back into the fold, and by Thursday evening, with moderates Dean Heller (R-NV) and Shelley Moore Capito (R-WV) saying they would vote for the passage of a final bill, revealed only at 10pm Thursday night, and to be voted on two hours later, when Murkowski, Collins and McCain, along with the Democrats, brought an end to Republican efforts to repeal the ACA, for now.

Among many odd aspects of the legislative process, one of the bills that the Republicans managed to produce in an effort to repeal the ACA were ever popular, often polling in the teens—they rank among some of the most unpopular legislative proposals in the modern era. Every major medical organization—from providers to patients to hospitals—was against it. Even on the terms that President Donald Trump campaigned on, or based upon previous Republican promises surrounding repeal, the bill also would have raised premiums for health insurance across the board, and would have kicked tens of millions of people off their insurance plans—Congressional Budget Office estimates ranging from 12 million to 32 million by 2026. Republicans seemed to be constrained by seven years of unrealistic promises and a beleaguered and flailing president desperate for a win, no matter how politically toxic it may have ultimately proven to be.

It’s unclear where this defeat leaves Republican efforts to repeal the Affordable Care Act. Last night in a bitter and tearful speech in the Senate, McConnell lashed out and Democrats, but seemed to signal that real efforts to bipartisan compromise might begin. In the House, this morning Paul Ryan seemed to signal the necessity of transitioning to addressing the budget and tax cuts ahead of the end of the federal fiscal year in October. Meanwhile, on Twitter, Donald Trump was back to insinuating that he would deliberately sabotage the ACA in an effort to force Democrats to accept his (as yet unarticulated) plan for healthcare.
Reservation liquor store closure leads to boom in nearby stores

According to a report from the Nebraska Liquor Control Commission, the closure of liquor stores in Whiteclay, NE has lead to a sharp increase in alcohol sales in surrounding communities. Located adjacent to the Pine Ridge Indian Reservation in South Dakota, the beer stores in Whiteclay have long been a problem for the reservation, selling four million cans of beer a year. Pine Ridge faces a multitude of problems, with 97% of the population living below the federal poverty line, an unemployment rate of 85% or above, and more than half of the adult population suffering from alcoholism. Since the closure of the liquor stores in Whiteclay in May, beer sales in Rushville, NE has more than tripled, from almost 4000 gallons of beer in April to nearly 13 000 in June. (Lincoln Journal Star)

NFL ends partnership with NIH over CTE study

The National Football League announced today that it was ending a $30 million partnership with the National Institutes of Health aimed at researching potential links between chronic traumatic encephalopathy and football. The move comes following the release of a report that found evidence of CTE in 110 of 111 deceased NFL players. This follows on years of contentious relations between the NFL and NIH, including arguments over a 2015 study that ultimately saw the NFL withdrawing funds after a researcher was critical of the NFL. (Bleacher Report)

Stuck in the middle with slug glue

A strong, stretchy bio-glue that sticks to wet surfaces and moves with the body has been developed by researchers at Harvard. Based upon a defensive mucus secreted by slugs, the glue has a broad range of applications, from treating surface wounds to attaching medical devices like pacemakers to organs. According to researchers, they were even able to seal a hole in a pig’s heart with the new material. The glue itself is made up of an adhesive that uses ionic charges to attach itself to cells in the body, and a biochemical shock absorber that allows it to stretch and flex without breaking or peeling away. The Wyss Institute at Harvard, which developed the glue, has applied for a patent on it, but claims the glue itself is cheap to manufacture. While the adhesive has proven itself mechanically, it has yet to enter medical trials on its safety. (BBC)

FDA seeks to cut nicotine in cigarettes

For the first time ever, the Food and Drug Administration is attempting to regulate the amount of nicotine in cigarettes. Nicotine is the component in tobacco responsible for its addictive qualities, and the FDA hopes that by reducing the amount of it in tobacco, potential future smokers will not become addicted in the first place. The FDA also announced an extension in the timeline for applications for e-cigarette approval to 2022, as well as extending the FDA’s timeline for the announcement of a formal e-cigarette framework. (NPR)

Head of Medicaid’s husband doesn’t accept it

Seema Verma, the head of the Centers for Medicare and Medicaid Services, worked with Vice President Mike Pence when he was Governor of Indiana to design that state’s Medicaid expansion, and has often decried the difficulty people in the system have in finding care—including from her husband, Sanjay Mishra, a pediatrician in Indiana who does not accept patients using the government program that covers over half of the children in Indiana (56%, or 727 000). (Kaiser Health News)
All hands on deck—addressing the nation’s opioid epidemic

Rebecca Cooney


In a new podcast, The Lancet United States of Health Blog spoke with four of the experts who contributed to the report: Richard J Bonnie, Aaron Kesselheim, David Clark, and Mark Schumacher. The following is an edited transcript.

Rebecca Cooney: The opioid epidemic itself has now turned into this evergreen front page story and is something being discussed in all corners of healthcare. But I think there is still an underappreciation of the actual scope. There are some parallels with the advent of the AIDS crisis in that it’s arisen very swiftly and it’s extremely lethal, but, in other ways those parallels fall apart because this is a very unique situation because of the complexity. In preparing this report, what were you thinking about in terms of how you characterize the magnitude of this epidemic?

Richard Bonnie: I think that we’ve had lots of conversations about this and, in particular, in thinking about the parallels and the differences with HIV and looking for analogies because as you correctly say, the magnitude of this is staggering. You mentioned one measure, of course, the overdose deaths. The slope of the curve is also amazing. Another thing to take into account is the number of people who have developed opioid use disorders. We’ve had an endemic that fluctuates over time with regard to opioid use disorder based on illicitly available drugs. Right now that number is approximately 600 000, which already reflects some transitions of people from prescription opioids. Of the number of people who have heroin disorders, a substantial portion of them began with prescribed opioids.

Cooney: Because this is a topic that is at the intersection of so many different areas—public health, medicine, ethics, law enforcement, politics—it clearly speaks to how difficult a problem it is to come up with actionable plans for curtailing the problem. Perhaps to start, we could discuss a bit about what spurred this particular report and how as a group you worked to encapsulate the issues.

Bonnie: The main motivation of the US Food and Drug Administration (FDA) to request this report was because of the complexity of the decisions that it was confronted with in some of the reviews of new products and some criticisms that they were running into on various proposed regulations. I think that they were genuinely looking for guidance as to how to think about that and how to incorporate these considerations into their regulatory decision making. But, in making these decisions, we have to balance the interests of pain patients who are suffering—their needs and interests as well as the potential harms of drug approval. This balance issue was also part of the complexity, because it requires some thinking about the effectiveness of these drugs, the treatments for pain, the alternatives, and in some global sense, the ways in which this can contribute to the public health problem of inadequately treated pain.

David Clark: As a member, I became very impressed with the diversity of the committee—so many different facets and angles and implications. As one of the pain physicians on the committee, I think the point of view that we need is to strike a careful balance between restraint on opiate prescribing and acting compassionately towards our patients. I believe that the committee was very receptive to both sides of that issue and in the end came up with a position that we were very comfortable with. We hope that the medical research, law enforcement, and other concerned communities can be reassured that we gave this issue very careful consideration.

Mark Schumacher: Over the discussions initially, it became apparent to the committee that FDA alone was not going to solve this. That it was going to require an all hands on deck approach. I think the committee worked to expand in many ways the complexity of who would need to be involved, in the broader sense across the country, including established organizations at the federal level, Centers for Disease Control and FDA themselves but, also the National Institutes of Health and the Drug Enforcement Agency. But we were also particularly focused about how this would come back to the state level and we also examined how that would interface with state medical boards and state schools of medicine and health sciences.

Bonnie: Consensus emerged pretty clearly once each of us were introduced to the other tiers of knowledge and literature and because we were all learning from each other as we were going along. I think that’s a noteworthy part of the experience.

Cooney: Something we wrestle a lot with and have editorialized quite recently at The Lancet is that as a medical
The discouraging part is that we were left in 2017 with essentially the same toolbox as we had in 2011. So we have not succeeded in translating our scientific findings to new therapies. That is a big challenge and is one that has been recognized and is being addressed by the Interagency Pain Research Coordinating Committee research and it is one that we feel is very important. We do call specifically for there to be an enhanced level of support or research at multiple levels. One is to understand better the neurobiology of pain, hopefully forming the foundations for treatments that might be developed for patients, which would help us get around this question of the problems with using opioids. If we have alternatives, maybe we won’t have to worry so much about opioid use disorder.

A separate more specific task was to look at the interaction of pain and the neurocircuitry of opiate use disorder or the correlates that we see in pre-clinical models, hoping to understand better why people might be more vulnerable or protected in certain instances, what the mechanisms are, and hopefully along the way, to learn something more about pain and opiate misuse in general.

Cooney: I think it’s fascinating that you use the word toolbox because I was thinking that a lot of this seems to stem from an overuse of opioids as a tool for physicians to treat pain. Looking at the epidemiological data and prescription data, it seems that 2010 was the peak of that wave of opioid prescriptions. But there has been some pull back and the report notes the idea of changing the national approach to improving awareness and changing prescription patterns.

Schumacher: I think in many ways it’s not back to basics but, what else is in the toolbox? Frankly. And that there are other non-opioid choices that are not perfect but can be effective for the management of pain, especially chronic pain. They include some use of the non-steroidal anti-inflammatory class of drugs, anticonvulsants, and pharmacologic management. A multi-model approach, if you want to use that term, for pharmacologic intervention of pain that can diminish the requirement of opioids or the overall dosing. I don’t think that we are at a state where we can completely eliminate opioids, the most potent analgesics we have in hand. But, I think where we’ve struggled is this idea of the same approach that physicians or providers use with these potent opioids for acute pain like post-surgical pain or end of life care, then consider the same tools or practices for months and years. For chronic pain conditions, opioids just don’t have the same effect and have great harm.

In summary, given the advancing knowledge, we want to redirect providers to at least consider alternative non-pharmacologic or non-opioid strategies potentially alongside opioid strategies with the goal to reduce the harm associated with any one of those.

Cooney: What do you think are the strongest recommendations of the report in terms of what the FDA or federal government can do to regulate opioids? How do we regulate the tool in the toolbox at this stage?

Aaron Kesselheim: One of the key regulatory recommendations is that the traditional approach the FDA takes to reviewing drugs is a very patient specific approach—the efficacy, the benefits, and the risks of the drug for that particular patient. But, given the societal effects of opioids that we’ve observed, the committee thought that approach was too limited and that instead the FDA needed to be prepared to take broader public health considerations into account when deciding whether to approve a new opioid formulation or new opioid dose level or new opioid derivative. And to consider how it is monitored and the types of post-market tools that it uses to continue its oversight of the opioid market.

After our review, we believe that the FDA has the authority to take a much more systematic approach to implementing these kinds of considerations in its review of new opioids and with regard to the opioids that are currently available on the market as well. This shouldn’t be about the next generation of products but should also look back at the products that have been available for decades and ask whether there are certain doses or formulations or derivatives or types of opioids that are more dangerous and need different kinds of monitoring.

Cooney: This report speaks to the tremendous amount of change that is going to need to take place in regulatory overhaul, societally how we respond, and in terms of
cooperation among the medical community and governmental agencies. Can you give us a sense of what degree of effort or how long these efforts might take to get some traction? And ultimately, from your perspective what does traction or success look like?

**Bonnie:** Well, as you probably heard me say, this is going to take a while. It’s taken a while for this epidemic to reach the proportions that it already has reached. It’s going to take a while to unwind it. We talked earlier about strategies and some are short term and some are longer-term strategies. As we go forward thinking about this, I think we may really want to systematically think about that.

**Schumacher:** One of the biggest struggles when mapping out a strategy or the sequencing or to try to respond as soon as possible would be the unintended consequences. For instance, unilaterally restricting opioid prescribing without having alternative strategies for managing patients’ pain. For example, we have millions and millions of citizens that were started on opioids, are in pain currently, and on opioids and some are on high doses. There’s a great concern that without a coordinated roll out of strategies that the unintended effect would be to push many of those patients into either illicit markets of counterfeit prescription medications or even down the path of very cheap versions of heroin or other synthetics, frankly, making matters worse. That is really a critical part as we discuss strategies.

**Clark:** It’s very tempting in desperate times to employ desperate measures. There are strong considerations for what you might consider to be fairly heavy-handed interventions. I would urge caution in implementing very strong strategies to immediately reduce prescribing because of the pitfalls that Mark mentions and in the sense of unfairness to the group of patients that we can’t quantify easily but who may be using their opiates responsibly and with good effects. So there has to be some sensitivity shown even when implementing short-term solutions. I believe reform of prescribing practices is critical, which can come through dissemination and reinforcement of use guidelines and much better education for prescribers, primarily physicians, but also dentists and advanced practice nurses in the US Education and changing expectations are key. And, ultimately, if we don’t do the research required to discover and develop alternatives, we are for the foreseeable future going to continue to wrestle with this problem because there will always be a desire to use these treatments even if they are substantially risky.
This week in health and medicine

Aaron van Dorn

ACA repeal staggers on
After a number of serious setbacks, Republican efforts to repeal the Affordable Care Act staggered on this week, with a number of key Republican senators announcing they would not support the current version. A Congressional Budget Office score of the new version found that 22 million more Americans would be without insurance by 2026 versus current law. However, that CBO score did not include an amendment authored by Senators Mike Lee (R-UT) and Ted Cruz (R-TX), which would allow insurance companies to sell insurance plans that would offer little in the way of actual protection. The Department of Health and Human Services released a report on the new amendment that found it would decrease premiums for both plans allowed by the amendment and more traditional insurance, a finding that many experts and the insurance industry lobby both said is the opposite of true. A vote on a straight repeal of the ACA is mooted for next week. (*Business Insider*)

Trump nominee for USDA’s top science position
The Trump Administration has put forward Sam Clovis, a former professor of economics at the Morningside College in Sioux City, Iowa, for the position of Undersecretary of Research, Education, and Economics, the Department of Agriculture’s top science position. The position has usually been filled by someone with a background in research, food policy or public health. Clovis, however, was co-chair of Donald Trump’s presidential campaign, holds a doctorate in public administration, and has worked as a conservative talk radio host. Since the inauguration, Clovis has served as the USDA’s top policy advisor, where he sent a memo ordering USDA scientists to stop sending out press releases or fact sheets regarding their work. (*Washington Post*)

New Jersey raises smoking age to 21
In an emerging trend in the fight against teen tobacco use, New Jersey has become the third state to raise the legal age to purchase tobacco products to twenty-one from the current age of nineteen. Governor Chris Christie signed the bill into law this week after vetoing a similar measure last year. The ban includes both all types of tobacco and electronic smoking devices. The measure is similar to ones enacted previously in Hawaii and California. (*San Francisco Chronicle*)

John McCain has brain cancer
Senator John McCain (R-AZ), a figure in national politics for decades and the 2008 Republican candidate for President, has a glioblastoma, a common but aggressive form of brain cancer, his office announced this week. Concerns over McCain’s health began last week when it was announced that he underwent surgery to remove a large blood clot above his left eye. McCain, 80, has not announced his plans for coming back to the Senate. He recent won reelection to another six year term, and his absence, reducing the number of Republican votes, might complicate GOP efforts to repeal the Affordable Care Act. (*New York Times*)

Looking at expired drugs
Drugs come with an expiry date, but that doesn’t necessarily mean that the drugs that pass by that date are no longer potent or have become toxic. The expiry date on most drugs just indicates the date by which the CDC and the drug manufacturer have determined that the drugs will definitely still be good by. According to researchers in California looking at a cache of forty-year-old drugs still in their sealed containers, many of the drugs retain almost 100% of their original potency. (*Stat News*)
CDC recommends measles vaccination for travel to Europe

A new travel health notice from the Centers for Disease Control is recommending that Americans visiting Europe who have not been previously treated for measles receive vaccination prior to visiting Europe. Since January 2016, the CDC has reported more than 14 000 cases of Americans contracting measles in Europe, in countries ranging from the UK, Sweden, Austria, Bulgaria and more. The report also stated that the majority of measles infections in the US stem from international travel. (KFVS)
FRIDAY, JULY 7, 2017—21:47

CMS prepares for launch of comparative hospice data

Larry Beresford

The US hospice movement was founded on a promise to deliver compassionate, professional, culturally sensitive interdisciplinary care and support to people struggling with terminal illnesses and to their families—at a time when the rest of the health care system was not terribly interested in the dilemmas of living well while dying.

Despite—or because of—this model’s extraordinary growth since 1974, America’s hospices continue to face high expectations for compassion, altruism and responsibility for the vulnerable patients they serve. A $16 billion Medicare sector that serves 1.7 million patients per year, Medicare agencies and contractors increasingly scrutinize hospices’ claims for hospice-appropriateness, while journalistic exposés in the Washington Post, Huffington Post, and elsewhere confirm that there is little tolerance when hospice programs fail to live up to their lofty mission.

But as hospice care has become less a humanitarian movement and more of a professional health service, it is also being held accountable to the standards other professional health services face, including measurable demonstrations of quality.

Sometime in July or August, the Centers for Medicare and Medicaid Services, which administers the Medicare program, will unveil a new government service and webpage called Hospice Compare, which will permit consumers and anyone else to look up a hospice’s quality scores and compare them to other hospices. Similar Compare websites have been launched for hospitals, nursing homes, home health agencies and other categories of health providers.

But not a lot is known about how and how many consumers rely on this information to choose providers.

A long and complicated path

It’s been a long and convoluted path, through multiple iterations, in order to agree upon hospice quality data that could be reported publicly—and the imminent rollout of Hospice Compare is just the beginning. Quality, to be comparable across sites, needs to be measured the same way with every patient. But some objective measures of health quality, such as mortality rates, don’t fit a provider type where the patients are expected to die within six months.

Researchers have spent years defining, testing, refining and winnowing sets of quality measures that might capture the quality of hospice care, sometimes described in terms of doing the right thing at the right time—every time. An early quality measure was the Family Evaluation of Hospice Care survey, developed by the National Hospice and Palliative Care Organization for use by hospices. But the requirements of quality data reporting eventually dictated the need for approved independent entities to send out the surveys to families and then tabulate the results.

Dying “well” remains a highly subjective concept. “As Dr Ira Byock taught us, death is a personal event, not a medical event,” notes Lin Simon, Quality Outcomes Specialist for Delaware Hospice. “For each person, the event could be considered differently. How to grasp that across the board and compare it between hospices makes it difficult.”

For example, it is important to assess the patient’s pain at the time of admission and, if that pain is at a higher level than the patient wishes, to take steps to try to bring it under control. That is the basis for one of the quality measures on Hospice Compare, which tallies how often this happens across all of the hospice’s admissions. Other questions addressed in the initial version of Hospice Compare include: Was dyspnea (shortness of breath) assessed and addressed for the patient? Were personal beliefs and values addressed—if that is desired by the patient? Were personal treatment preferences honored?

Hospice agencies have a lot of concerns about how Hospice Compare measures are defined, and about the time lag, a year or more between actual provision of care and when the quality data get posted, says Lynn Stange, Chief Compliance and Consulting Integrity Officer for the hospice consulting firm Weatherbee Resources, Hyannis,
Massachusetts. Providers also worry about whether the results will present them in a favorable light.

Will the measures truly discriminate between high quality hospice care and not so high quality? Will the high-quality hospices be able to use their quality scores in promoting their service to the community? For small hospices with fewer cases represented in their performance scores, a few bad ratings could impact their overall scores. Publicly reported poor quality scores could be an embarrassment to a hospice—but also an impetus to work on elevating its quality, Stange says. “Not just to change your scores but to propel actual quality improvement.”

**What Else Goes into Hospice Quality?**

On June 1, hospices were offered an opportunity to review the quality data that the government intends to report about them later this summer and, if they found inaccuracies, to request reconsideration. Quality measurement is a moving target, with more scores being added as fast as the government can work out their reliability and feasibility.

Coming in 2018 is the reporting of a satisfaction survey called the Hospice CAHPS (Consumer Assessment of Healthcare Providers and Systems), which is sent to survivors of deceased hospice patients several months after the death to rate the care their loved one received. Another measure in the works is to count the number of professional visits made by the hospice team to the patient’s home in the last three or seven days of the patient’s life—when care needs presumably are greater.

“This is a big deal for hospices as well as for consumers,” Simon says. “The measures will be increasingly refined, but I’d say give it some time before you look at the measures as the truth of how different hospices perform.” It also depends on what matters most to each individual from their hospice care, and how well they can learn to read the rating keys to help answer that question, she says. “I would want my own loved one’s hospice accountable for all of these measures.”

The measures aren’t perfect reflections of hospice quality, says Charlene Ross, partner of consulting firms Hospice Fundamentals and R&C Healthcare Solutions. “But it’s a start.” The initial measures focus on process—in other words, did the hospice team take the correct steps in providing care—rather than outcome, which is the actual impact of the care as experienced by the patient and family. But researchers will continue to pursue the Holy Grail of measurable outcomes from the subjective experience of receiving hospice care. In time, Hospice Compare will offer a Five Star rating of providers, which will help consumers make quicker choices.

“Eventually we’ll get to real quality reporting, given that a lot of smart people are continuing to work on this,” Ross says. “I recently moved to Hilton Head. I am trying to figure out how to find a doctor, a dentist, a hairdresser, so I go online to do it. If I needed to go to a hospital or nursing home, I’d probably use their Compare website. Eventually people will learn to do the same with hospices.”
With BCRA in doubt, McConnell lays groundwork for exit
With the Senate Affordable Care Act still unable to garner support from 50 Republican Senators to secure passage, Senate Majority Leader Mitch McConnell (R-KY) has begun to suggest that the Senate may need to pass a smaller bill aimed at shoring up the ACA. The admission was remarkable both in its candor regarding the problems facing the bill designed to be passed without Democrats in the Senate, but in stating baldly that the fixes needed for the ACA are achievable, and that Democrats would support moves to improve former President Barack Obama’s signature healthcare law. McConnell’s admission, at odds with his previous statements about the necessity to repeal the ACA, are also at odds with President Donald Trump, who has repeatedly suggested that he would be willing to let the health insurance market fail in order to extract concessions from Democrats. (CNBC)

Amendment would limit prices for drugs developed with Defense Department money
An amendment added to a Defense Department appropriations bill by Senator Angus King (I-ME) would limit the amount drug companies could charge in the US for drugs developed with funds from the Department of Defense. The move comes after several drugs developed in part with taxpayer funds have seen price points far outstrip those offered in Europe and other high income countries pay. The amendment would affect drugs that had higher prices than what was charged for it in seven other countries, based on a formula looking at median price and per capita income versus the US. (Stat News)

Study finds drop in number of opioid prescriptions
According to a recent Centers for Disease Control report, the number of opioid prescriptions issued by doctors dropped 13% from 2012 to 2015, raising hopes that efforts to control the opioid crisis are having an effect, despite still being three times higher than the rate in the late 1990s. The explosion in opioid prescriptions saw an attendant increase in the number of people moving towards illegal opioids like heroin and abusing prescription opioids in unapproved ways. (Chicago Tribune)

Trump names head of CDC
Brenda Fitzgerald, an obstetrician and the head of Georgia’s Public Health Department, has been named by Trump to head up the CDC. Fitzgerald has been active in politics in Georgia, running twice in primaries for Republican nomination to Congress. Fitzgerald is a strong proponent of vaccines, and seems to take a more nuanced approach to abortion, decrying graphic anti-abortion ads run by an opponent in one of her bids for Republican nomination. She has practiced medicine for more than thirty years in Georgia. (NBC News)

FDA approves sickle cell treatment
After the recent death of Mobb Deep co-founder Prodigy following complications from sickle cell disease brought the blood disorder back into the news, the Food and Drug Administration has announced the first new treatment for sickle cell disease in twenty years. The drug, approved for those five years and older, is the second drug approved for the debilitating disease. People with sickle cell disease in the United States have a life expectancy of 40 to 60 years, and can cause organ damage and extreme pain. (FDA)
Ohio looks at monitoring nerve drug used by opioid users

Gabapentin, a drug approved by the FDA for use in the treatment of epilepsy and nerve pain, from the after effects of singles to restless leg syndrome, has increasingly come to be used by opioid users to increase their high or to stave off the effects of withdrawal. Ohio’s Board of Pharmacy began including it as part of its monitoring of controlled substance usage, despite the fact that Gabapentin is not listed as a controlled substance. However, sales and prescriptions of the drug have been on the rise, making it the fifth most prescribed drug in the US in May. While the drug is not a risk for overdoses, the risks of taking the drug over long periods or high doses is unknown. (Kaiser Health News)
This week in health and medicine
Aaron van Dorn

Senate GOP leadership continues work on BCRA
Following this week’s pre-vote collapse of Republican support for the Better Care Reconciliation Act, Senate Majority Leader Mitch McConnell (R-KY) continued work on the bill, in the hopes to appease both moderates concerned over the bill’s devastating cuts to Medicaid and conservatives who decry the bill as overly generous. The Senate is in recess until July 11, and McConnell hopes to have a bill drafted by Saturday to be sent to the Congressional Budget Office for a new score ahead of a quick vote in July, prior to the long August recess. McConnell’s plan currently appears to involve offering moderate GOP senators a small amount of money for the opioid crisis while appeasing the conservatives with unannounced concessions of their own. President Donald Trump, meanwhile, spent the morning calling for an immediate repeal of the Affordable Care Act, with a replacement to come at some point down the road, something he has decried in the past. (Washington Post)

As opioid crisis grows, treatment doesn’t keep pace
A new report by insurer Blue Cross Blue Shield has found that between 2010 and 2015, the rate of opioid addiction increased by more than five times, far outstripping the rate of growth of medically-assisted drug treatment, which only grew by 65% during the same period. The report also found that medically-assisted opioid treatment was unevenly distributed, with states with the highest rates of opioid addiction providing less drug treatment. The report also found that those most likely to become addicted to opioids were those prescribed short course—less than 90 days—of high dose opioids, with 6·2% becoming dependent on opioids. (LA Times)

Ohio town looks at ending opioid treatment
In a small town in Ohio facing the brunt of the opioid crisis, city councilman Dan Picard has proposed possibly ending emergency medical services for those who have required multiple emergency overdose treatments. Middletown, Ohio, a town of 50,000, has seen over 600 opioid overdoses so far in 2017—already more than in all of 2016, and according to the fire department, four or five a day on average. At $36 per treatment—and with some patients requiring multiple doses—the city is expecting to spend $90,000 this year on Naloxone, a drug that can reverse opioid overdoses, 50% more than their entire budget for all other medicines aboard emergency response vehicles. Critics say it’s unclear if the plan is legal, and the town’s fire chief, Bryan Oliver, says that only 15% of emergency calls are for those with multiple overdoses. But it’s another indication of how deeply the opioid crisis is affecting small towns around the country. (NPR)

Trump nominates Jerome Adams as Surgeon General
Following the acrimonious ouster of previous Surgeon General Vivek Murthy, the Trump Administration has nominated Jerome Adams for the position. Adams, an anesthesiologist and currently the Health Commissioner for Indiana, has experience working with Vice President Mike Pence, who appointed him to the position. In that position, Adams worked with the extensive HIV/AIDS outbreak in rural Scott County, Indiana, which stemmed from a large uptick in opioid usage. Adams is an advocate for needle exchanges, something that Pence was notably against when he became governor of Indiana. This is the second Pence-affiliated person to fill a major medical role in the Trump Administration, after Seema Verma, now the head of the Centers for Medicare and Medicaid Health Services, who also worked with Pence in establishing Indiana’s Medicaid expansion. (New York Times)

FDA moves to spur generic drug development
The Food and Drug Administration has announced a change in policy designed to spur development of generic
drugs. The FDA will now fast track all generic drug development until three generic versions of a given medicine have been improved. To make things as explicit as possible, the FDA also published a list of 170 older drugs that do not have generic versions, including the antibiotic amoxicillin, Nabilone, a drug used to treat nausea and vomiting due to cancer treatments, and Verteporfin, used to treat a number of blood vessel disorders in the eye. (Stat News)

Teen pregnancy rates at all time low, as births from older women increase
Teen pregnancy rates in the United States are at an old time low, according to a new report from the National Institute of Health Statistics. The teen pregnancy rate dropped 9% over the previous year, and has dropped 67% since 1991. In contrast, the rate of women giving birth at an older age has increased over previous years, with a 1% increase over 2015 in women aged 30–34, and 2% in those aged 35–39, and women aged 40–44 saw an increase of 4% over 2015, all record highs since the mid-1960s. However, the overall birthrate of the US saw a fall, with fewer than 4 million births in 2016, a 1% decline over the previous year, and an all time low for the US. (CNN)
This week in health and medicine
Aaron van Dorn

Senate unveils ACA repeal bill
Republicans in the Senate finally revealed their half of Republican efforts to repeal the Affordable Care Act this week, with a bill that substantially follows the path laid down by the House’s American Health Care Act, passed in May. As with the AHCA, the Better Care Reconciliation Act would end the ACA’s Medicaid expansion and allow states to waive the guaranteed essential health benefits, such as maternal and pregnancy care, addiction services, and the ban on pre-existing conditions. It would also repeal the ACA’s taxes on those making more than $200 000 a year and on insurance companies. The GOP needs 50 votes in the Senate to pass the bill, and several Republican senators have signaled that they have “concerns” over the bill, but how strong those concerns are remains to be seen. (New York Times)

Republican governors wary of Senate healthcare bill
Thirty-one states have adopted the Affordable Care Act’s Medicaid expansion, which has helped to drop the level of uninsured in those states, and governors of those states are wary about the prospect of seeing the Medicaid expansion repealed in the Senate’s ACA repeal bill. Those concerned include Republican governors John Kasich (Ohio) and Brian Sandoval (Nevada), which both saw hundreds of thousands of people receive health insurance coverage through the expansion. Also at risk for states like Ohio, West Virginia and Maine are provision sin the ACA that help fight against the ongoing opioid epidemic that’s especially vicious in those states. (AP)

Withheld data led to common herbicide being called “probably carcinogenic”
In 2015, when the International Agency for Research on Cancer, a division of the World Health Organization, declared that the herbicide glyphosate, commonly sold as Monsanto’s RoundUp weedkiller, was “probably carcinogenic,” contradicting conclusions of its safety by the US Environmental Protection Agency and the EU’s European Food Safety Authority, it caused a number of reactions, including a lawsuit in California against the agribusiness giant Monsanto. But as part of the discovery process in that lawsuit, it’s emerged that a scientist for the IARC did not disclose research—research they were involved in—that would have suggested the product was not, in fact, a carcinogen, because the IARC had a policy against disclosing unpublished research. Despite the find, and the scientist’s admission that if it had been disclosed it probably would have altered the IARC’s classification of glyphosate, the IARC does not plan on changing its conclusion regarding the chemical. (Mother Jones)

EPA Board of Scientific Counselors shown the door
In a surprise move, EPA Administrator Scott Pruitt has declined to renew the tenure of dozens of members of the EPA’s Board of Scientific Counselors, an advisory council designed to provide guidance on the science produced by the EPA’s research and development programs. Board members are chosen by the administrator and serve three year terms, and are generally provided with a second term. Pruitt previously announced that nine members of the board would not be renewed. This new round raises that number to 56, leaving only eleven members left on the board, and all meetings for board committees have been canceled through the fall. (ThinkProgress)

Last year’s flu vaccine ineffective for older adults
Centers for Disease Control and Prevention have announced that last year’s influenza vaccine was only 42% effective in staving off the illness, lower than the 46% effectiveness average over the last ten years. The vaccine was largely effective for young children, at 60%, and for
adults aged 50–64. But it offered no clear benefit to adults aged 18–49 and those 65 and above. ([St Louis Tribune])

**Legalized marijuana leads to slight uptick in car crashes, claims report**

According to the Highway Loss Data Institute, legalized marijuana in Colorado, Washington and Oregon has led to a slight uptick in insurance collision claims, an increase of 2.7% since marijuana was legalized versus neighboring states. Critics of the study have questioned the validity of comparisons between Colorado, Washington and Oregon with their far more rural neighbors. Insurance industry research has also shown an uptick in claims beginning in 2013 after a long period of decline, which might also be related to the rise of cellphones during driving or declines in infrastructure spending. ([Chicago Tribune])
This week in health and medicine

Aaron van Dorn

Manslaughter charges in Flint Legionnaires outbreak
Five state and local officials have been charged with involuntary manslaughter in a case involving the outbreak of Legionnaires’ disease during the Flint, Michigan water crisis. Those charged by the Michigan attorney general’s office include the current Director of the Michigan Department of Health and Human Services, Nick Lyon and former emergency manager of the City of Flint, Darnell Earley. The attorney general alleges that Lyon cancelled research into the outbreak by Wayne State University over protests, saying that the state “couldn’t save everyone” and that people “have to die of something.” Republican Governor Rick Snyder criticized the charges, and expressed support for Lyon and Dr Eden Wells, a state health department official facing lesser charges. (CNN)

New Jersey putting fish to work
Camden County in New Jersey has found an interesting way to help combat mosquitoes—and more importantly, the diseases they can help spread, like West Nile, encephalitis and Zika. The county Health Department plans to release more than 200,000 small fish such as minnows and killifish into ponds, abandoned pools and other stagnant bodies of water. The small fish will be released all over southern New Jersey, and can eat hundreds of mosquito larva a day. Mosquito-borne diseases have reached into New Jersey, with one person dying from encephalitis this year, and three deaths have been attributed to West Nile virus in the last few years. (Philadelphia Inquirer)

State attorneys general pursue drug company marketing on opioids
Attorneys general from several states have initiated investigations into drug companies that manufacture opioids, looking into the marketing and sales practices of the painkilling drugs. A bipartisan group of states—Ohio, Massachusetts, Texas, Illinois and Pennsylvania—are looking into claims that manufacturers have misrepresented the harms of opioid drugs and spending millions promoting addicting opioid painkillers. (US News & World Report)

Teenagers’ use of tobacco drops to record low
The Centers for Disease Control and Prevention reports that teenagers’ use of tobacco products, including e-cigarettes, has fallen to an all-time low. The rate of use showed a sharp drop over statistics for 2015, with only 11.3% of high school students using e-cigarettes in 2016, versus 16% the previous year. Apparently too distracted by their fidget spinners to vape, this is the first drop in e-cigarette usage the CDC has found since 2011, when it began tracking them. The study also found that only 8% of high school aged students used cigarettes. (Washington Post)

Cleveland Clinic, Oscar open new insurer on Ohio marketplace
Despite continued turmoil in the individual insurance marketplace, the Cleveland Clinic and Oscar Health are creating a new health plan for the Ohio marketplace, even as Anthem pulls out. The troubles are largely attributable to the Trump Administration’s refusal to commit to continued payment of cost-reduction subsidies (CRS) to insurers, and the uncertain prospects of the American Health Care Act. The new health plan would be similar to managed care networks like the Kaiser Health System in California. (CNBC)

Nevada law forces drug companies to justify drug pricing, insulin price hikes
A law signed by Nevada Governor Brian Sandoval (R) requires pharmaceutical companies to disclose how they...
set prices on certain drugs, and requires them to justify any insulin price increases above the rate of inflation. However, industry representatives say the legislation closely resembles similar legislation which has been struck down by federal courts, as it would provide information that would allow pharmaceutical corporations to engage in price fixing. (AP)
Gamechangers—who is playing, who is being played?
Rebecca Cooney

Take the case of abiraterone (Zytiga). In LATITUDE, an elegant phase III trial comparing abiraterone vs. placebo for high-risk metastatic prostate cancer, the investigators reported a 38% reduction in relative risk of death in men who had not received previous treatment for metastatic disease. By all of our conventional standards, this is a remarkable, laudable achievement and findings that are certain to change practice. But according to a report by AHIP, the annual per patient price of Zytiga is $115 152. That is in line with other cancer drugs, many of which cost on average about $8500 a month it the USA.

With many patients requiring multi-year treatment with the drug, the total cost for treatment quickly spirals upward and whether that price is justified is a more contentious proposition. While the data to date indicate that abiraterone is a powerful and effective drug that significantly improves outcomes for some men with prostate cancer, that is not necessarily true of other high-priced drugs that come to market, many of which are approved in the absence of any longer term data and some with very little efficacy data at all.

Consider some of the other exciting gamechanging agents. On the basis of 149 patients from five uncontrolled, single arm clinical trials, the PD-1 inhibitor pembrolizumab (Keytruda), was granted accelerated approval for treating patients with microsatellite instability-high or mismatch repair deficient solid tumors, a designation that has been heralded as an important first and a bellwether for a new set of “tumor agnostic” drugs. Similarly, larotrectinib, a selective tropomyosin receptor kinase (TRK) fusion protein inhibitor, generated substantial buzz at ASCO 2017 because of data from a trio of phase I and II trials showing antitumor activity in 38 of 50 pediatric and adult patients who collectively had 17 different cancer types. Larotrectinib has already been granted orphan drug and breakthrough therapy designation and is likely to follow an accelerated FDA approval path for treatment of TRK fusion-positive solid tumors. But TRK fusions are rare, involving only about 5–3% of cancer cases. Importantly, identifying these patients requires genetic testing that is unlikely to be covered by insurance, another financial consideration beyond the cost of the drug itself. Larotrectinib is a drug to watch as it could serve as a powerful example of the current system in action—demonstrating the rapid market introduction of a drug with potential, although one without long-term efficacy data, that will likely be priced in the $100K or more range.

It is that rather nebulous concept of potential that seems to make a difference when it comes to the price tag. In a recent white paper put out by the life sciences firm Trinity Partners, the authors analyzed the most expensive drugs to be approved during 2014-16 and found some striking results—of the costliest drugs, many addressed patients with rare diseases (91% of those over $100K), and the majority required long-term chronic dosing. 80% of the highest tier drugs (over $200K) were for pediatric conditions, and 70% of the top tier had first-in-class designation. Their analysis found that about half of the drugs priced over $100K per patient per year had received fast-track designation or accelerated approval by the FDA. When considering the question of where value and price meet, observational data such as these reflect the emphasis the US system places on drugs that incorporate disease rarity, novelty, innovation, and perhaps, above all else, potential.

Unfortunately, the interaction of the various factors that contribute to drug pricing continues to be an opaque process and a topic that has been neglected in the larger national conversation on the costs of healthcare. Although there are some indications that this may begin to change, the situation does not inspire much optimism. Just this week, the US Senate Committee on Health, Education, Labor, and Pensions (HELP) held one of three hearings planned for this year to discuss drug pricing. Tuesday’s hearing, “The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay”, which was to serve as a primer on how drug pricing is set and how pricing affects consumers, appears to have done little to inform lawmakers as it quickly devolved into a partisan dispute. Chris Murphy (D-CT) said, “I hope eventually we can sit down and have a conversation on drug pricing that is meaningful and relevant, but this is irrelevant...if 23 million Americans lose access to health insurance, they can’t afford prescription drugs. So it doesn’t really matter what we do.”

Murphy makes a reasonable point, but when it comes to drug pricing, and especially for pricing new, promising drugs, it might not be the right point. Drug pricing is inextricably linked with the health and sustainability of programs such as Medicare and Medicaid. Returning to the case of Zytiga, according to data from 2015, for just under...
17 000 beneficiaries, Medicare spent $790 049 711—nearly a billion dollars—out of an approximately $85 billion gross Part D spending budget. Drug expenditures are not stable. They have risen precipitously in the last decade and will likely continue to, increasing Medicare’s per beneficiary costs, the amount that patients pay out of pocket, as well as the burden on taxpayers. Accepting the status quo and failing to address excessively high drug prices puts the entire system in jeopardy. Although the more general discussion about what needs to be done to rein in the costs of drugs is beginning at what seems an awfully remedial point, an effective move may be to simply start asking—just how much will this cost? It was clear at ASCO 2017 that the question is gaining momentum. From Twitter threads to posters to side conversations all challenging the cost of care and financial toxicity, there was a real sense that these considerations are finally receiving the attention they have long deserved.

If physicians and researchers don’t champion the cause of protecting patients from extreme prices associated with new drugs, when it comes to game-changing regimens, no one wins.
This week in health and medicine

Aaron van Dorn

Senate Republicans edge closer to passing AHCA
The pathway for passage of the American Health Care Act remains narrow, but Senate Republicans are sounding markedly more hopeful for a route to passage than they did last week. GOP Senators in states heavily dependent on the Medicaid expansion and where the Affordable Care Act remains popular are looking to extend the timeline for phaseout of the Medicaid, from four years to seven, and remain concerned about repeal of the ACA's essential health benefits for those with preexisting conditions. There are also concerns that moves to appease more moderate GOP Senators will drive away the ultra-conservatives. However, Senator Bill Cassidy (R-PA) said that chances of the bill passing through the Senate are “better than 50-50.” (New York Times)

Nevada looks at single payer plan
The Nevada legislature passed a plan that would bring single payer healthcare to the state. The measure would open up Medicaid to any resident, regardless of health or income for a fee. The bill is currently with Republican Governor Brian Sandoval, who has not stated whether he plans to sign or veto the measure. Medicaid, the income-based federal and state healthcare plan, is generally cheaper than Medicare, the program aimed at the elderly and disabled. The bill would allow those who don’t have access to health insurance to buy into the government program, and it would allow residents to use ACA tax credits to purchase plans in the new state-run health insurance. (Vox)

Collins to stay on at NIH
Ending months of speculation, the Trump Administration announced this week that they have asked Francis Collins to stay on as the Director of the National Institutes of Health. Collins was Director under former President Obama, and the Trump Administration asked him to stay on in a temporary basis during the transition. (Washington Post)

Fentanyl analog responsible for string of overdoses in Georgia
A new form of the synthetic opioid fentanyl is responsible for over a dozen overdoses and at least four deaths, according to health authorities in Georgia. The overdoses are believed to be linked to a counterfeit version of Percocet. Authorities say that the counterfeit pills contain transdermal substances, and can cause harm from being absorbed by the skin. The Georgia Bureau of Investigation said that since 2015, they’ve discovered nearly 500 counterfeit pills that contain transdermal drugs, including one that resembled the non-transdermal oxycodone that contained fentanyl, furanyl fentanyl, and U-47700, a street drug referred to as “pink.” (Patch)

Rich and poor and health healthcare
According to a new study, the United States has one of the highest levels of inequality in health outcomes, behind only China and Portugal in the study, which looked at 32 countries. The report found that 38% of people in the lowest third of income distribution rated their health “fair or poor,” compared to only 12% in the highest third. The study attributed the gap to the high number of uninsured people and the broader lack of social services. (USA Today)

Puerto Rico declares end to Zika epidemic
The territorial government of Puerto Rico has announced that its Zika epidemic outbreak has ended. The government reported that there have only been around ten cases a month since mid-April, down from nearly 8000 cases a month during the same period last year. Puerto Rico was the part of the United States hardest hit by the Zika virus, with 40 000 confirmed cases to mid-May, though experts warn that that figure is probably low. (Stat News)
This week in health and medicine

Aaron van Dorn

AHCA’s chances in the Senate look shaky

Senator Richard Burr (R-NC) said this week that chances of passing a replacement for the Affordable Care Act this year look slim, calling the American Health Care Act passed by the House GOP last month “not a good plan.” Senate Majority Leader Mitch McConnell (R-KY) has also tried to lower expectations, saying he didn’t see how they could get to fifty votes in the Senate. However, other Republicans are sounding a more hopeful note, such as Senator John Cornyn (R-TX), who said he believes the Senate will vote on an as-yet unwritten measure by “the end of July at the latest” (The Hill).

Insurance company will determine what was an emergency after the fact

Blue Cross Blue Shield of Georgia has announced that it will begin making determinations for what qualifies as an allowable emergency room visit after the fact in July. The insurer says the policy change is to discourage people using emergency rooms as a place to receive treatments for colds or flu or other issues better treated by a general practitioner or at an urgent care clinic. Critics of the change, such as Medical Association of Georgia, say the move might discourage people who are unsure if they need emergency treatment—someone who may be having a heart attack but fears it might just be indigestion—from seeking appropriate medical treatment. (WABE/NPR)

Mylan may have overcharged taxpayers by $1·27 billion for EpiPens, HHS says

The Department of Health and Human Services released a report this week alleging that Mylan, the company that manufactures EpiPens, an anti-anaphylactic shock medication used by those with severe allergies, has overcharged the US government by $1·27 billion over ten years. The report alleges that Mylan miscategorized the brand name product as a generic, and returned Medicaid a 13% rebate, instead of the actual 23% rebate. The report says that Medicaid may have overpaid $444 million between 2006 and 2014, and $826 million between 2015-16. Mylan agreed to a $465 million settlement on similar charges in the fall of 2016, but the status of that agreement is unclear. (Stat News)

Iowa teen’s healthcare costs $1 000 000 a Month

Wellmark Blue Cross & Blue Shield, Iowa’s largest insurer, has cited the case of a teenage boy with hemophilia as emblematic of its decision to leave the individual insurance market in the state next year, a move that could leave tens of thousands of its policy holders without insurance. The boy’s treatments cost more than a million dollars a month, and insurance experts believe that Wellmark’s decision to leave the market might have influenced other insurance companies in their decision to exit as well, for fear of having to give the teen a policy. (USA Today)

Alzheimer’s Death Rate More than Doubles in 15 Years

The death rate among people with Alzheimer’s disease rose by 55% between 1999 and 2014, according to a report from the CDC. Alzheimer’s, a fatal form of dementia, is the sixth leading cause of death in the US, and the fifth leading cause among those 65 and older. During the fifteen year period, the death rate rose from 16.5 to 25.4 per 100 000. The report suggests that the rising rate means that an increasing number of caregivers would benefit from support and case management services. (CDC)
Keeping chickens in your backyard also has downsides
The CDC has announced that there have been 372 cases of salmonella infection across 47 states so far in 2017, with over 70 cases requiring hospitalization. They fault the popular trend of keeping chickens in the backyard. Salmonella can exist on the skin of healthy chickens, where they contract it from their feces. The CDC recommends not allowing chickens on patios or in your home, and to not kiss chickens. (WCVB)
Telepsychiatry: making treatment available to Americans in under-served locations

Ray Cavanaugh

Many people in rural areas either live prohibitively far away from a population center or cannot afford the transportation to one. So a serious, potentially fatal treatment gap persists. Suicide rates are rising on a national level, but particularly so in rural areas. For 2015, the rural suicide rate was about 40 percent higher than the nationwide rate. Rural communities often have a “lethal triad” consisting of gun prevalence, high rates of substance abuse, and a lack of access to emergency facilities in general and mental health ones in particular.

While some (generally those unacquainted with telemedicine) may find it impersonal, telepsychiatry can help mitigate the shortcoming of mental health treatment in the US, especially in rural communities, where residents might live hundreds of miles from someone who could provide them with appropriate services. Fortunately, there has been a rise in the utilization of telepsychiatry in rural areas.

Communications technology has come a long way since 1994, when the AMA issued an opinion against doctors delivering services through telecommunications. In 2017, “Numerous studies already exist demonstrating the efficacy of telepsychiatry in a myriad of settings,” says Robert L. Caudill, MD.

Caudill—an Associate Professor of Psychiatry at the University of Louisville, where he also serves as Director of Telemedicine and Information Technology Programs—has seen telepsychiatry become an increasing part of medical schools, as well as rotations and residencies. He senses that “the acceptance of telepsychiatry by practitioners is somewhat generational with younger doctors more open to rapidly embracing it.

For current and prospective providers, one crucial issue is how to ensure security and Health Insurance Portability and Accountability Act of 1996 (HIPAA), which set out national standards for electronic healthcare transactions and records. Skype, the prevalent free video-calling platform, is risky—Skype is not HIPAA-compliant, and one can assume the same of its competitors. Clinicians can best adhere to HIPAA standards by dealing with a reputable partner—one that has “a presence within major telemedicine organizations such as the ATA [American Telemedicine Association],” advises Caudill.

Providers also should know that even with telepsychiatry, the clinician must be licensed in the state where the patient is located. Though such rules place some degree of restriction, Caudill believes telepsychiatry will greatly improve the mental health landscape of rural areas, which “have been often marginally served by locum tenens and other temporary solutions of varying quality when they [have] been served at all.” The available technology “offers the opportunity to break this paradigm and offer high-quality care even to those who are most geographically isolated. Funding for services remains a challenge but geographical isolation need no longer be the barrier it once was.”

Even in non-rural areas, Caudill expects telepsychiatry will be “pretty close to the norm within 20 years,” though “there may be certain patients who prefer an in-person visit either initially or at some point along the way.”

Telepsychiatry is also gaining acceptance in emergency settings. And though some may think that suicidality and homicidality would be more difficult to evaluate remotely, Caudill contends that, “Skilled clinicians are skilled clinicians. A psychiatrist familiar with the patient group most often seen in emergency department settings would rapidly make the adjustment to a telepsychiatry based interaction.”

In certain cases, telepsychiatry might prove more conducive than a face-to-face session. As Caudill points out, “Adolescents often relate better to video images than in-person adults.” Additionally, “Patients dealing with certain types of trauma may feel more secure in a room where they are not in close proximity with other people. While the literature is not mature in this area, best practices may one day suggest use of video-teleconferencing over in-person exams in some settings.”

In his view, an added benefit of telepsychiatry is its inherent physical remoteness. He explains how “the mental health professional is by definition coming in from a great distance and unlikely to be part of the social fabric of the community.” Because of this geographic separation, “patients do not have concerns of disclosing painful private histories to someone they may have to interact with locally in a different setting such as church or school.”

The benefits can also extend to the clinicians, as telepsychiatry provides practitioners such as Caudill, “who grew up in a more urban setting to enjoy the professional rewards that come from practicing with a rural-based patient population while not physically relocating—thus having it both ways.”
In 2011, when concerns about prescription analgesic overdoses were starting to accelerate, Whisman picked up a paperback mystery in an airport bookstore. At that time, Kentucky’s legislature was considering a bill which would impose new limits on prescribing opioids—such as requiring doctors to do a complete medical history and physical exam before writing an opioid prescription.

As she recalls in the airport novel, a drug addict meets his dealer in a parking lot where the dealer extolls his product: it’s morphine. The good stuff. Straight out of hospice. “When I read that, I was shocked at my own naivety about how these issues were coming to be viewed in the larger culture,” Whisman says. “It made me realize that we in hospice needed to pay more attention to what’s happening in society and make sure we’re part of the dialogue—because we put a lot of these drugs out into the world. We are probably one of the groups with the highest rates for prescribing controlled substances, because our patients experience a lot of pain. We can’t ignore the social problems of drug abuse and diversion. We have to open our eyes and consider all of the issues involved.”

**An agency-wide examination of opioids**

The first part of this article described how other hospices have addressed the challenges of prescribing opioids in the midst of an epidemic of prescription drug abuse. Bluegrass Care Navigators serves many areas, including the poor, rural Appalachian counties of eastern Kentucky that have been stereotyped in the media for street diversion and abuse of Oxycontin, an extended release synthetic opioid tablet often dubbed “hillbilly heroin.”

Bluegrass Care Navigators decided to conduct a thorough, quality-focused, agency-wide examination of its practices regarding opioid prescribing, dispensing and use. “Multiple issues had converged for us, including a general sense that if society was paying more attention to these issues, then our staff was, too. We said: let’s not assume that we’re doing anything wrong—but let’s also not assume that we’re doing everything right,” she relates. “We considered ourselves to be a leader in the hospice industry and we wanted to find out if we could improve our awareness and our processes. We decided that we are all accountable for providing socially responsible care of dying patients.”

An interdisciplinary committee was convened to look at all aspects of abuse, addiction and diversion in society and in the hospice’s caseload, leading to a robust set of policies on safe prescribing. A survey of staff found that 90 percent were thinking about these issues and two-thirds said abuse and diversion could be serious problems among their own caseload—even though the patients were all terminally ill. “We divided into three core work groups—clinical, regulatory and educational, and looked hard at all of those issues,” Whisman says. An intensive, video-enhanced four-hour course on safe prescribing was presented to all hospice staff.

A guiding principle in rewriting the agency’s policies and procedures was “universal precautions,” a term used in infectious disease medicine to convey that professionals should not make assumptions about who is infected based on stereotypes but instead treat all patients the same—as if any of them could be infected.

“I didn’t want our hospice to be the opioid police or to change our open-hearted approach to our patients or be suspicious of them,” Whisman says. “How could we help our staff take this journey with patients and families? We wanted to support them and help them find a way to stand alongside their patients, regardless of who may be struggling with addiction issues.”

The agency worked on adapting its electronic health record to the demands of safe prescribing, and on safely disposing of drugs after a patient dies. Each new hospice patient is now assessed for risk and given informed consent to the agency’s agreement for the dispensing of controlled substances. That agreement must be signed by the patient before controlled substances can be dispensed. On every staff visit to the home, pills are counted in the presence of the patient and family, which conveys how seriously staff takes these issues. Prescriptions generally are limited to a two-week supply or less.

The hospice can provide a lockbox to store the drugs and give the key to the patient if the home appears unsafe or there is fear that drugs may be stolen. “It may be necessary to move the patient to a different setting if they can’t be safely cared for at home. We also have a substance abuse and diversion plan of care that gets activated should we become aware that something is wrong,” she explains. “We emphasize to our teams that pain is not just physical and that psycho-social and spiritual issues can impact how it is experienced by the patient.”

People choose to work in hospice because it can be very fulfilling, Whisman notes. “How can you still feel fulfilled...
accompanying patients on this journey? How can we be part of the solution—better stewards of careful prescribing?” And what can hospice do about the challenge of a dying patient who has horrible pain and needs pain medications, but is an active addict? “We don’t shy away from that challenge, but we try to handle it in the safest way possible. We have to take it case by case, depending on how close the patient is to death and how much pain they have. We see if there are ways to address the pain without opioids.”

Three years after roll-out of the agency-wide safe prescribing initiative, many questions are being revisited. Bluegrass is now repeating its educational program and looking at what other data points should be collected in order to assess how it’s performing, Whisman says. “We never came to conclude that we were wrongly or loosely or overly prescribing opioids. But we realized we could all be more aware of the issues and our own practice—and have accountability for that. The general answer is yes, we’re doing a good job. But we can always get better.”
This week in health and medicine

Aaron van Dorn

State AG seek to join ACA lawsuit
Fourteen state attorneys general from Democratic states are seeking to join a lawsuit brought by House Republicans over insurance subsidies provided by the Affordable Care Act. Originally brought under the Obama Administration, an initial ruling argued that the ACA did not explicitly authorize the government to provide cost-sharing subsidies to insurers. When the Trump Administration came in, it and the House GOP requested the lawsuit go on hold. While the Trump Administration has continued to make the cost-sharing reductions, it has conspicuously refused to state that it will continue to do so. The state AGs argue that the instability that the Trump Administration has artificially created is driving up insurance costs for the state and endangering the ACA marketplaces needlessly. (ABC)

Trump Administration allegedly attempts to extort insurers for AHCA support
Seema Verma, the head of the Centers for Medicare and Medicaid Services, is reported to have offered insurance industry officials an offer: if they agreed to publically support the Republican ACA-repeal effort, the American Health Care Act, then the Trump Administration would agree to fund cost-sharing reductions, payments scheduled under the ACA to reimburse insurers for policies sold on the ACA-established healthcare marketplace. Insurers expect premiums on the marketplace to rise sharply next year due to policy uncertainty created by the Trump Administration’s unclear approach to healthcare. (New York Magazine)

Controversy over pelvic exams
Two doctors groups stand opposed on the issue of pelvic exams, used to examine the health of a woman’s reproductive organs, offers no known benefit, and can lead to false-positives and unnecessary surgery. The American College of Obstetricians and Gynecologists recommend yearly pelvic examinations, while the American College of Physicians recommends the test only for pregnant women and those exhibiting signs of illness or disease. A study published this week found that when informed of the limited utility of the test, around 60% of women decide to forego the test. Both groups agree, however, that all women from 21 to 65 should undergo periodic Pap smear tests. (NPR)

Oregon eyes raising tobacco age limit
The Oregon State Senate is looking at a new measure aimed at raising the legal age to purchase tobacco products in Oregon, from 18 to 21. According to supporters of the bill, the measure is aimed at pushing back readiness availability of tobacco into full adulthood, as 90% of smokers begin smoking prior to the age of 18. Around 12% of Oregonians currently smoke tobacco, which has held steady for the last five years after steep declines. Other tobacco measures under consideration include raising the taxes on cigarettes and applying a tax to e-cigarettes, and an effort to require those who sell tobacco products to register with the state. (Statesman Journal)

Tick Season is Here
The weather is warming up and people are engaging in more outdoor activities, but people should make sure to protect themselves from ticks before heading out into the woods. Thanks to a combination of reforestation efforts and climate change, the CDC is warning that they expect this summer to be a bad one for ticks and tick-borne infections. Reforestation has created larger habitats for deer and rodents, which carry ticks, and warmer temperatures and shorter winters has meant the range for ticks has increased.
The CDC recommends using an insect repellant containing DEET on your skin, and treating clothing and boots with products containing permethrin. *(Time)*

**California botulism outbreak traced to nacho cheese**

Nine people have been sickened after consuming nacho cheese sauce from a family owned gas station. The Valley Oak Food and Fuel in Walnut Grove, CA, is still open for business, but is no longer selling food. Investigators have not yet determined if the nacho cheese sauce was mishandled by the gas station, causing it to become infected with bacteria that produce the toxin that causes botulism, or if responsibility lies with the distributors or manufacturers. In the meantime, go for the chili. *(CBS)*
Hospice and opioids: finding a safe balance

Larry Beresford

America’s hospices, which collectively care for 1·6 million terminally ill patients per year, have been advocates for pain management, working to overcome its documented under-treatment (see the Institute of Medicine’s 2011 report, Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research).

Hospice clinicians believe that there is no absolute maximum dose of opioids for relieving intractable pain, and that patients themselves are the most reliable source for information about how much pain they are actually experiencing. Dame Cicely Saunders, who founded St Christopher’s, the first modern hospice facility, in England in 1967, was said to personally greet newly admitted patients and promise them that the hospice team would work tirelessly to control their pain.

But the Centers for Disease Control and Prevention (CDC) has documented a quadrupling of overdose deaths from opioid prescriptions since 2000. Some of those deaths occur when taking pain medications as prescribed, while others result from the non-medical use of the powerful drugs or their diversion to the street by patients or someone else in their household.

The dangers of opioids are a problem that affects all health care providers, says Keith Lagnese, MD, chief medical officer of Family Hospice and Palliative Care, Pittsburgh, PA, a long-established non-profit affiliated with the University of Pittsburgh Medical Center health system. “We’re trying to balance meeting our patients’ needs in efficient, clinically appropriate ways with preventing diversion or misuse of these drugs—and there has to be a balance,” he says.

“As a health care industry and as a medical subspecialty, we’re still quite young, and we need more research into palliative care. It behooves us to give more thought to how to treat our patients’ pain by non-pharmacological or non-narcotic means,” Lagnese says. Alternatives worth more study include a variety of non-opioid analgesics and combinations of drugs, acupuncture, body work, mindfulness meditation, complementary therapies and medical marijuana.

“In the face of this opioid epidemic and backlash, we in hospice might be seen as the last bastion of freer prescription writing to relieve our patients’ suffering,” he says. “But I’m seeing more narcotic contracts or agreements between hospice physicians and patients.” Such a contract might specify, for example, that only one doctor can write opioid prescriptions for the patient and only one pharmacy can fill them.

Pennsylvania is one of many states with statewide prescription drug monitoring programs, electronic databases listing all opioid prescriptions written recently for a given patient. Hospices in Pennsylvania are licensed health facilities and thus required to run a database query on patients when they come into hospice programs, Lagnese says. “While this poses administrative burdens on hospice physicians, I think it’s a good thing. But what if we have patients coming into our inpatient hospice who die within days or hours of admission? Should I be taking care of their suffering first, or querying the database?”

In March of last year, CDC issued a Guideline for Prescribing Opioids for Chronic Pain, which recommends against opioids for many forms of chronic pain that lacked rigorous scientific evidence demonstrating long-term efficacy. CDC, along with a number of other stakeholders, wants providers to better assess patient risk and address the harms of opioid use. But for patients who are terminally ill with limited life expectancy, limits on opioids might seem terribly cruel.

When new regulations are proposed to limit opioid prescribing, exceptions are often made for patients who have
cancer or a terminal illness, or are enrolled in a hospice or palliative care program. But is that just a way to avoid the difficult national conversation about reconciling the needs of patients who have the greatest pain and suffering with the dangerous side effects of opioids—for both patients and society?

**Frequent Assessments of Response to Therapy**

Charles Mills, MD, Medical Director for Hospice and Palliative Care in the Elliot Health System in Manchester, NH, says he doesn’t think his own pain prescribing practices have changed in response to the opioid crisis. “But I’ve always been more aware of the issues. Palliative care providers generally are better informed about how to use these drugs,” he says, and they make frequent assessments of how their patients respond to therapy. “But hospices are taking notice of these issues, absolutely.”

Pain can be under-treated as easily as over-treated, and untreated pain can lead to depression or even suicide, notes Lilly Chen, MD, a hospice physician with Kaiser Permanente in Martinez, CA. She chairs the Substance Abuse and Diversion Special Interest Group of the American Academy of Hospice and Palliative Medicine (AAHPM), the medical society representing doctors working in hospice and palliative care—which is also trying to address these dilemmas at the national level.

In general, society is more accepting of heavy-duty narcotic doses for patients who are dying. “But what if the patient has a substance abuse disorder and debilitating terminal cancer?” Chen poses. “In hospice care, we aim to treat the patient and family together as the unit of care, and that’s where problems can come up.”

The patient has a life-limiting illness with pain and symptoms that need to be well controlled—or else the family will carry with them horrific memories of how their loved one died. Yet it’s not uncommon for a family member to take advantage of the situation and steal Grandma’s pain pills. “We usually screen for a history of substance abuse in the patient and family—but it can be a large extended family, with lots of other people coming into the home,” Chen says. “The diversion of these drugs becomes especially problematic when the patient runs out of a needed pain prescription. We’re not in the home all of the time, but sometimes we need to set limits.”

Chen’s hospice has considered in certain circumstances using urine drug screening tests, which can tell if a patient is taking other drugs than what the doctor prescribed—but also if they’re not taking the drugs that were prescribed, suggesting the possibility of diversion to the street. “A lot of the work of hospice care is about establishing trust with the patient and family in the challenging circumstances of the end of life,” she says.

“We have restricted medications for some patients to very limited quantities at one time—which means frequent deliveries—or else counted the pills on every visit. Or we try to find alternative treatments. We also have a wonderful chaplain who can pick up on issues of spiritual pain that might be closely entwined with the physical pain.”

Todd Cote, MD, Chief Medical Officer of Bluegrass Care Navigators, a large hospice and palliative care agency in Lexington, KY, says his medical specialty is working to develop national guidelines on opioid prescribing. “Most of us feel that if we don’t, the feds and the states will mandate what we need to do. It’s a complex issue. Our agency has tried to tackle it agency-wide.”

In Part Two of this series, learn how Bluegrass Care Navigators organized and undertook an agency-wide quality improvement initiative to make sure that its prescribing practices were as safe as they could be.
This week in health and medicine

Aaron van Dorn

Aetna plans exit of ACA marketplace
Health insurer Aetna has announced that next year it plans to exit the federal health care marketplace from the last two states that it was selling plans in, Nebraska and Delaware. Currently, every state-based exchange has at least one insurer in the marketplace, with more urban and densely populated areas having more. The Trump Administration has continued to make cost sharing subsidies to insurers on the marketplaces, but has conspicuously refused to affirm that those payments will continue. As turmoil regarding federal healthcare laws continues, insurers are becoming wary of the marketplaces, and some states may end up with no insurance options on the exchanges. (Toledo Blade)

Price questions use of opioid substitution
Health and Human Services Secretary Tom Price questioned the use of opioid substitution treatments, saying they only substituted “one opioid for another.” Price was on a listening tour regarding the current opioid epidemic in West Virginia when he made the comments. Price’s comments, however, contravened current HHS policy regarding medication-assisted treatments using medications like buprenorphine and methadone as a substitute for other opioids. Public health advocates, including a series of tweets from former Surgeon General Vivek Murthy, fired by President Trump earlier this year, see the substitution treatments, which lower the chance of overdose death, as a better option than abstinence-based treatments. (Mother Jones)

Breach at nuclear waste storage facility raises health concerns
A recent collapse of a tunnel containing radioactive material left over from the World War II Manhattan Project in Washington State has brought a new focus on health concerns in the local community. The Hanford Nuclear Reservation in Washington State is half the size of Rhode Island and contains 56 million gallons of radioactive waste from the creation of the atomic bomb that was dropped by the United States on Nagasaki, Japan on August 9, 1945. During an inspection this week, a twenty-foot hole was found in a tunnel leading to a storage area with 28 rail cars filled with contaminated materials. Officials said that there was no evidence of radiation being released from the facility, but locals have been concerned about the risk of thyroid cancer in the area for decades. However, repeated studies have yet to find evidence of elevated levels of thyroid cancer in the area. (ABC News)

Conservative senators want insurance requirements relaxed in ACA replacement
After the House passed the AHCA, the initiative moved to the Senate, where conservative Senators are working to undermine minimum insurance coverage guarantees put in place by the Obama Administration in the ACA. However, they’re facing push back from more moderate Republican Senators, as the coverage guarantees are among the laws most popular aspects. Other things the conservative Senators would like to see rolled back are bans on pre-existing condition restrictions and cuts to the growth of Medicaid programs aimed at the poor and disabled. (Associated Press)

New Jersey Republican faces tough critics at town hall
Republican Tom MacArthur, a New Jersey Congressman and co-author of an amendment to the GOP’s AHCA is largely credited with saving the bill by getting the hardcore conservative House Freedom Caucus onboard after weeks of resistance, faced a tough crowd at a town hall in his district this week. MacArthur spent five hours answering questions, often hostile, from constituents on subjects from his support of President Trump and the recent firing of FBI Director James Comey to calls for single payer healthcare. But most questions focused on his support for Republican efforts to
dismantle the Affordable Care Act, which he faced during an often hostile five hour period. (*Washington Post*)

**Hep C infections triple over five years**
A new CDC report has found that hepatitis C infections have tripled from 2010 to 2015, from less than 900 cases to nearly 2,500. The highest rates were among young people in their twenties who inject drugs. The areas with the largest increase were Appalachia, and the rural Midwest and New England, areas hardest hit by the opioid drug crisis. However, the majority of the 3.5 million people with hepatitis C infections in the US remain baby boomers. (*CNN*)
This week in health and medicine
Aaron van Dorn

House passes AHCA on party line vote
After several months of intraparty wrangling and several false starts, Republicans were able to pass the American Health Care Act on a party line vote yesterday. Previous attempts to pass the bill were stymied by the House Freedom Caucus, a group of hardline conservative Republicans who objected to the bill, saying that it did not do enough to repeal the Affordable Care Act. New Jersey’s Tom MacArthur seemed to be able to bridge the gap when he proposed an amendment that would allow states to opt out of pre-existing condition coverage. The bill now heads to the Senate, where it is unclear how the Republican caucus there will deal with repeal efforts. The bill itself was not scored by the nonpartisan Congressional Budget Office prior to the vote on it, and has proven extremely unpopular with the public, polling in the teens since March. The CBO score of the bill is expected next week. (New York Times)

Doctors, hospitals, insurers against AHCA
While the GOP was celebrating passing the AHCA through one chamber of Congress, a wide range of doctors’ groups, hospitals and insurers were coming out against the bill that would slash Medicaid funding and is expected to increase the number of uninsured Americans by numbers similar to an earlier iteration of the bill, which the CBO said would increase the uninsured by 24 million people by 2026. Unlike the other groups, which came out against the bill early, insurers largely remained on the sidelines until right before the bill passed. (New York Times)

Research on prostate cancer diagnostic tools
Prostate cancers can be so slow growing that they are relatively harmless, and the consequences of treating them can be worse than the cancers themselves. There is currently no way to differentiate between that type of prostate cancer and a more deadly kind, so patients may undergo invasive, often unnecessary tests and treatments that can leave them incontinent and impotent. But researchers continue to investigate new group of tests, from genetic to imaging, that will improve diagnostic outcomes. (Stat News)

NIH institutes grant point system
In an effort to open up funding opportunities to a broader range of scientists and research institutions, the NIH has announced that it will institute a point system for grants, restricting the number of grants that any one individual can hold without approval. According to the NIH, this will affect only 6% of investigators it currently funds. (Nature)

Minnesota Somali community faces measles outbreak
Minnesota’s tight knit Somali immigrant community has been at the center of Minnesota’s worst measles outbreak in decades, with over forty cases in 2017. The Somali community has been the target of anti-vaccine activist groups like the Vaccine Safety Council of Minnesota in recent years, conducting numerous meetings and distributing anti-vaccine literature in the community. MMR vaccination rates have plummeted in the Minnesotan Somali community in recent years, from 92% in 2004 to only 42% in 2014. (Washington Post)

Half of countries receiving US aid allow for legal abortion
According to a Kaiser Family Foundation Policy Brief, the Mexico City Policy recently reimplemented and expanded by the incoming Trump Administration would have wide ranging impacts on countries currently receiving US foreign aid. The Mexico City Policy would prevent NGOs from discussing or counselling about abortion services, even with funds from other countries, as a condition of receiving US funds, including in countries where abortion services are legal. Restrictions on funding would go beyond programs that provide family planning services, and would include programs like PEPFAR, which helps in combatting HIV/AIDS, water and sanitation efforts, and programs to fight non-transmittable diseases. (Kaiser Family Foundation)
Hospice houses for the homeless fill a growing need in an aging society

Larry Beresford

Welcome Home is dedicated to the principle that no one should be alone at the end of life, offering custodial care for people who otherwise could find it very difficult to achieve a peaceful death. Even though death with dignity may seem a foreign concept when talking about homelessness, as they age, homeless people experience many of the same illnesses as everyone else, including cancer, heart and lung diseases—but they have significantly shorter life expectancies, and their circumstances may accelerate an illness’s progression.

“We are a home for people who are admitted to a hospice program and we collaborate with the hospice team. We cover the basic needs, starting with food and shelter, and then love and non-judgmental presence. We help residents tell their stories, and reconcile with their families—or we become their families,” Campbell explains.

A cadre of volunteers helps keep the home running, assisting with laundry and cleaning. They might take a resident to a thrift shop or bank, or on a fishing trip. There is a dinner club where people in the community bring a home-cooked meal once or twice a month. “Or they make it here, or they bring a pizza, and then they join us for the dinner,” Campbell says. Costs averaging $200 a day per resident are covered by donations and grants, but Welcome Home is not covered by insurance or government funding.

A handful of other hospice houses for the homeless have sprung up around the country, but they are just scratching the surface of need, Campbell says. “We have a silver tsunami headed our way. It’s a crisis in America, and it’s not just about the stereotypically homeless, but for any of us who won’t be able to pay for nursing home care or for someone to come into our homes and care for us.”

Since its introduction in 1974, hospice care in America has been delivered in patients’ own homes, whenever possible, with family members serving as caregivers. Hospice units or facilities or residences are less widely available; and for many at the end of life the alternative is a nursing home bed, often in collaboration with a hospice. But how does a hospice team provide coordinated, professional end-of-life care to a terminally ill patient whose primary residence is a tent under the freeway?

Homelessness is a complex phenomenon. On a single night in January 2015, 564,708 people were counted experiencing homelessness, according to The State of Homelessness in America: 2016 by the National Alliance to End Homelessness. Many of them were living on the street, in an emergency shelter or in transitional housing.

The Department of Housing and Urban Development’s definition of homeless includes anyone living in a place not meant for human habitation, but also those at imminent risk of losing their primary nighttime residence, or who are fleeing domestic violence. Others are “couch surfing” or doubling up with family and friends. And plenty more are one paycheck—or one medical crisis—away from losing their homes.

The Social Model of Hospice

Hospice houses like Welcome Home or The INN Between, located in a former school in Salt Lake City, Utah, follow the social model of hospice homes, which primarily provide a roof, bed and meals, and a team of staff and volunteers to manage the resident’s personal needs. When more comprehensive clinical care is needed, a licensed, Medicare-certified hospice team—physician, nurse, social worker, chaplain, home health aide—can come into the facility as if it were the patient’s own home.

Other examples include Abbie Hunt Bryce Home in Indianapolis, Indiana, opened in 2004 to address the needs of the dying poor, and The Alpha Project in San Diego, California, which takes an alternate approach of trying to get homeless people with life-threatening illnesses into their own rented studio apartments. Joseph’s House in Washington, DC, has a special focus on people with HIV/AIDS.

Thirteen-bed INN Between, which opened in 2015, offers socialization, art classes and “a big garden out back,” as well as case management to help residents apply for all of the
benefits to which they are entitled, says its director, Kim Correa. But it can get complicated.

These homes face zoning barriers, NIMBY (Not In My Back Yard) attitudes from neighbors, and financial pressures. And the homeless population can be a challenge. Because they are preyed upon out on the streets, they don’t have much trust in people, Correa says. “Most of our residents have been homeless for more than a year. When they come here, they go through a transition period where they feel the rug could be pulled away any minute. Eventually we get them settled in and it’s like a switch is turned on: ‘Oh, this is what a home feels like,’” she relates.

House rules emphasize kindness, respect and the need to stay on the right side of the law—with no illegal drug use. “We can’t make an addict quit overnight, but we try to get people enrolled in methadone clinics or involved in AA/NA meetings.” A significant portion of the homeless population is struggling with mental health and substance abuse issues, which may preclude becoming functional members of society again, Correa notes. “Yet society expects them to pull themselves up by their bootstraps. For some, that will never happen, and we as a society are still obliged to take care of them, one way or another.”

“We also deal with individuals who have developed some interesting coping skills on the street—not to say they’re manipulative,” Campbell says. “We’re taking care of people who’ve learned to put up their personal walls just in order to survive.” But most, regardless of whether they have a home or not, need certain things in order to have a peaceful death, “things we have to take care of at the end of our lives.” She cites the work of palliative care expert Ira Byock, who has described such things for dying patients in his book, The Four Things That Matter Most: They include the need for forgiveness and love and an opportunity to express gratitude and say goodbye.

“Despair and loneliness can kill you—or hasten your death,” Campbell observes. “Our residents need to know that they are loved and cared for by people who will remember them. Our volunteers are learning about death and dying, and our residents are our teachers. They teach us about courage at the end of life—like reaching out to someone you fought with 20 years ago to now ask for their forgiveness and love.”
This week in health and medicine

Aaron van Dorn

Drugged drivers killed more than drunk drivers
An updated study from the Governors Highway Safety Association found that, for the first time, drivers with drugs—both prescription and illegal—that impaired their driving were responsible for more automotive deaths (43%) than those who had consumed alcohol (37%). Using data from the National Highway Traffic Safety Administration, the report found that marijuana was the most common drug, but cited the use of multiple drugs as an especial danger: marijuana alone only slightly increases the risk of driving, while benzodiazepines and opioids increase it moderately. However, drugs combined with alcohol brought an extremely increased risk. (CBS)

CDC yellow fever vaccine supply likely to run out this summer
The CDC reports that it’s likely to run out of its current supply of yellow fever vaccine, following manufacturing constraints and a large increase in demand globally. In 2001, only around 5 million doses were required annually, but that number has since risen to 34 million. The CDC plans to import stamaril, a yellow fever vaccine approved in over 70 countries by not the US, through an “expanded access” program. But due to restrictions, that will reduce the number of facilities that can give the vaccination from 4000 to 250, so if you require a yellow fever vaccination for this summer, schedule it early. (Washington Post)

Pre-hospice programs keep people out of hospitals
A rising care system for people nearing the end of their lives allows people to stay out of the hospital, even if they are outside of hospice care’s standard six month or less to live time frame. 10 000 baby boomers turn sixty-five every day, and many of them will have chronic conditions that could be treated in a hospital. Pre-hospice programs aim to keep people out of hospitals, but to provide at home care normally associated with hospices. New rules in the Affordable Care Act have made these kinds of pre-hospice palliative care programs affordable for health care providers. (NPR)

Partners and Brigham and Women’s Hospital settle over research fraud
The US attorney in Boston announced this week that Partners HealthCare System and Brigham and Women’s Hospital in Boston have agreed to a settlement of $10 million in a case involving accused fraud and scientific misconduct at a lab run by Piero Anversa. The lab researched stem cells and the heart, and accepted tens of millions of dollars in NIH funding before being closed in 2015 by Brigham and Women’s Hospital. (Boston Globe)

Type 2 diabetes may be tied to brain deterioration
Researchers looking at overweight patients with type 2 diabetes found significant deteriorations in areas of the brain that control memory and planning versus healthy control subjects, or those with diabetes of normal weight. Researchers suggest that the combination of diabetes with being overweight have a greater effect on the brain than either independently. (New York Times)

Energy Drinks May Not Be Great For You
All appearances to the contrary, a new study finds that commercial energy drinks that contain more than 320 mg of caffeine may be bad for your heart, even compared to a control drink that contained the same amount of caffeine along with lime juice, cherry syrup and carbonated water. Trial participants were given the drinks for six days, and found that those who drank the commercial energy drink had an increase in the QT interval, a measure of how long it takes the heart’s ventricles to beat again. An increase in the QT interval is linked with heart arrhythmias. Those who drank the energy drinks also saw spikes in blood pressure that lasted more than six hours. (Atlanta Journal-Constitution)
This week in health and medicine

Aaron van Dorn

Memory improvement from “pacemaker”-style brain implant
Scientists have demonstrated improvement in memory in some people with the use of a pacemaker-like device implanted in the brain in epilepsy patients. The implant delivers electric pulses in very carefully timed bursts that can move the memory system from periods of low activity to a higher functioning level. Previous studies have demonstrated mixed results with similar techniques, but the researchers hope that they can build on this system with patients who suffer from traumatic brain injury, dementia and Alzheimer’s. (New York Times)

FDA issues warning on use of codeine cough syrup in children
The FDA has issued its strongest warning against the use of codeine and tramadol-containing medicines for children this week. Codeine is frequently used in cough syrups to prevent pain and suppress cough, and tramadol, while not approved for pediatric use, is frequently used off label for children. Products with the drugs will now carry warning labels, although this will not apply to over-the-counter preparations that contain codeine. The move follows a 2015 safety evaluation, and a recommendation that children not be given medicines containing codeine from the American Academy of Pediatrics. (Stat News)

AHCA negotiations continue, according to White House
Following pressure from the Trump Administration, anxious to have an accomplishment on healthcare prior to the end of its first one hundred days, House Republicans are reportedly continuing to negotiate on a version of the AHCA that can clear 216 votes. It’s unclear what is being debated, although a repeal of pre-existing conditions ban appears to be in the mix. What is clear that at the moment a bill does not exist, or if a new bill that could win the support of the House Freedom Caucus could clear the 216 vote threshold, let alone pass the Senate. (Politico)

Cherokee Nation sues retailers over opioids
The Cherokee Nation is suing several major national pharmaceutical retailers, including Wal Mart and major drug store chains like CVS and Walgreen’s, alleging that they haven’t done enough to prevent the flow of opioids from illegal prescriptions on tribal lands. The tribe maintains that the companies have not done enough to ensure that illegal prescriptions are not filled. (CBS News)

Hawaii LGBT fertility bill receives pushback from healthcare lobby
A bill under consideration by the State of Hawaii would require health insurers in the state to cover fertility treatments for married LBGT couples. Under current Hawaiian law, insurers are required to cover one round of fertility treatment for married opposite sex couples. The new bill would require insurers to extend that coverage to all married citizens. Insurers contend that the requirement would open them to covering fertility treatments for surrogate mothers, and would move into some murky legal territory. (Hawaii News Now)

March for Science
This weekend will see an organized March for Science, centered on Washington, DC, but embracing satellite marches in cities around the country and the globe. Organized in response to the election of President Donald Trump, the organizers also point to proposed, unprecedented levels of spending cuts for programs ranging from the EPA to the NIH. Organizers intend the event to raise the importance of funding basic scientific research, and the put the need for scientific literacy and public engagement at the forefront of conversations about national priorities. (CNN)
This week in health and medicine

Aaron van Dorn

Trump signs bill allowing states to defund planned parenthood
President Trump signed a bill in a closed-door session on Thursday that would allow states to preventing federal funding from being given to Planned Parenthood, as well as other groups that perform abortions. The new legislation reverses a rule put in place in the last days of the Obama Administration. Federal law already prevents federal funds from being used to provide abortions, so the new rule prevents Planned Parenthood from providing broad range of other services, such as cancer screenings, contraception and sexually transmitted infection screening. (New York Times)

Trump threatens ACA cost sharing reduction
After President Trump threatened to stop the Cost Sharing Reduction, or CSR, to insurers as a way to force Democrats to bargain on repealing the Affordable Care Act, Democrats are demanding that CSR be fully funded as permanent, mandatory spending in any omnibus bill that’s passed. Current government funding runs out on April 28. CSR are part of the ACA that reduces the cost of deductibles and other out of pocket expenses for those using insurance. The government reimburses insurers for the cost, and if funding for CSR were withdrawn, many insurers would likely leave the marketplace. (Bloomberg)

New York City trans fat ban sees results
According to a new study, a 2007 ban on the use of trans fats in restaurants has seen a reduction in heart attacks and strokes when compared to areas that did not implement the ban. Hospital admissions in New York saw a 6% drop in heart attacks and strokes beginning three years after the ban, or a drop of 43 heart attacks and strokes out of 100,000 people a year. The FDA announced in 2015 that the food had until 2018 to cut out trans fats from products in the US. (CBS News)

Missouri Senate passes prescription drug monitoring bill
The State Senate of Missouri has passed a prescription drug monitoring bill aimed at preventing patients from approaching multiple doctors or pharmacies to obtain opioids, the only state in the US that lacked one. The bill would give doctors and pharmacists access to a database of patient data that would inform them of existing prescriptions a patient may have. The bill was passed over the objections of some members, who had privacy concerns. As a result, the final bill specifies that data collected will be purged after 180 days. (Columbia Daily Tribune)

New technique can detect previously undetectable virus levels
A new method of detecting the presence of viruses is able to do so at levels previously undetectable. The new technique called SHERLOCK, a derivation of CRISPR gene editing system, is able to detect viruses and cancer cells at a sensitivity a thousand times greater than previous techniques. Developed by the Broad Institute at MIT, the system is also much cheaper and faster. The new system has not yet been approved by the FDA, however. (Science)

Schools consider letting students use sunscreen
Washington State is considering letting students use sunscreen while they’re at school. Currently, the FDA lists sunscreen as a drug, so it’s prohibited from being brought into k-12 schools without a note from a doctor. Only four states have explicit rules allowing students to use sunscreen, but six states in addition to Washington are considering adopting the policy. (Stat News)
Raising awareness to end Parkinson’s

Rebecca Cooney

The Lancet United States of Health Blog spoke with John L Lehr, CEO of the Parkinson’s Foundation, and Allison Willis, MD, MS, a Parkinson’s disease specialist and assistant professor of neurology and biostatistics in epidemiology at the University of Pennsylvania, about a new initiative to close the gap in sex-based disparities.

Rebecca Cooney: First off, bring us up to speed about what we know about the epidemiology of Parkinson’s and who is most affected. I know that, for example, there are data that suggest that there is an increased prevalence in men and particularly in aging men. What can you tell us about the different groups that are affected?

John Lehr: You are correct. Men, generally speaking, have a higher prevalence than women. Currently, right now in the United States, there are about 1 million people with Parkinson’s and then there are about 10 million people worldwide. The average age of onset for Parkinson’s for most people is in their early 60s. We know that as the population in the United States and actually around the world ages, that the number of people with Parkinson’s is likely to grow, to increase. I think that is something that we all need to be very mindful of because the needs of people with Parkinson’s disease are highly variable but tend to be very significant. It is an early degenerative disease and it implicates many systems of the body. Not just movement but gastrointestinal, cognitive, mental health, sensory, sleep, so all of those things mean that a number of different specialists starting with a movement disorder specialist need to be involved in care.

Cooney: What is also important is that with a growing disease burden, the question becomes whether we have adequate care for individuals. Now, you recently became CEO of Parkinson’s Foundation. It would be great to hear about what the efforts of your organization are and what the big issues are that you’ll be addressing at the Foundation.

Lehr: Last year in July, two organizations—the National Parkinson Foundation based in Miami and Parkinson’s Disease Foundation based in New York—merged and became one organization, the Parkinson’s Foundation. It would be great to hear about what the efforts of your organization are and what the big issues are that you’ll be addressing at the Foundation.

Cooney: Turning now to Dr Willis to bring up the issues around where we are going with the science and how we...
Dr Willis, what can you tell us about the new initiative that you’re working on?

Dr Allison Willis: The new initiative we’re working on with the Parkinson’s Foundation is based on several observations about Parkinson’s disease epidemiology. So as you mentioned, we have historically found that Parkinson’s disease is more common in men than women. That is, men seem to have a greater risk of Parkinson disease than women and that has been replicated in studies in different populations all over the world. However, because women in the United States are successful in aging, there are more older adult women, and because age is the number one risk factor for Parkinson’s disease, the absolute number of women with Parkinson disease in the United States is almost equal to the absolute number of men who have Parkinson’s disease.

Parkinson’s disease incidents increases as you get older but there is no plateau for that. The risk of Parkinson’s disease continues to rise and, therefore, you have a large number of people who have Parkinson’s disease who don’t develop symptoms or receive a diagnosis until they’re in their 70s, mid-70s, late 80s, mid-80s, however, those people are less likely to come to an academic medical center for care. Women are also less likely to be seen at a specialty center and to receive either basic or advanced care for Parkinson’s disease.

Being a Parkinson’s disease specialist myself, a researcher, and also someone who cares for people with Parkinson’s disease, we noticed that there was a mismatch between the number and the kinds of people with Parkinson’s disease that we could count and the kinds of people who came to our academic medical centers who had Parkinson’s disease. This new initiative, “Women and PD Teams to Advance Learning and Knowledge (TALK),” is focused on understanding healthcare disparities in Parkinson’s disease, on understanding why women who are diagnosed with Parkinson’s disease are less likely to see a neurologist, which is the standard of care for Parkinson’s disease. Why women with Parkinson’s disease have a lower risk and improved survival after being diagnosed with Parkinson’s disease, but have greater disability from Parkinson’s disease.

If you think about what that tells us that can help everyone who has Parkinson’s disease, figuring out why women have a lower risk of Parkinson’s disease or why women seem to be protected from it, can lead you down scientific pathways that can lead to medications or mechanisms that could lower or stop the progression in everyone. If you can understand why women have greater disability and worse outcomes after being diagnosed with Parkinson’s disease, that may help inform design approaches to care, care models, approaches to delivering clinical services in a way that specifically targets and understands the unique needs of women with Parkinson’s disease.

To give more information specifically about the Women in PD Talk initiative from the Parkinson’s Foundation, what we are doing is setting up a network of research and treatment hubs across the country that are focused on developing a research agenda to understand healthcare disparities and sex differences in Parkinson’s disease. It will be a network of movement disorder specialists, patient advocates, patients, and their care partners who are trained to advocate for research efforts that will lead to patient-centered outcomes research. We are coming together to ask and develop questions that we will pursue with the Parkinson’s Foundation and with the National Institutes of Health, with the goals of putting forth a research platform that is specific to sex disparities or gender-related healthcare disparities in Parkinson’s disease.

Cooney: It is always great to hear about these sort of multi-pronged initiatives that target the improvement of the health infrastructure itself, and that are supporting researchers and keeping patients at the heart of those efforts. We wish you all the best with the launch of this initiative, as well as the broader goal of increasing awareness this month.

Join the conversation on Twitter following the hashtag: #EndParkinsons
This week in health and medicine

Aaron van Dorn

Marijuana users take up more spaces in drug treatment than opiates, cocaine

A report compiled by the Philadelphia Department of Behavioral Health and Intellectual Disability found that, from 2011 to 2015, marijuana users took up more spaces in Philadelphia-area drug treatment programs than opiate or cocaine users. In 2014, alcohol abusers made up the largest number of treatment spaces, at nearly 2500, but marijuana users took up over 1800 spaces, to only 1764 for heroin users and less than 1,000 for cocaine users. Prescription opioid users made up only 311 spaces. The report found that most marijuana users were not there voluntarily, but at the behest of parole or probation officers, and often for those who were not convicted of drug-related crimes and failed drug tests. The same trends were in evidence not just in Philadelphia, but in New York, Los Angeles and Chicago. (The Philadelphia Inquirer)

Nearly half of American adults infected with HPV

According to a report by the National Center for Health Statistics, 42% of American adults are infected with the human papilloma virus, or HPV, and a quarter of men and 20% of women are infected with a particularly high-risk strain that leads to 31,000 cases of cancer a year. There are two effective vaccines for the virus, although administration of them to children is still controversial in some states. (New York Times)

FDA approves genetic disease home testing kit

At-home genetic testing company 23andMe has been given approval by the FDA to begin selling kits designed to test for genetic disposition towards 10 types of conditions, including Alzheimer’s, Parkinson’s and celiac disease. The company had to prove to the FDA that the reports were easy for consumers to understand, and that the results met the FDA’s accuracy requirements. Previously, the FDA had required 23andMe revise its strategy for selling a previous product that offered information on a much broader spectrum of conditions. (CNN)

Oklahoma syphilis outbreak

Oklahoma is seeing the largest outbreak of syphilis infections in recent memory in Oklahoma County, the location of Oklahoma City, the state capital and home to just over 700,000 residents. Public health officials say that 80 individuals have been infected, almost all of them intravenous drug users. Officials believe the outbreak comes from users exchanging sex for drugs, and having multiple sex partners. (US News & World Report)

Virus may trigger celiac disease in mice

Researchers have found that a common but usually harmless virus, the reovirus, can trigger an immune response to gluten in mice that had been genetically engineered to be predisposed to celiac disease. They began looking at the virus after they found people with celiac disease had higher levels of antibodies for the reovirus. This study adds to evidence that there’s a link between celiac disease and infection with viruses like the rotavirus and the hepatitis C virus. (Live Science)

Mutation may be why you won’t stop playing Candy Crush at midnight

Researchers have identified a genetic mutation that causes changes to our circadian rhythm, or internal clock, that governs when you become tired and wake up. The mutation, which is on gene CRY1 and affects about 1.2% of people, causes some people to exist on a 24.5 hour sleep schedule. Researchers had volunteers stay in a studio apartment with no external time cues—windows, television or...
internet access—and left to their own devices for weeks at a time, naturally fell into a longer circadian rhythm. At 1.2%, the number of people with one or two copies of the mutation aren’t enough to account for all insomniacs—so put that phone down an hour before bed—but people who do have it spend their whole lives trying to get on the regular schedule. (Today)
Plotting the course for improving health

Rebecca Cooney

The Lancet United States of Health Blog spoke with Dr Victor Dzau, President of the National Academy of Medicine, about the Vital Directions Initiative and to share some of the insights from the new discussion paper.

Rebecca Cooney: Thank you for taking the time to talk about this new paper from the National Academy of Medicine. I was actually able to tune in for the webcast and one of the most impressive parts of the discussion was the effort to make this topic transcendent politics. Michael Leavitt, the former governor of Utah, a former administrator of the EPA, and former Secretary of Health and Human Services suggested that, “This isn’t about political disagreement. This is an economic and humanitarian imperative.” Which I thought was a nice way of phrasing it. With so much going on this week [Ed’s note—the vote on the American Health Care Act was originally scheduled for Thursday, March 23, 2017 and then subsequently pulled the next day when it failed to garner enough votes to pass.], it is an interesting week for you to put out this paper. It really speaks to the void and how one-sided the discussion has been recently about how to improve the nation’s health and healthcare system.

I thought what might be a nice way to start is to talk a little bit about the “economic and humanitarian imperative”. Especially because this paper is a road map, so to speak, to give us a sense of the road we’re on, where we’re trying to go, and how we might get there. I think we often talk about the three goals of better health and wellbeing, high-value healthcare delivery system.

Let’s talk a little bit about what the Vital Directions Initiative is and what the committee thought were the most important problem areas of the state of health in the US.

Victor Dzau: I think our intention was exactly what you said. Both in terms of what Governor Leavitt said as well as what we clearly articulated in our report. That is to say, “Look. This is a lot more than just arguing about coverage provision.” As I said in my opening remarks, “As a physician and a policy leader, whatever plan it is, we must insure that everybody has access to healthcare and nobody should be denied coverage.” We believe in that. In a sense we are an organization that advises the government. We try not to get straight into political arguments, but deal more in terms of evidence base and what we think the country needs. Which is why our focus is very much without all of those debates and rhetoric. We are looking at what we need to do with the time that we have, with the resources that we have, in order to deliver the very best care and improve the health of the nation. That’s really the principal message.

What we said was, “We need to cut through all the noise, rise above it, and as a beacon, shine the light on what we all have to do in order to reach the endpoint of better health and wellbeing for the nation.”

That’s a timely message. Of course, what exactly we need to do is what the series of papers is all about. Eighteen months ago, we anticipated that we were going to have a new US administration. I convened a group, the steering committee, and kicked off this idea of identifying future directions called Vital Directions for Health and Health Care in the United States. This steering committee was deliberately chosen to include people who are experts, policy makers, previous policy makers, healthcare leaders, and researchers all coming together in a non-partisan—bipartisan—way. We looked very carefully at the balance of who’s at the table and that’s why we ended up with people like Tom Daschle, Michael Leavitt, Mark McClellan, Peggy Hamburg, and many others. Of course a lot of public health, healthcare delivery experts, decided to come together and say, “What are the things you want to tell the new administration that we need to do in order to keep the three goals of better health and wellbeing, high-value health care, and strong science and technology.”

They came up with a whole set of ideas which resulted in convening 150 leading experts. That pretty much covers a lot of waterfront—anywhere from caring for the aging population, to in-house substance abuse, to precision medicine, to payment reform, and so on. The series is an entire resource.

We had a big public meeting called National Conversation. 400 people came and got together on the web to discuss and validate this. From all that input, we worked since September to create a final publication that summarizes or synthesizes all these ideas.

We identified four action priorities:

• Pay for value—deliver better health and better results for all
• Empower people—democratize action for health
• Activate communities—collaborate to mobilize resources for health progress
• Connect care—implement seamless digital interfaces for best care

There are so many important pieces—social determinants, population health, and activating communities. You can’t solve the problem if you don’t get engagement of your community by having different sections coming together. Education, transportation, security, housing, environment, city planning, and health—if they all come together and plan appropriately this is going to be the way by which you can really improve health.

As you know, recently we put out a report on health equity (Communities in Action: Pathways to Health Equity). The role of communities, exemplars of community that came together to do things that can really make a difference. This goes back to the idea of how fragmented we are, but communities are coming together. From that we can drive changes upwards, if you will, and suddenly part of the discussion is to say, “Make sure that communities are supported with enough funds.”

There has been a lot of discussion about Medicaid dollars and sometimes how restricted the dollars are. The idea, of course, is to be more flexible so you can come up with solutions. Now, that resonated really well with both Republicans and Democrats.

Another facet of course is that patients need to be educated, empowered, have access to information, to partner with their providers to make decisions together, to make choices. That resonated also strongly with both sides of the isle.

Finally, there is the idea of connected care. Coming back to social, medical, activity services, to the integration of information, technology, and interoperability are essentially important.

These four priorities, we believe, if executed, could really move the nation forward and truly improve health whatever the health plan is. We also have to strengthen infrastructure. You need to train the workforce for the future. You’ve got to be sure that in fact that side is strong. You’ve got to be sure that you have good evidence, generated in real time, with information and technology. We also gave Congress a list of eight priorities as a checklist. Policy makers need to be thinking about infrastructure and what to consider next. This checklist is a way to help.

Cooney: What makes this a useful set of recommendations is that it does target those mid-level ideas as well as the higher level goals. That has been sorely lacking recently, a way of looking at the health situation more comprehensively. Now that this paper has been released during a very intense period of debate and discussion about potential reform underway, what is your hope about bringing this information to the forefront? What needs to happen, from your perspective, to help bring consensus?

Dzau: Absolutely. We recognized right away that this is only useful if we’re able to bring the message out and make sure that the policy makers and the public will hear this. There’s nothing to disagree with—quite frankly, you could argue a little bit about policies here or there. But we believe this message is so strong that we’re going to have a full court press.

We have already started going up to The Hill and met with major Senators, both Republican and Democrats. I think they’re going to use this framework as a resource, especially when they get to the next level. This is a really important road map to look at and we (the National Academy of Medicine) want to be there when they need some ideas or advice. We’re ready to help and I can bring together the very best minds to help them.

Cooney: It’s lovely to hear a glimmer of hope and optimism in the face of all that’s going on, especially through a more realistic approach. The only way to move forward is to really build consensus at this point and this framework and your efforts are an excellent first step in doing that.
This week in health and medicine

Aaron van Dorn

Ohio limits prescriptions of opioids to seven days for adults

In an effort to combat the country’s ongoing opioid crisis, Ohio Governor John Kasich has signed a rule that prevents doctors and dentists from prescribing more than a seven day dose of opioid pain killers, and only five days for a minor. Opioid prescriptions can currently be issued for a 30–90 day supply of the drugs. The order will be enforceable by law, and medical professionals who violate them could face losing their licenses. The order is expected to reduce the number of opioid pills in the hands of residents by over 100 million annually. The order will go into effect this summer. Ohio saw over 3000 deaths due to opioids in 2015. (Columbus Dispatch)

Antibiotics research gets boost from global organization

CARB-X—short for Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator—an international group founded in July of last year to provide research funding and assistance to groups researching a broad spectrum of antibiotics related areas, has issued its first payments totaling $24 million to eleven different companies taking different approaches to researching new antibiotic strains. The companies are also eligible for up to $24 million in additional funding over the next three years. CARB-X was created by the US and UK governments, and includes a number of other organizations, including the Wellcome Trust. CARB-X aims to invest $450 million in antibiotic research over the next five years. (Washington Post)

Red states look to expand medical marijuana

Despite the uncertainty over the status of legal marijuana under new Attorney General Jeffson Sessions, the State of Georgia is looking to expand its existing medical marijuana law, and the State of West Virginia has passed a medical marijuana bill. In Georgia, a bill was passed in the state senate this week that would expand the law to include six new medical conditions, including Alzheimer’s Disease, AIDS, and Tourette’s Syndrome, along with patients in hospice care. The bill was passed by a vote of 46-5, and goes to Republican Governor Nathan Deal for his signature. In West Virginia, the State Senate passed a bill that would legalize medical marijuana and set up a commission to develop policies and regulations for controlling its distribution and scope. The bill passed by 28-6, and now heads to State House of Delegates for a vote. The House recently rejected a medical marijuana bill of its own, by 64-9. (Atlanta Journal-Constitution, Metro News)

Massachusetts considers raising tobacco purchase age

Health advocates, led by the American Cancer Society, are advocating for changes in the smoking age in Massachusetts. The Massachusetts state legislature has voted several times over the last couple of years to raise the legal age to purchase tobacco from 18 to 21, but the efforts have been unsuccessful. Advocates argue that a higher smoking age would prevent younger teens from beginning to smoke. Opponents argue that raising the age is a blow against personal freedom, and would hurt retailers who sell tobacco products. In 2016, the State Senate passed a bill raising the age, but the House of Representatives did not take the bill up. (WCVB)

FDA approves first drug to treat severe form of multiple sclerosis

The Food and Drug Administration has approved the sale of a drug to treat all types of multiple sclerosis. Ocrelizumab’s effects were strongest with relapsing multiple sclerosis, halting the disease with few side effects. But it also had an impact, albeit more mild, on the more severe primary
progressive multiple sclerosis, which until now has been resistant to treatment. The researchers see this as a first step towards better treatments for primary progressive MS. (New York Times)

Marathons cause kidney injuries
According to a new study by kidney specialists at Yale University, running marathons at least temporarily damage kidneys in around 75% of runners. The researchers suggest that the damage is likely due to the stress of running. While the damage is definitely real, the study suggests that it might not be time to call a halt to marathons just yet. Those sampled before and after the marathon showed that by the next day, the temporary damage to their kidneys was well on its way to being repaired. The author suggests that the next step is to look at whether it’s safe for people with pre-existing kidney problems are at greater risk for injury than those who do not. (The Atlantic)
This week in health and medicine

Aaron van Dorn

With AHCA fate still in the air, GOP turns to essential health benefits
As Republican House leadership scrambled from Wednesday night into Friday morning to craft an Affordable Care Act replacement bill that could win support from the most conservative members of the caucus, they began looking at rolling back an often overlooked aspect of the ACA: essential health benefits. The ACA guarantees a list of ten essential policy coverage that insurance plans sold to small groups and individuals must cover, including things like maternity and child care costs, prescription drugs, hospital stays and preventative care. Members of the House Freedom Caucus would like to see these requirements removed, but what that means for more moderate members of the Republican caucus remains unclear. Also unclear is how repeal of essential benefits, which does not directly affect the budget of the ACA, would be able to pass through the Senate via the reconciliation process. (STAT)

Illinois considers legalizing recreational marijuana
While the state of state-level marijuana laws remain unclear under new Attorney General Jeffery Sessions, some Illinois lawmakers are forging ahead with a proposal to legalize regulated businesses to produce and sell marijuana, and for individuals to possess up to 28 grams of marijuana for personal use. The proposed legislation would levée a $50 per ounce tax on wholesale sales, and a standard 6.5% sales tax on retail sales. The legislation is unlikely to come up for a vote this year. (Chicago Tribune)

Two thirds of cancer attributed to DNA mistakes
A new study in Science suggests that nearly two thirds of cancers are caused not by heredity or environmental factors, but by random mistakes in DNA caused by replication errors. The study found that 66% of cancers were caused by random DNA error, 29% by environmental factors like lifestyle and smoking, and only 5% by inherited factors. Some cancers, however, were much more likely to be attributable to the DNA replication error factor, as much as 95% for cancers such as prostate or brain. Other cancers, such as lung, were much more likely (65%) to be attributable to environmental factors. (Live Science)

Doctor details potential treatment for sepsis
An intensive care doctor in Norfolk, Virginia, Dr Paul Marik, has proposed a potential treatment for sepsis. Marik adapted the technique from a study that suggested intravenous vitamin C might be of use for a patient when all other treatments had failed. He also added corticosteroids and thiamine to the mix, and found that the patient made a quick recovery. He says that of 47 sepsis patients he has treated with the technique, all but four recovered, and those four eventually died of their underlying conditions. The treatment needs further validation, but Marik is hopeful that the technique can help reduce the 300 000 Americans who die from sepsis each year (NPR)

Pharmacist convicted of racketeering, but not guilty of murder in 2012 meningitis outbreak
Barry Cadden, pharmacist and owner of New England Compounding Center, has been found guilty of racketeering and mail fraud, in a case involving a nationwide outbreak of fungal meningitis. He was found not guilty of the twenty-two counts of second degree murder. Over 700 people were infected with fungal meningitis after using steroids manufactured at Cadden’s compounding pharmacy. Cadden was accused of using expired ingredients and issuing drugs that had not been confirmed sterile. (CNN)
Male fertility test? There’s an app for that
Several competing smartphone-based male at-home fertility tests are working their way towards consumers, allowing men for the first time to easily and privately test their fertility rates. The devices consist of a base that your smartphone slides into, essentially turning the phone’s camera into a microscope, and a disposable microchip that you dip into a semen sample, and insert it into the base. Unlike other current FDA-approved at-home male fertility tests, it counts both the number of sperm cells present, as well as the percentage of them that move. The creators claim an accuracy rate in the mid-90s for both devices, and they hope to expand the abilities to other tests. (The Verge)
Invasion of privacy—a new bill may give employers access to genetic testing information

Rebecca Cooney

The sparse wording of the bill proposes that genetic testing results obtained from employees in the context of wellness programs would be considered exempt from the landmark Genetic Information Nondiscrimination Act (GINA) that was passed in 2008. GINA is a federal law that prevents the use of genetic information from being used to discriminate against individuals for health insurance and employment. In response to the bill, the American Society of Human Genetics (ASHG) issued a firmly worded letter to the committee indicating its opposition and outlining some of the detrimental effects of the proposed legislation, including the potential for coercion of individuals to provide genetic information, the violation of the existing provisions for keeping sensitive information private, as well as a troubling financial penalty that could be used against employees who chose to withhold genetic information.

The Lancet United States of Health Blog spoke with Nancy Cox, PhD, director of the Vanderbilt Genetics Institute and president of the American Society of Human Genetics, to further discuss the implications of the bill.

**Rebecca Cooney:** Thank you so much for taking the time to speak with us today. This is a very interesting story and one that has a lot of different layers of nuance to it. At least from my initial read of the text of the bill, it doesn’t seem to do much other than to open a door to obviate the protections of GINA through workplace wellness programs by suggesting that this information would be provided on a voluntary basis, which in and of itself, might seem to some as fairly innocuous. Until you map out what the potential of lifting those protections could be.

The ASHG is a fairly vocal organization when it comes to matters that might impinge on privacy concerns around genetic testing—can you articulate for us what about this legislation is cause for concern from the perspective of geneticists?

**Nancy Cox:** Yes. So, the first thing to keep in mind is that many genetics society and genetics professionals worked for more than a decade to get the GINA enacted. It was a really long, uphill battle to make sure that genetic information couldn’t be misused, or used in ways that were unscientific or just downright wrong by people who have no business having it in the first place, and to ensure that patients would have some privacy with respect to the genetic susceptibilities they may carry, which, after all, is not anything that anyone can do anything about. And so, to see these protections eroded in this way is quite distressing because this would do nothing short of essentially gutting the GINA through this legislation. It’s really very damaging to GINA.

**Cooney:** There are two really important pieces from the letter that ASHG sent in advance of these deliberations last week that I think might be worth touching on. One is that it would allow an employer to be able to request information for an employee, but also for anyone in the employee’s family, including family medical history. But it would also carry with it a penalty that if someone elected not to disclose that information, there would be a pretty hefty financial implication [Ed’s note—the bill would allow employers to impose a financial penalty of up to 30% of the cost of the employee’s health insurance. As the ASHG letter notes, on an average family plan of $18 142, choosing not to disclose genetic and health information would cost an additional $5443.]

**Cox:** Exactly. So you’re between a rock and a hard place. You either must disclose information that historically employers had no ability to know and use or pay such a penalty that you may not be able to afford to be insured.

**Cooney:** In the last few days, I’ve noticed social media from other scientists and health professionals who have raised questions about what this bill is actually intending to do, what are the sponsors hoping to achieve? And, though we don’t know at this stage whether it will actually pass, I’m very curious, what can we do at this stage? If this were to come to pass, are there steps that we could take to help mitigate some of the consequences?

**Cox:** Well, a stitch in time saves nine. I think that effectively forcing people to undergo genetic testing that they do not want to have is not a road that we want to go down, and part of the reason that it was so important to get GINA passed in the first place was to really preclude even the possibility that companies would inappropriately use genetic information to try to get rid of employees who might cost them money in the future or who might be more likely to use health services. In the current climate, employers have no access to any genetic data even if a patient has chosen themselves to undergo genetic testing as part of a wellness program. Only genetic physicians and genetic counselors would have access to that information, and the employer would know only summary data on the number of employees at risk for this, that, or the other condition.
They wouldn’t know which individual employees might be at risk of any particular disease or condition.

We can all appreciate that once that information is effectively required, the opportunity for misuse is simply there and how do you prove that someone was fired because they have increased risk for developing breast cancer as opposed to whatever it is that the employer is saying. That is why these protections are so important. They really insure that the information cannot be misused against employees. I think from the perspective of participation in genetic studies, where information is provided back to patients, it is a major concern. It really puts the whole Precision Medicine Initiative at risk because that information could then be required to be returned to employers.

Cooney: That’s actually a really important offshoot that could potentially put legislators in a bind given the Precision Medicine Initiative (now called “All of Us”) is one of the few bipartisan hallmark achievements and that has big proponents on both political sides involved. It is such an important aspect to consider that legislation like HR 1313 would fundamentally be putting human subjects at a disadvantage by asking them to participate knowingly if there is some risk that would have to be reported or be fined.

One question that I have to you concerns the utility of genetics for general healthcare at this stage. I can’t really think of a scenario where de-identified information would actually be beneficial in the context of a wellness program. There seems to be a logical flaw to this legislation in painting the lack of genetic information as a limitation for employer-sponsored wellness programs as any results they would have access to would be de-identified and not necessarily useful unless considered in aggregate.

Cooney: That really seems like a ploy to open the door for allowing privacy violations rather than a practical add value to a workplace wellness program at this stage, given where we are with the science.

Cox: Yes. It’s very unnerving to me. I’m curious to know who’s actually pushing for this part of the legislation and what the rationale is.

Cooney: Right. From the cursory digging that I’ve done, it’s also very opaque as to why there is a mandate for “preserving” workplace wellness programs when there isn’t a lot of good evidence supporting many of them. It seems to be a covert way to get at the fundamental protection of these data. That is really disturbing and it is alarming that this bill can proceed at this pace without having some of these more probing questions being asked. I suppose, if this comes to pass, there is some recourse legally from the Equal Employment Opportunity Commission, but can we expect that geneticists will be increasingly more vocal?

Cox: Of course. We hope to rally enough people, who in turn will rally their representatives, to ensure that this doesn’t pass as it is currently written. Because again, fixing things after the fact can be much more difficult. But if it is passed, I think the various medical and genetic societies will be working hard again to get these protections into place.

Right now, nothing can happen to a person who refuses to provide genetic information that they might have. Why is it that anybody would want to see people fined for wanting to keep their genetics private?
This week in health and medicine

Aaron van Dorn

AHCA moves towards floor vote in House
The American Health Care Act, the long touted Affordable Care Act replacement bill, narrowly continued its progress towards becoming a law after being voted out of the House Budget Committee Thursday. However, the vote was a lot closer than the bill’s defenders might have wished, with three Republican Representatives joining all of the committee’s Democrats to vote against the bill, 19-17. The next step is for the bill to be passed through the House Rules Committee before being brought to a floor vote, tentatively scheduled for next week. (Politico)

Sign of HIV “hidden reservoirs” found
While current HIV therapies can keep levels of the virus to undetectable levels, doctors have not been able to eliminate the infection from the body. According to a study in Nature, researchers were able to identify a protein, CD32a, which might give them a heads up in future treatments. HIV viruses can hide within T cells in the body for years at a time without becoming detectable, either to the body or to treatment therapies. The researchers hope that the new insight will allow them to develop further treatments towards the long goal of irradiating the infection. (Scientific American)

Trump’s budget plan holds severe cuts for health
President Trump’s plan for his budget has been released, and the road map looks rocky for health priorities. While the budget is a long way from being approved by Congress, the outlines of Trump’s priorities show a huge increase for the military and money for Trump’s border wall, and small to enormous cuts for everything else, including cuts to the National Institutes of Health, environmental protections, the Centers for Disease Control, the State Department’s 60-year-old Food for Peace Program, and money for Meals for Wheels. (Vox)

Mayo Clinic to privilege privately insured patients over Medicare or Medicaid
According to accounts of a speech to employees late last year, Mayo Clinic CEO Dr John Noseworthy said that given two similar patients, the hospital system should prioritize the one covered by private insurance over ones covered by government funded insurance like Medicare and Medicaid. Medicaid, which along with Medicare restricts the level of reimbursement to doctors and hospitals, has seen an enrollment increase due to the Affordable Care Act Medicaid expansion. The Mayo Clinic said in a statement that about half of their patients come from Medicare or Medicaid. Experts said that while it’s common for hospitals to strike a balance between patients from private and public insurance programs, but usually not in so many words. (Stat News)

Canadian cystic fibrosis outcomes markedly better than US
Canadian cystic fibrosis patients live ten years longer than patients in the US, according to a new study, with patients in Canada living to an average of 50·9 years, compared with 40·6 years for the US. Both countries have tracked data on patients through national registries (around 6000 patients in Canada and 45000 in the US) and both have seen improvements, but 2005 saw Canadian outcomes to begin to outstrip the US. The researchers say there are multiple factors at play, but the main drivers are a lung transplantation metric that may weigh against cystic fibrosis patients in the US, variations in insurance systems and coverage, and a shift in Canada in the 1970s towards placing cystic fibrosis patients on a supplemented, high-fat diet. (CNN)

FDA advisory panel says harms outweigh benefits for prescription opioid
With a vote 18-8, an FDA advisory panel says that the harms outweigh the benefits of a reformulated Opana ER,
a prescription opioid manufactured by Endo International. The drug was reformulated in 2012 to make it harder to crush after reports that it was being abused by snorting. The reformulation also timed to block the release of a generic version of the drug. Users discovered how to dissolve and inject the reformulated drug, however, leading to a large HIV outbreak in Scott County, Indiana in 2015. Indiana health officials said that nearly everyone of the 215 people diagnosed with HIV in Scott County had injected Opana ER. (NPR)
This week in health and medicine

Aaron van Dorn

ACA replacement bill being drafted in secret
Republican lawmakers continue to work on a bill to fulfill their promise to "repeal and replace" former President Barack Obama's signature health care law, the Affordable Care Act. GOP lawmakers have had difficulty so far in satisfying all of their various factions while also producing a bill that won't be politically toxic upon unveiling. The current state of the bill is unknown, after a leaked draft last week was shot down by the ultraconservative House Freedom Caucus for not going far enough to dismantle the ACA. Senator Rand Paul of Kentucky spent this week wandering around the Capitol with a portable copy machine and a camera crew, attempting to find the room where the secret bill was available for view by select members of the GOP caucus. Paul, who has said that he will not support any repeal legislation that does not fully do away with the ACA, was blacklisted from viewing the bill-in-progress by GOP leadership. (Washington Post)

Asbestos-related deaths continue decades after ban
The CDC is reporting that deaths from malignant mesothelioma, a type of cancer linked to exposure to asbestos, has remained steady, rising slightly from 2479 deaths in 1999 to 2597 deaths in 2015, despite the banning of asbestos-containing products in the 1970s. It can take twenty to fifty years before exposure to asbestos can result in negative health consequences, so researchers are concerned about the rise in those aged 25 to 44, who died due to mesothelioma and related problems, 682 since 1999. Asbestos was used widely throughout the United States, from home insulation and in break pads, to lining plumbing and in hair dryers. (CNN)

Pregnant women with Zika at 20 times greater risk for birth defects
According to a report from the CDC, babies of women who are pregnant and infected with the Zika virus face a 20 times great risk of experiencing a birth defect. The risks of microcephaly and brain abnormalities were even higher, up to 30 times greater than in the general population. While the majority of Zika infections have been found in Brazil, the infection has spread north into Central America and the United States, with an outbreak in Miami and Texas (CBS)

Sickle cell gene therapy appears successful
Researchers at a children's hospital in Paris report that they have successfully caused remission of symptoms in a boy with sickle cell disease. The boy underwent an experimental gene therapy at age 13, and in the fifteen months since has shown no further complications from the debilitating disease, which causes pain, fatigue and can cause blood clots and death. Sickle cell disease is more common among those of African descent, and approximately 100 000 Americans have the disease. (Chicago Tribune)

Republican politicians speak out in support of Planned Parenthood funding
While no concrete plans have been put forth, leaked Republican plans for repeal of the Affordable Care Act have included bans on Medicaid funding being used for Planned Parenthood, the organization that provides basic women's health services around the country, in addition to abortion. However, several Republican politicians have spoken out in support of the health care organization in recent days, include Massachusetts Governor Charlie Baker, who has promised to use state funds to continuing funding Planned Parenthood clinics in the event that federal funds become unavailable. In the Senate, Maine Senator Susan Collins and in the House, Pennslyvania Representative Charlie Dent have both expressed concerns about defunding the popular program. (Charlotte Observer, The Hill)
Fitness tracker fad reaches its logical endpoint
A British company will begin selling a fitness tracking condom later this year, allowing users to track a number of pertinent “statistics” related to a certain subset of physical activities, including duration, skin temperature, and a number of other more graphic measurements. The data collected will be anonymous, according to the company, but they say that you will be able to share this vital data with friends and the world at large, including a world-wide leader board. The novelty item is expected to be sold for $75. (Huffington Post)
This week in health and medicine

Aaron van Dorn

Leaked draft of GOP ACA replacement
A leaked draft of a proposed Affordable Care Act replacement obtained by Politico shows an evolving process, according to Sarah Kliff at Vox. The leaked bill bears a lot of similarities to now-Secretary of Health and Human Services Tom Price’s Empowering Patients First Act. Like that proposed bill, the draft proposal still depends largely on high-risk pools and replacing the total ban on preexisting conditions with a more consumer-friendly version of the continuous coverage plan proposed by Price. The draft would also ditch the ACA’s Medicaid expansion without replacing it. It’s unclear if this bill reflects the GOP’s current thinking, or could receive enough votes from GOP lawmakers to pass. (Vox)

Immigrants avoiding health care for fear of deportation
With President Donald Trump rescinding the Obama Administration’s previous criminal-first guidelines on deportation of undocumented immigrants, many immigrants find themselves avoiding health care at clinics and hospitals for fear of being caught up in Immigration and Customs Enforcement raids. There has been no evidence that raids have been undertaken at hospitals, but rumors about raids at Brooklyn hospitals last week caused several patients to cancel appointments, according to hospital spokespeople. But not all of the rumors are unfounded: last week, ICE agents in Virginia did pick up six homeless men utilizing a church’s hypothermia shelter. (Stat News, NBC)

Overdose deaths have tripled since 1999
Drug overdose deaths in the US have soared, rising from six out of every 100,000 in 1999 to 16 out of 100,000. A major driver has been the rise in opioid abuse, especially among white and middle aged Americans, accounting for half of the rise. Adults aged 45–54 years old had the highest rate of overdose death, at 30 out of 100,000. The rise in overdose deaths in whites has been 7% a year, compared with 2% in African Americans and Hispanics. (CBS)

Bipartisan Senate change to ACA would expand access to OTC medication
A bill sponsored by a bipartisan group of Senators has been proposed that would enable consumers to use health savings account (HSA) or flexible spending account (FSA) funds to purchase over-the-counter medications. Ninety percent of doctors recommend and ninety percent of patients prefer to treat with OTC drugs prior to seeking medical attention, and every dollar spent on OTC drugs saves six to seven dollars for the health care system. The Affordable Care Act removed OTC drugs from purchase eligibility with HSAs and FSAs. (The Hill)

Trump Administration signals coming legal marijuana crackdown
This week, Trump Administration Press Secretary Sean Spicer signaled that the Department of Justice would likely begin increasing enforcement of federal marijuana prohibition, even in the eight states and the District of Columbia that have legalized the $6 billion industry under the Obama Administration, which largely deferred to state law regarding marijuana policy. The shift would expose a tension for new Attorney General Jeff Sessions, who is a vocal supporter of states right, and an avowed critic of marijuana legalization. (Bloomberg)

Owning a cat not linked to mental health issues
A study following 5000 people born in 1991 and 1992 until eighteen has found no evidence that owning a cat during pregnancy or childhood had any impact on mental health issues as people grew. Mental health and cats have been linked popularly due to cats being the primary host of toxoplasmosis, which has been linked to schizophrenia. (Psych Central)
An alarming trend in fatty livers

Ray Cavanaugh

The rate of NAFLD among US children has tripled over the last 20–30 years, rising from 3–4 percent to 10–11 percent, according to Dr Naim Alkhouri, Director of the Metabolic Liver Center at the Texas Liver Institute in San Antonio.

NAFLD is caused by an excess of fat in the liver. While the liver is supposed to contain some amount of fat, if more than 5–10 percent of the liver’s weight consists of fat, then the person likely has NAFLD.

The majority of children (and adults) with NAFLD are asymptomatic. Those who are symptomatic might present with persistent fatigue, abdominal pain, skin manifestations of spider-like blood vessels, or jaundice, among other possible symptoms.

Though in many cases NAFLD doesn’t harm the person, serious problems can emerge if it develops into its more serious form: nonalcoholic steatohepatitis (NASH), a condition which consists of liver inflammation and swelling, and can progress to the scarred liver of cirrhosis and, ultimately, liver failure.

Fortunately, NAFLD can be reversed, as long as it hasn’t reached an advanced stage. Lifestyle changes, such as better nutrition and increased exercise, are currently the best-known way of mitigating and possibly reversing its effects. Fish oil, with its omega-3 fatty acids, has been mentioned as carrying potential benefit. And it’s important to avoid soft drinks with high fructose content, which have been shown to contribute to NAFLD.

Weight reduction is crucial in helping to alleviate NAFLD. However, the weight loss should be gradual, as rapid weight loss can exacerbate NAFLD and also can trigger the condition in one who doesn’t have it. As of yet, there are no widely accepted medications for juvenile NAFLD; clinical trials are underway for medications intended to treat adult NAFLD. Vitamin E has shown some efficacy in at least one juvenile NAFLD study.

Prevalence of NAFLD appears to vary according to ethnicity, with higher rates in those of Asian and Latino descent and lower rates in those of African descent. There is also a gender disparity, with boys having considerably higher rates than girls—likely owing in part to males’ increased tendency to store fat in the abdomen.

Liver biopsy has been the standard method of diagnosing NAFLD, but hospitals more recently have been seeking less invasive methods. Among them is magnetic resonance elastography (MRE), which is used by the Mayo Clinic.

When he was previously with the Cleveland Clinic, Alkhouri helped to develop a NAFLD calculator, which involves entering the blood liver enzyme count and platelet count into a mathematical equation. The goal of this calculator is to avoid having to perform a liver biopsy, but Alkhouri advises that, for now, the calculator “needs further validation.” In order to diagnose the more advanced condition of NASH, a biopsy is needed.

Alkhouri relates how the focus of current research involves “understanding the natural history of NAFLD in children,” finding “biomarkers to replace liver biopsy,” and, of course, striving to identify effective treatment.

Specialized clinics for juvenile NAFLD are found in such locations as Phoenix Children’s Hospital, Rady Children’s Hospital in San Diego, Morgan Stanley Children’s Hospital of New York-Presbyterian in Manhattan, and the Children’s Hospital at Montefiore in the Bronx.

Though juvenile NAFLD has been on the radar of the medical community for about “15 years or so,” many pediatricians “still don’t screen routinely,” and getting them to become more proactive about screening has proven “a slow process,” says Alkhouri. In fact, most children with NAFLD are unaware of their condition because of a “lack of consistent screening practices among pediatricians.”

The statistics Alkhouri shares are troubling: some 35–50 percent of obese children have NAFLD, and 20 percent of children with NAFLD have the advanced form of NASH. Also, 10–15 percent of children with NAFLD are in a predicament that could be described as “pre-cirrhosis.”
Though most cases of juvenile NAFLD are caused by excess weight and associated insulin resistance, “up to 7% of non-overweight or obese children may have NAFLD,” according to a new study that Alkhouri and others will present at the upcoming International Liver Congress, held in Amsterdam this April.

The obesity crisis, though, is the driving force behind the surging rates of both juvenile and adult NAFLD. And, despite increasing awareness in the medical community, he sees the issue as “getting worse” in the next ten years.

The percent of children with NAFLD who will need a liver transplant down the road is “not known at this point,” but Alkhouri points out that “the histology of NAFLD is identical to alcoholic liver disease.”

Which means that, in terms of livers, obesity is the new alcoholism.
This week in health and medicine

Aaron van Dorn

Patent Office moves CRISPR case forward, future still unclear

On Wednesday, the US Patent Office announced a decision to the status of the patents pending in the CRISPR gene editing case. Two institutes, the University of California and MIT’s Broad Institute, have filed patent claims related to technology that allows the editing of genes in cells. The Patent Office preserved the Broad Institute’s claim to a patent on the ability to edit genes in eukaryotic cells, while also allowing UC’s patent application for the ability to edit DNA in all cell types. The UC is expected to appeal the ruling, but with costs for both sides already approaching $15 million apiece, experts believe a compromise might be a viable option for both parties. (Stat News)

CDC high security lab shutdown over air hose concerns

The Centers for Disease Control’s high security Biosafety Level-4 Labs have been temporarily shut down after it was discovered that the air hoses connecting researchers’ protective suits to air supplies were not approved for that use. There’s no evidence that the hoses have caused any researchers ill harm, and the suit’s built in HEPA filters should have blocked any stray pathogens. The CDC expects to have the hoses replaced and the labs up and running next week. (US News & World Report)

Seema Verma testifies before Senate committee

Seema Verma, President Donald Trump’s pick to head up the Center for Medicare and Medicaid Services, testified before the Senate Finance Committee this week, offering few details on what kind of policy she would choose as head of CMS. Verma is a health care consultant who has worked with Vice President and former Indiana Governor Mike Pence to set up their unusual Medicaid expansion, the Healthy Indiana Plan 2.0. Critics charge that HIP 2.0 is notably less generous than for enrollees than other Medicaid programs, and Indiana, which has been racked by a series of serious public health problems, still ranks at the bottom of the states in health outcomes. (Indiana Star)

ACP releases lower back pain guidelines

The American College of Physicians has released a guideline on dealing with lower back pain based on a review of randomized controlled trials published through April 2015. The three recommendations include recognizing that pain generally fades over time, and utilizing non-pharmacological treatments such as heat, massage and acupuncture. NSAIDs are also recommended as pain relievers. For chronic pain, the guidelines recommend the above, in addition to exercise such as yoga or tai chi. And finally, the guidelines recommend the use of drugs and especially opioids be reserved for a last line of treatment when other avenues have been exhausted. (Clinical Advisor)

Flu vaccine effectiveness

The CDC reports that this season’s influenza vaccine is about 48% effective in stopping the illness. This is inline with the effectiveness of the vaccine for the 2015-16 flu season, which stopped about 47% of infections, and greater than the 19% effectiveness rate of the vaccine for the 2014-2015 season. This year’s vaccine is about 73% effective against the influenza B strain, but only 43% against the influenza A (H3N2) strain, which has been dominate this year. (NBC)

Seoul virus outbreak continues

The Seoul virus, a hantavirus that is transmitted contact with rodents, continues to spread among rat breeders in the Midwest and West. The virus, which causes mild, flu-like symptoms, is usually not considered serious. Authorities believe the outbreak started at a rodent breeding facility in Illinois. (ABC)
This week in health and medicine

Aaron van Dorn

Republicans face angry townhall crowds over ACA repeal
In scenes strikingly similar to the summer of 2009’s Tea Party protests, Republican members of Congress are facing large demonstrations against the idea of repealing the Affordable Care Act. The meetings have been notable for politicians leaving meetings unexpectedly or shutting down events early after being met with large crowds of angry constituents. The protests also follow reports from a Republican conclave in Philadelphia late in January where many members expressed concerns about the lack of a plan to replace the ACA, as well as concerns that any replacement would result in worse outcomes than the ACA. (Politico)

Unlicensed clinic in Toledo gave dozens false Alzheimer’s diagnoses
A bizarre case in Toledo, Ohio, where an unlicensed memory clinic, the Toledo Clinic Cognitive Center, run by Sherry-Ann Jenkins, opened in 2015 and diagnosed dozens of people with Alzheimer’s disease. Jenkins, who has a doctorate in physiological science and whose husband is a licensed doctor with the Toledo Clinic, is now at the center of an expanding lawsuit. At least one person who received the false diagnosis committed suicide. The clinic closed abruptly in early 2016, but there is no word of criminal charges so far. (Stat News)

Tom Price becomes Secretary of Health and Human Services
Republican Congressman Tom Price of Georgia has been confirmed as Donald Trump’s Secretary of Health and Human Services in a middle of the night party line vote, 52-47. Price’s nomination has been seen questions about the ethics of hundreds of thousands of dollars in stock purchases in medical companies the Congressman has made. Democrats and ethics experts have accused Price of lying under oath regarding the details of his stock acquisitions and lawmaking surrounding companies that Price owns a stake in. Republicans contend that Price, an orthopedic surgeon, has the experience and qualifications to lead on health care. Price has been a strong opponent of the Affordable Care Act, and will now be in charge of the administration of the law. (New York Times)

Woman gives birth on floor in Mississippi jail
A sheriff in Macomb County, Georgia is defending his actions after an eight months pregnant woman in jail on a driving offense was forced by jail staff to give birth to her son on the floor of her jail cell. Following repeated requests to go to the infirmary, the woman was repeatedly sent back to her cell. The child, a boy, weighed less than five pounds at birth. (WTOC)

French Presidential candidate makes pitch for US scientists
Emmanuel Macron, a liberal candidate in France’s current presidential race, has made an unusual pitch for American scientists concerned about government interference and mismanagement under the new administration: come to France. While the pitch, largely based around climate change, probably has some tongue in its cheek, critics point out that the US still spends more on basic research than France does. (Washington Post)

Connecticut teens innovate new, disgusting fad
A survey of Connecticut high school students, published in a study in Pediatrics, has identified a new trend: dripping. According to the study, one in four teens survey engaged in the practice. E-cigarettes work by drawing a fluid from a replaceable reservoir, which is then heated into a vapor and inhaled. Dripping involves manually dropping a greater amount of the e-cigarette fluid onto the exposed heating element and inhaling the stronger vapor. This results in a greater rush and (for flavored e-cigarette liquid), a stronger flavor. The study found that teens who were white, male and have used other forms of tobacco were more likely to engage in “dripping.” (CNN)
This week in health and medicine

Aaron van Dorn

Most Americans endorse vaccinating children
82 percent of US adults polled by Pew Research said that healthy children should be required to receive the measles, mumps and rubella vaccinations. Only 17% of respondents believed that it should be up to the parents to decide. The poll also found that there’s a political dimension to the results, with 73% of conservative respondents saying that schools should require vaccinations for children to attend, versus 90% of liberal respondents. (Live Science)

Fentanyl sold as cocaine responsible for twelve overdoses in eight hours at one hospital
In a grim report from the CDC on the ongoing opioid epidemic in the United States details how twelve opioid overdoses—three fatal—in New Haven, Connecticut in one eight hour period resulted from fentanyl—a synthetic opioid fifty times more potent than heroin—being sold falsely as cocaine. Fentanyl is cheap and easily made, and it has become increasingly common to find it mixed in with other drugs. When drug users are unaware of the potency of the drugs they are taking, it is very easy for them to overdose and die within minutes. (ABC)

Ohio counties running out of room in the morgue
The pace of the opioid epidemic is outstripping some Ohio counties ability to process the deaths. Montgomery County, Ohio, a largely rural county in the southwest corner of the state, has faced 145 overdose-related deaths in 2017 so far. Opioid-related deaths made up 60% of the total deaths the county dealt with in January of this year, and if that pace maintains, the county will more than double the number of overdose deaths over last year. (CNN)

Cleveland Clinic doctors and nurses call for break with Trump
Hundreds of Cleveland Clinic doctors and nurses issued an open letter calling for the hospital group to publically break with President Donald Trump following his immigration executive order from last week, which saw a resident from the hospital system barred reentry to the US. The Cleveland Clinic is scheduled to hold a fundraising event this month at Trump’s Mar-a-Lago resort in Florida. (Washington Post)

Games people play
New research adds evidence to the idea that older people who engage in mentally stimulating activities tend to stave off mental decline more than those who don’t. The research looked at a number of activities thought to engage the brain—computer use, games like bridge or chess, going to the movies and social activities, and reading books—and found that people who had engaged in the activities, with the exception of reading books, were 20% to 30% less likely to suffer mental decline. (Sci-Tech Today)

Super Bowl Sundaaawk!
According to researchers at the University of Florida, you’re ten times more likely to choke during big games like the one coming up this weekend, as well as holidays. The researchers place the blame on being distracted and eating with great speed. They recommend slowing down, smaller bites and enjoying your wings and pretzels. (NBC)
Berkeley doctor wants to help California patients, hospices with aid-in-dying law

Larry Beresford

The legal mechanism is complicated, with safeguards such as consent from two physicians and a 15-day waiting period, designed to prevent ethical abuses. Many California doctors are unclear on how it works, or whether they would be willing to participate for their patients. Shavelson (author of the book *A Chosen Death*, Simon & Schuster, 1995) has consulted on 22 patients who have taken the lethal cocktail with him present. In a podcast interview for the *United States of Health* Blog, he explains his role as an end-of-life care consultant for dying patients and how he has built working relationships with local hospices, which are specialized programs of palliative care for patients with incurable terminal illnesses.

Shavelson insists that his clients enroll in a hospice program because that’s where they will get the best comfort care while waiting for the option process to unfold. Hospice aims to relieve pain and other symptoms of a terminal illness, offer spiritual and emotional support, and facilitate a peaceful final phase of life, with opportunities to say farewells and wrap up life’s business. But its longstanding philosophical goal has been to neither hasten nor postpone death’s natural advance.

Historically, US hospice leaders have spoken out against legalizing medical aid-in-dying on the grounds that making high-quality hospice and palliative care more widely accessible could relieve the suffering of dying patients, thereby obviating their requests to shorten their lives. But the public by and large disagrees, with majorities favoring legalization. What happens when that opinion prevails legally? How do hospices reconcile their ethical stance with the requests made by actual patients?

In California and in Oregon, which was the first state to legalize aid-in-dying on the grounds that making high-quality hospice and palliative care more widely accessible could relieve the suffering of dying patients, thereby obviating their requests to shorten their lives. The public by and large disagrees, with majorities favoring legalization. What happens when that opinion prevails legally? How do hospices reconcile their ethical stance with the requests made by actual patients?

In California and in Oregon, which was the first state to legalize aid-in-dying on the grounds that making high-quality hospice and palliative care more widely accessible could relieve the suffering of dying patients, thereby obviating their requests to shorten their lives. The public by and large disagrees, with majorities favoring legalization. What happens when that opinion prevails legally? How do hospices reconcile their ethical stance with the requests made by actual patients?

In California and in Oregon, which was the first state to legalize aid-in-dying on the grounds that making high-quality hospice and palliative care more widely accessible could relieve the suffering of dying patients, thereby obviating their requests to shorten their lives. The public by and large disagrees, with majorities favoring legalization. What happens when that opinion prevails legally? How do hospices reconcile their ethical stance with the requests made by actual patients?

In California and in Oregon, which was the first state to legalize aid-in-dying on the grounds that making high-quality hospice and palliative care more widely accessible could relieve the suffering of dying patients, thereby obviating their requests to shorten their lives. The public by and large disagrees, with majorities favoring legalization. What happens when that opinion prevails legally? How do hospices reconcile their ethical stance with the requests made by actual patients?

How can hospices respond?

The challenge for hospices in California is to be clear on what they will or will not do. How will they promote their patients’ comfort, peace of mind and personal autonomy regardless of whether the patient wants to pursue an option they don’t endorse? Hospices are spending a lot of time talking about how to respond. Can staff discuss the option with their patients? Can they offer resources and referrals? Can they be present when the patient ingests the lethal prescription? Most—but not all—have stopped short of allowing their physicians to write the prescription for a lethal medication. Few are refusing to be involved at all, but some, particularly those that are part of Catholic health systems, walk a very fine tightrope.

Jennifer Moore Ballentine, a California-based consultant and educator in end-of-life care at the Iris Project, is offering education to health professionals in Colorado this month on the range of possible responses to its new aid-in-dying law. “Love it, hate it, opt in, opt out, public acceptance certainly seems to be accelerating, and it is going to shake up hospice and palliative care,” she says.

“In both California and Colorado, I see significant upheavals in how hospice is done, and in how hospice is perceived. Many hospices are trying to thread the needle on aid-in-dying—respecting patient choices but perhaps not directly participating. Many have already tweaked their policies several times.” For years providers battled misperceptions that “hospice is a place where they pump you full of morphine and you die,” Ballentine adds. “This has definitely changed the air that everyone breathes about hospice and end-of-life care—and not in a good way.”
Hospice by the Bay, headquartered in Larkspur, California, has done a lot of soul-searching about the end-of-life option, going back to before the bill was passed, says its chief medical officer, Dr Molly Bourne. The agency, which as Hospice of Marin was the second hospice to open in the US in 1975, strives to be practical in focus and to maximize autonomy and personal choices for its terminally ill patients.

“We met with all the people who work here, and with our ethics committee. We spent a lot of time educating staff and getting prepared, and then we studied how we responded when it happened—did staff still feel prepared?” At least six of the hospice’s patients have taken the lethal medication since it became legal, Bourne says.

“We tried to consider how we could have a neutral response. We won’t prescribe the lethal medication, and our staff will step out of the room for a few minutes when it is ingested by the patient.” But they can accompany patients on their journeys up to that point, whatever they decide to pursue, Bourne says.

“People have contacted us about it, and when we say we don’t prescribe it, they ask: Okay, who does? We had heard about Lonny and, as we got to know him, we learned that he has a lot of integrity. We have shared patients with Lonny. But we encourage our patients to first discuss it with their primary care physician, who knows them best,” she says.

**A very different death**

“In hospice, we see death and dying all day long. This is a very different form of death. When you walk away from a patient visit, knowing that they have set a death date, you might say something like: ‘If you’re not here next Thursday, thank you, it’s been an honor to know you,’” Bourne relates.

“We also spend a lot of time debriefing as a staff on these cases. We know that sometimes just having the medication on hand can give patients a feeling of security knowing that they have an out, even if they don’t go through with it. But this is a very dangerous medication. You don’t just leave it lying around the house.”

Shavelson says he is seeing a rapid evolution in the response by hospices just over the first seven months since the law was enacted. Requests have been greater than expected. He has talked to nurses who have to leave the room when their patient ingests the lethal medication because of agency policy, don’t feel right about that and start pushing to change the policy. “Hospice nurses are the most patient-centered people on earth. Hospices one by one are getting to where they won’t abandon their patients—whatever that entails,” he says.

“But one final step needs to happen. I’d like to see hospices take it over entirely, with no more me involved. I predict within a couple of years I can stop what I’m doing. I’d like to put myself out of business by having hospices step up,” he says. “I believe the people who should be doing this are hospice doctors, since they are the most capable of helping patients know their options and make appropriate decisions, of recognizing when the 15-day window of opportunity is about to close,” he adds. “If you really understand how this option works, the hospice setting is just the right place for it.”
This week in health and medicine

Aaron van Dorn

Trump Administration cancels ACA ads days before enrollment deadline

The incoming Trump Administration has canceled $5 million worth of television advertising previously purchased and paid for by the Obama Administration in the days leading up to the 2017 ACA marketplace enrollment deadline of January 31. A Department of Health and Human Services representative said the decision was made to “look for efficiencies.” The decision comes at a crucial time for ACA enrollment, as the system has seen major surges of people enrolling at the last minute. If they are unable to enroll, they will be hit with a tax penalty. (New York Times)

Cluster of amnesia cases in Massachusetts possibly linked to opioid

Researchers for the Massachusetts Department of Public Health are looking into a series of unusual amnesia cases that seem to be associated with opioid use, although the connection is unclear. Beginning with four patients who were seen between 2012 and 2015, researchers noticed that they all had unusual damage to two small structures in their hippocampus, resulting in anterograde amnesia—and all a history of opioid abuse. Researchers looked back through similar cases, ultimately identifying fourteen individuals who shared similar characteristics. Only one of the additional cases did not have history of opioid abuse. Researchers are unclear on what the link is between the symmetrical damage to the hippocampus and opioid abuse is. (CNN)

AI as good as dermatologists in recognizing potential skin cancer

A machine-learning algorithm that checks images of skin lesions performs as well as dermatologists in recognizing potential cancers, according to a new report. Researchers at the Stanford Artificial Intelligence Laboratory created the program, which was tested against over twenty board certified dermatologists. According to the researchers, the implications of the new technique could be profound. With early detection of skin cancer essential to survival, they envision a smartphone application which would allow for an immediate diagnosis if a skin lesion is worrisome or not. (CNet)

Human-animal hybrids hold hope for organ transplant, ethical concerns

Researchers at Kinki University in Nara, Japan, have reported developing embryos that are chimeras, incorporating human stem cells into fetal pig embryos with the hopes of generating human-transplantable organs. The need for transplantable organs is real, with 22 people in the US dying every day while waiting for an organ transplant. The concerns of ethicists, however, are real as well. While the human cells developed in the pig embryos so far is a tiny percentage of their total cells, concerns exist that profound changes in the pigs might be introduced, including concerns about brain development and cognition. Further research will focus on concentrating the human stem cells in specific organs. (LA Times)

Concerns over Trump prompt surge of IUD requests

Expressing concern about the future of contraceptive access under the Trump Administration, requests for intrauterine devices (IUD) have surged sense the election of Donald Trump, according to a report commissioned by Vox. According to a survey of 2500 doctors who provide IUDs across the country, requests for the contraceptive device were up sharply over the same period in 2015. The rate was even more sharply pronounced in areas carried by Hillary Clinton in the election. Contraceptives are covered as a basic feature in insurance plans thanks to the Affordable Care Act, and Republican promises to repeal the health insurance program are leaving many looking for a longer term birth control option, such as an IUD, which can last up to ten years. (Vox)
New Jersey to provide new parents with a “baby box”
Following a longstanding policy in Finland, new and
expectant parents in New Jersey can now register to receive
a “baby box,” a sturdy cardboard box filled with essen-
tial baby needs such as diapers, wipes and more. The box
also contains a mattress and can double as a baby bed for
newborns. To receive the box, parents have to register
online and complete a course of instructional videos on
how to care for a newborn, including breastfeeding and
safe sleeping practices. New Jersey has partnered with
a company that manufactures the boxes, The Baby Box
Company, to provide the baby kits. (Huffington Post)
The Women’s March and what is at stake

Mary Beth Nierengarten

The record numbers of people who participated in the Women’s March in Washington DC and in sister cities around the nation and globe showed that faith in some of democracy’s finest offerings—the right to assemble, the right to free speech—are alive and strong and remain a way that citizens hope can shape the direction of their country and their lives.

For those who I talked to at a sister march in St Paul, MN, the motivation to march was just as much about promoting human rights as it was about pushing back on the threats to these rights by the new Trump Administration. In a spirit of solidarity and celebration, people marched with signs held high showing the collage of issues that concern them—the rights of workers, immigrants, the LBGT community, disabled persons, the environment, and, of course, women’s health and reproductive rights.

Addressing the nearly 100 000 marchers at a rally on the steps of the state Capital, Rep. Betty McCollum (D-MN) urged women to send a clear message to Washington to “keep your hands off our healthcare,” and in a later article in the Minneapolis Star Tribune, honed in on what many women fear: “With an open Supreme Court seat and large Republican majorities in Congress, the threats to women’s health are the most serious in a generation,” she said.

What are the threats?

Two main threats could, in the near term, become reality as the Republican-controlled Congress readies itself to use the power of the purse to defund Planned Parenthood and follow through with the new administration’s pledge to repeal the Affordable Care Act (ACA).

Defunding Planned Parenthood. Defunding Planned Parenthood is very much in play, said Usha Ranji, Associate Director, Women’s Health Policy, Kaiser Family Foundation, in a web briefing for journalists on Wednesday, January 25.

Defunding Planned Parenthood means halting all federal funds from Planned Parenthood clinics, which, she said, basically takes away the two major sources of public funding for family planning services. These two sources are Medicaid and the Title X Federal Family Program that cover 40% and 19%, respectively, of the public funding for these services.

“These are funds which are for family planning services such as contraceptives and screening and managing sexually transmitted disease infections,” she said, emphasizing that no federal funds are used for abortion services.

Although no one yet knows exactly what is forthcoming, a reconciliation bill in the works that would allow for changes in taxes and spending will likely include the ban on federal dollars to Planned Parenthood. “Previous versions of the reconciliation bill have included the ban on federal funds to Planned Parenthood,” said Dr Ranji.

If past is prologue, the ban is expected to be in the upcoming bill. With only a $1 vote majority needed in the Senate to pass, it likely will.

Although she said that Trump and others have suggested that funds for family planning services could be redirected to other community health centers, Dr Ranji wonders if these other clinics will be able to handle the “high volume of women” that rely on Planned Parenthood clinics. “Certainly, it would take some time,” she said.

Repealing the ACA. The other main change expected, but without specifics, is repeal of the ACA. Whether it will be repeal and replace, or repeal or delay, what seems certain is that the new administration and Congress is on its way to repeal.

Saying that a full repeal could include removing coverage for preventive services, which includes contraceptive coverage, Dr Ranji said that the new administration could eliminate or scale back on these services short of full repeal. New staff under the Health Resources & Services Administration (HRSA), one of three organizations responsible for determining preventive services under the ACA, could redefine what they consider are women’s preventive services or scale back on, for example, the types of contraceptives covered, she said.

Another provision under the ACA that could be at risk is the prevention of gender discrimination in setting premium costs. Gender rating, or charging women more than men for the same insurance coverage, was routine in the individual market prior to the ACA, said Dr Ranji, adding that it previously cost women an estimated $1 billion more annually.

Although eliminating such provisions as pre-existing conditions and maintaining coverage for dependents up to age 26 would have a significant impact on women’s health, Dr Ranji pointed out that many people are talking about keeping these popular provisions. She said there is less consensus around maintaining the benefits level required for maternity coverage. “Certainly, changes to premium ratings are in play,” she said.
Identifying and treating “super-utilizers”

Ray Cavanaugh

And the top one percent of patients account for more than 20 percent of healthcare costs, according to the Agency for Healthcare Research and Quality. Gaining traction in the US is the term, “super-utilizers,” which refers to a small section of the population that accounts for a large portion of emergency room visits and puts a heavy burden on hospital services and public health budgets. The term reached a significant audience by way of a 2011 Atul Gawande article for *The New Yorker*, which profiled the work of New Jersey doctor Jeffrey Brenner, who identified super-utilizer hotspots in a way akin to how police identify crime hotspots.

These types of patients can be especially challenging because they’re often dealing with homelessness, addiction, and mental illness. Owing to these issues, they frequently bounce from emergency rooms to shelters to jails. Super-utilizers have existed for decades, but only in the last few years is the issue starting to be addressed in a coordinated way, as hospitals, insurers, philanthropic foundations, and lawmakers in different parts of the country realize that something has to be done about a population of patients who amass astonishingly disproportionate costs to the system and yet continually fail to get the care they need.

There is currently no comprehensive fixed criteria for what constitutes a super-utilizer. Some groups, such as the Centers for Medicare and Medicaid Services, mention “individuals with 4 or more visits per year,” but there are patients who make far, far more visits than that. Some, in fact, can accumulate more than 100 annual ER visits, and cases can be found which considerably exceed even that amount.

Some visit the ER to get a warm, safe place to sleep and a few adequate meals. Staying in a hospital isn’t most people’s idea of a fun time, but for someone who is homeless, a hospital stay can seem like an enticing alternative to a night on the streets (particularly when it’s cold) or in a homeless shelter, many of which can be chaotic and dangerous. In a $250,000 pilot program that launched in late 2015, the University of Illinois Hospital & Health Sciences System tried an approach that might seem radical to some: give super-utilizers free housing. Twenty-five such patients are currently receiving $1000 per month for housing, which is more cost-effective than having them accumulate $3000 daily bills in hospital ERs.

Another possible solution is having specialized community paramedics deal with super-utilizers so they don’t make as many ER trips. Such paramedics go beyond their conventional role of emergency response and provide outreach care to patients who otherwise would call 911 for transport to the ER. One community paramedic program in Minnesota, for example, has already seen super-utilizer ER use decline by 60–70 percent.

Community paramedicine programs are surfacing in both urban and rural settings around the country. California, for example, has 13 community paramedicine pilot projects underway in a dozen locations, according to the state’s Emergency Medical Services Authority. California’s community paramedics are also identifying the most frequent 911 callers and connecting them with the type of services—be they medical or social—that can lower numerous ongoing ER visits.

Along with frequent emergency room visits, super-utilizers often enter the criminal justice system and are incarcerated with dangerous offenders instead of receiving treatment for chronic mental illness or substance abuse issues. In an effort to divert nonviolent super-utilizers away from prisons and place them in venues where they could receive more appropriate care, the Illinois Criminal Justice and Informational Authority has worked with the Illinois...
Hospital Association to keep track of super-utilizers by creating a super-utilizer data bank, which would enable authorities to know when they come into contact with a super-utilizer.

Super-utilizers tend to “end up in jail or prison because local law enforcement have arrested them multiple times for low-level offenses like disturbing the peace or retail theft,” says John Maki, executive director of the Illinois Criminal Justice Information Authority. “We’ve heard from law enforcement that they will end up arresting and taking them to jail because they feel as if they have no other way to respond to them.”

“Correctional facilities are often by design severe places, governed by strict rules and procedures,” Maki points out. “If you are suffering from a mental illness, you will likely struggle in this kind of environment. The symptoms of your mental illness will likely lead you to act out in ways that will lead to further punishment, the end of which is typically disciplinary segregation.”

“When criminal justice and health systems work together in ways to identify and direct super-utilizers into community-based services, they can produce much better outcomes for this population,” says Maki. “For instance, crisis stabilization centers provide law enforcement with a much more effective alternative for people they encounter with serious mental illness than jails or emergency rooms.”

Through the creation of data banks, community para-medicine, and experiments with free housing, more providers in the US are getting serious about striving to meet the needs of super-utilizers while lowering costs to the system.
This week in health and medicine

Aaron van Dorn

Child dies in California’s severe flu season
This flu season is proving a deadly one in California, where a child has succumbed to the illness. Deaths are up sharply this year over last, with fourteen people under the age of 65 dying so far, compared with only three at the same time last year. Experts also warn that the number of deaths attributed to influenza are likely underestimated, due to the flu not often being listed as a cause of death. (LA Times)

Public health organizations express concern over malaria funding under Trump
With incoming President Donald Trump using his inaugural speech to declare that his administration would put “America first,” many on the front lines global public health are concerned about the US’s continued support of projects to combat malaria around the world. The US currently accounts for 35% of the international funding to combat malaria. Bill Gates of the Gates Foundation has called upon Trump to maintain funding at levels established by George W. Bush and maintained by Barack Obama. (Huffington Post)

Outbreak of Seoul virus among rat breeders
Seoul virus, a form of hantavirus linked to rodents, has infected eight people across the US who breed rats. Hantaviruses were only discovered in 1993, and cannot be passed from human to human, but from interaction with rodent bodily fluids, urine or feces. Rats are often traded among rat breeders, so the CDC is working with local health organizations to see if there might be more unreported cases. (NBC News)

Vapers for Trump
Tobacco lobbyists are hoping to use new US President Donald Trump’s promise to rollback federal regulations to create a more favorable environment for e-cigarettes and other forms of tobacco, as well as a repeal of a 2016 law that treats e-cigarettes as cigarettes. The stakes for the tobacco industry are large, as a recent report from the Surgeon General showed that cigarette usage among young people has fallen, with e-cigarettes becoming the most commonly used form of tobacco among those 18-24. (Business Insider)

Poverty harder on women’s heart health than men’s
While people from poorer backgrounds are more likely to suffer from heart trouble, According to a new review, poor women are at greater risk of heart trouble than men. The review looked at over one hundred studies covering 22 million people. Heart disease is the leading killer worldwide, but according to the report, women in poverty have a 25% greater chance of heart attacks than men in similar circumstances. (US News & World Report)

Collins to stay as head of NIH, at least for now
The incoming Trump Administration has asked Francis Collins to remain as head of the National Institutes of Health, at least temporarily. No further details of Trump’s plans for the NIH were forth coming, but Collins has met with Trump and expressed interest in staying on in his position. (Washington Post)
CBO scores potential fallout from Affordable Care Act repeal

Aaron van Dorn

According to the new report, the CBO estimates that the number of uninsured Americans would jump by 18 million people in the first year after repeal, with the number of uninsured spiking to 32 million by 2026. The cost of insurance premiums on the individual market are estimated to increase by 20% to 25% in the first year over projects based on current law, jump to 50% the following year and double by 2026 when the bill’s delayed Medicaid expansion repeal takes place. The CBO also estimates that repeal would leave about 10% of the nation’s population with no insurers participating in the nongroup market, leaving those without employer- or government-provided health care without options for insurance coverage.

House Majority Whip and Louisiana Congressman Steve Scalise took to Twitter to decry the report, stating, "CBO misses the point. Obamacare will be replaced with lower costs and more choices," and "The CBO report assumes no Obamacare replacement. In reality, we will provide people with coverage that they want and can actually use.” However, Republicans in Congress have so far offered no details on the “replace” aspect of “repeal and replace.”

LOS ANGELES, CALIFORNIA—JANUARY 15, 2017:
Sen. Kamala Harris, D-Calif, at podium, cheers health care workers to save the Affordable Care Act across the country outside LAC+USC Medical Center
The rally was one of many being staged across the country in advance of President-elect Donald Trump’s inauguration on January 20. Trump has promised to repeal and replace the health care law, and the Republican-controlled Senate on Thursday passed a measure taking the first steps to dismantle it.
AP Photo/Damian Dovarganes
This week in health and medicine

Aaron van Dorn

Nevada woman dies from antibiotic resistant bacterial infections
According to Nevada public health officials, a woman infected with *Klebsiella pneumonia*, a bacteria commonly associated with urinary tract infections, has died. The infection has proven resistant to all 26 antibiotics available in the US, raising concerns over an increase in entirely drug-resistant bacteria, often referred to as “superbugs.” While still uncommon, the issue of antibiotic resistance is concerning to researchers and clinicians, as the pace of bacteria developing resistance seems to be outpacing the development of new antibiotics. (Stat News)

Stress can contribute to heart attacks, Sanford vindicated
While it’s long been a staple of popular culture that stressful situations can contribute to heart attacks, there’s finally some evidence to back up the assertion. In a longitudinal and cohort study, researchers at Harvard and Massachusetts General Hospital (published in *The Lancet*) have found that overstimulation of the amygdala, a small area of the brain that reacts to stress, anxiety and fear, can cause increased activity in the bone marrow and inflammation of the arteries that can lead to a heart attack. (Medpage Today)

The state of marijuana in 2017
Following a year that saw the expansion of legal marijuana in one form or another to half of the states, and a new year that brings a great deal of uncertainty to the legality of marijuana going forward, the National Academies of Science, Engineering, and Medicine have issued a new report that takes a look at the state of marijuana research, summarizing more than ten thousand studies that looked at the effects of marijuana. The report argues that, contra the FDA, which declined to reschedule marijuana in 2016, there are benefits to the drug in numerous areas, including pain reduction, nausea and can help with chronic pain. However, the report also identifies a number of gaps in the research on both the positive and negative effects of marijuana, and suggests some avenues of research and regulatory changes that could help fill in the gaps. (Forbes)

New peanut allergy guidelines leave parents shell-shocked
The changes in guidelines for the introduction of peanuts and other potential allergens to infants—listen to our interview with Dr Matthew Greenhawt, one of the authors of the new guidelines here—have left many parents feeling confused, conflicted and even guilty. While the new guidelines are based on the best currently available science and backed by clinically controlled trials, parents are frustrated by the feeling that they were doing the wrong thing for their children raised under the old guidelines. (New York Times)

CVS reduces price of generic version of EpiPen
Last year, drug company Mylan severely hiked the price for the EpiPen, the commercial name for an Epinephrine autoinjector used to treat anaphylactic shock for people with severe allergies. In 2015, the EpiPen represented 89% of the market for Epinephrine autoinjectors. In response, CVS has announced that it will be selling a generic Epinephrine autoinjector for a sixth of the price of an EpiPen. Adrenaclick, the generic version offered by CVS, will sell for $110 for a two pack, versus $600 for a two pack of the EpiPen (Mylan also offers a generic version of the EpiPen, for $300 for a two pack). (CNN Money)

Biosensors may soon know you’re sick before you do
A new study has shown that an array of biosensors—such as smartwatches and fitness trackers that measure movement, heart rate and skin temperature—might be able to predict when an illness is coming on before you’d be able to feel it. The research suggests that close measurement of your biometric signs—up to 250,000 times a day—might be able to reveal a baseline level of your physiology, and note when significant deviations occur that might mean an illness is coming on. (Huffington Post)
FRIDAY, DECEMBER 30, 2016—03:45

Year in review
The Lancet USA 2016

Rebecca Cooney and Aaron van Dorn

The future of the Affordable Care Act
In the acrimonious lead-up to the presidential election, scrutiny of the ACA or Obamacare intensified, focusing on whether the contentious law would continue to be viable in the face of a Trump presidency and Republican calls to “repeal and replace” it with a hitherto unknown alternative. Since then, a new rally of “repeal and delay” has emerged signifying that Republicans are aware of both voter backlash from supporters touting the expansion of coverage to nearly 20 million Americans as well as the potential to introduce unforeseen volatility in the health-care market if exchanges are eliminated. Others suggest that the substantial price increases for plans in states such as Minnesota and Oklahoma, a serious and ongoing point of criticism of the ACA, may be plateauing and could represent a one-time market correction to bring the price of health-care plans in line with the actual costs of care. With no consensus on the part of Republicans, mixed signals from Trump, and stalwart Democratic support, the fate of the most significant overhaul of the health-care system in half a century is still unknown.

For more, listen to podcasts on the viability of a public health care option with Salomeh Keyhani and Alex Federman, health sector growth and the ACA with Peter Ubel, and what the outcome of the election means for US health policy with David Himmelstein.

Opioids and the decline of life expectancy
While the opioid epidemic continues to rage across the country, new data released this year by the National Center for Health Statistics illuminated a fearful consequence—increasing numbers of middle-aged white Americans dying has contributed to life expectancy declines. Although the dip in life expectancy in this group was relatively small (in white men, 78.9 years in 2013 and 78.8 years in 2014; in white women, 81.2 years in 2013 and 81.1 years in 2014), it reflects the disturbing trend that the uptick in deaths associated with opioid abuse is substantial enough to influence life expectancy from birth of white Americans as a group. Importantly, drug overdose surpassed other categories such as gun violence to become the leading cause of accidental death in the USA as if 2015. With no signs of abating, the toll of opioid abuse is likely to continue, dragging life expectancy estimates along with it.

The EpiPen and drug pricing
Seldom do issues of health raise the ire of both sides of the aisle as much as drug pricing has in 2016. After word spread that drug maker Mylan had raised the price of the epinephrine autoinjector EpiPen by nearly 400%, Congress, in a rare alliance with consumers and advocates, pushed for an explanation. During the heated rounds of a committee hearing, the pharmaceutical company tried to link the price hikes to reduced profits from taxes and increased production costs. Congress wasn’t buying. But since the hearings in September 2016, there has been relatively little additional discussion about the issue of setting drug prices and regulation of drug manufacturers along with other important topics like the inability of CMS to negotiate pricing. While attempting to avoid similar scrutiny of their pricing practices, pharmaceutical companies may be chastened for now, but without any substantive changes in legislation or regulation, it is likely just a matter of time before they become emboldened again.

For more, listen to a podcast on drug pricing with Peter Bach and read EpiPen’s price-gouging response “sickens” Congressional panel.

The Zika epidemic hits home
With a similarly exotic name and previous absence in North America, the emergence of Zika virus evinced parallels with the Ebola virus epidemic that began in 2014. Fortunately, Zika, the mosquito-borne virus, is generally less lethal, though not without another set of dire complications. In 2016, after WHO declared the outbreak a public health emergency, came the first scientific consensus that Zika caused birth defects and neurological problems, notably, microencephaly in infants born of mothers who were infected. Zika swiftly became a household word as one of the hotspots of the outbreak, Rio de Janeiro, Brazil was also set to host the 2016 Summer Olympics. The Olympics proceeded amid concerns of mosquito abatement, poor local health infrastructure and sanitation, as well as the risks posed by spread via international travel and sexual transmission. But Zika also became a domestic issue. As of the end of this year, over 4500 US cases have been acquired from travel and 216 cases have been attributed to local acquisition, primarily in Florida. CDC has reported that 17 babies in the US have been born with Zika-related birth defects.
For more, read Zika virus continues to spread, CDC issues Florida travel advisory and Obama rejects Zika funding approved during Democrats’ sit-in.

**Flint water crisis**

Since the Fall of 2015, when local and state officials acknowledged the grave situation of major lead contamination in the water supply in Flint, Michigan, the saga has continued to drag on. Government and independent sampling have indicated some improvement in the last year in the quality and levels of lead present in the Flint drinking water supply, which became tainted when the city switched from a Detroit-based water system to the Flint River without taking adequate precautions to control for corrosion. But grave concerns persist. In June, officials removed restrictions and maintain that filtered tap water is now drinkable for all Flint citizens, including pregnant women and children. No timeline, however, for potable unfiltered water has been presented publicly. The mistrust between the public and officials, along with the threat of negative health outcomes from lead exposure, remains.

**Restriction of abortion rights/contraception coverage**

Abortion rights continued to be a contentious issue in 2016, with many states continuing to enact new and novel forms of abortion restrictions that went far beyond limiting what gestational age abortions could be performed. The Supreme Court reversed a Court of Appeals decision and struck down a Texas law that placed severe restrictions on the kinds of facilities abortions could be performed. Texas responded by changing the rules of how miscarriages and aborted fetuses could be treated, requiring that mothers provide cremation of burial services instead of disposing of them as medical waste. Oklahoma’s Supreme Court struck down a law that would require that abortion providers have admitting privileges at local hospitals, a stance that abortion rights advocates and medical professionals argue is unnecessary for a safe and effective procedure. Most recently, Ohio’s Gov. John Kasich signed a bill that would outlaw abortions after twenty weeks, but vetoed a more severe law that would have outlawed all abortions once a fetal heartbeat was detectable, often as early as six weeks after conception, and often before a woman may know she’s pregnant. With the incoming Trump Administration getting to fill at least one and potentially several Supreme Court positions, for the first time in a generation there’s a very real possibility that the landmark law Roe vs Wade, legalizing abortion across the United States, could be overturned.

**Cancer Moonshot**

Recalling John F Kennedy’s ambitious call to place a man on the moon within ten years, President Barack Obama announced a “cancer moonshot” at his State of the Union address in 2016. Headed up by Vice President Joe Biden, the goal of the program was to accelerate research funding to develop a decade’s worth of progress on preventing, diagnosing, and treating cancer in five years. The aim of the program is to build a national cancer data ecosystem to allow researchers and clinicians to share patient data that has often remained locked into individual institutions, as well as to make it easier for patients to find clinical trials applicable to their diagnoses. The program hopes to continue to encourage public-private cooperation to streamline both the research pipeline and disseminating the most effective treatments and methods of detection.

For more, read Biden Pledges for Open Data for Cancer Moonshot.

**CRISPR court battle**

In a story that has echoes of the fight between Isaac Newton and Gottfried Leibniz over who invented calculus in the 17th century, one of the biggest medical news stories has little to do with medicine and a lot to do with patents. The central technology at question, the CRISPR gene-editing tool, has the potential to revolutionize working with DNA, but the story in 2016 was who owns the rights to—and who gets the money from—it. Two groups of researchers (Jennifer Doudna at UC Berkeley and Emmanuelle Charpentier at the Max Planck Institute for Infection Biology in Berlin, and Feng Zhang at the Broad Institute at MIT and Harvard) filed patents concurrently over the technology. Doudna and Charpentier filed their patent first, but Zhang’s was issued first. At stake is potentially billions of dollars, for both the researchers and the companies that want to make use of the technology. At least four companies looking to use the technology have received investments totaling $5 billion dollars, but depending on who ends up receiving the patent—and the potential outcomes range from only one of the groups, both or no one, if the patent office decides the technology isn’t patentable—any commercial exploitation of the technology will require a license from whomever holds the patent. The hearings and deliberations of the patent office are expected to continue through 2017, but the potential consequences are enormous.

**Failure to reschedule marijuana**

This year was a remarkable one for marijuana, with three states voting to join Colorado and Washington in outright legalizing the drug for recreational use and a number of other states legalizing medicinal usages, making medical marijuana legal in half of the states. But marijuana advocates had hoped for a larger victory, when the DEA announced over the summer that they were considering rescheduling the drug. Drug scheduling, the system by which the FDA classifies drugs, ostensibly organizes them...
by their potential for harm or abuse as well as their benefit. Schedule I drugs, which includes heroin, LSD, MDMA and marijuana, are those the FDA feels have no benefit and significant harms. Marijuana advocates who had hoped that the DEA would follow the lead of states in approving a reduction in marijuana's scheduling were disappointed when the FDA and the DEA declined to change its status. The FDA cited a lack of compelling evidence from controlled clinical trials of the benefit of the drug. It’s an open question if the incoming Trump Administration will continue the Obama Administration’s policy of turning a blind eye to states experimenting with marijuana legalization (which remains illegal at the federal level), but it seems unlikely marijuana will be rescheduled any time soon.

For more, listen to a podcast on rescheduling marijuana, research, and health with Rosalie Liccardo Pacula and read How Should Hospices Handle Legalized Medical Marijuana?

Theranos no more?
The story of the rise and fall of the high-flying medical testing start up is one of the strangest and most fascinating medical stories of 2016. Created by Elizabeth Holmes, then a nineteen-year-old college dropout, on the promise of a new way to replace a whole panel of blood tests that would traditionally require vials of blood with only a finger prick, the company eventually rose to a nearly $10 billion valuation before the fact that their much ballyhooed technology didn’t actually work brought it all crashing down. It’s a story of secrecy, suspension of disbelief, scientists driven to suicide, and black turtlenecks that sounds more like a technothriller than real life, but the tale remains fascinating.

For an in-depth account, read the article by Vanity Fair.
Voices in medicine
Medical training in an age of uncertainty

Ishani Premaratne

Standing on the floor of the Javits Center the night of Tuesday, November 8, I figured my medical school assignments could wait—after all, history was about to be made right there under that enormous, triumphantly blue-tinged glass ceiling. But as the hours passed, and the merriment of Hillary Campaign supporters at what was intended to be a victory party moved from optimism into a shocked stupor, I stared at the TV monitors while reporters and camera crews scurried about trying to catch the reaction of the crowd. It was 11pm and tears had already started streaming down my face.

My classmates and I at Weill Cornell Medicine had class the next day at 8am. As we shuffled into the classrooms across the street from our residence hall, we glanced at each other’s distracted gazes, some of us more visibly shocked than others. At 9:30am our professor offered some words of encouragement and solace to those of us staring at him glassy-eyed, paused ever so briefly, and then proceeded with his lecture on antibodies.

As an aspiring physician, and particularly as a woman, I cannot deny that this presidential election left me in some ways broken. I was raised to believe fiercely that a woman’s worth should be no less than a man’s, and that fierceness breathed fire into my rage in the aftermath of the election. My questions about the future of health-care delivery in America, and concern for the preservation of inclusivity in medicine, are ones that will continue to drive my motivation to keep working.

There is a deeper question to be answered here: what kind of training will doctors receive during the Trump years? How does the tenor of the country, and potential changes to the Affordable Care Act (ACA), translate to the tenor of the medical school classroom and clinic, or does it matter not at all? My inkling is that it does matter, but as a medical student who is at the very beginning of her training, the answer to this question also scares me because of what it means for my future patients.

The potential damage may come in the form of rolled back benefits if the ACA is in fact repealed or sufficiently weakened. For example, we must consider the possibility that gutting the law would also mean gutting the requirement that insurance companies cover those with pre-existing conditions. What this means for doctors-in-training is that the patients whom we are less likely to see in primary care centers are those who are suffering from chronic illnesses, and the as many as 30 percent who will develop a chronic illness in the next eight years. Instead, we will see these patients in emergency rooms only after preventable complications have already occurred. On balance, this means that our outlook as physicians will necessarily trend towards crisis management instead of prevention and early intervention.

The potential damage also comes in the form of exacerbated sociocultural barriers to care, which is something that I became particularly attuned to as an undergraduate student in Boston speaking to members of minority communities about their interactions with medical practitioners. The structural and social barriers to the doctor-patient relationship among these populations became real to me in the many conversations I had with them. infused with their powerful narratives and an unabated flow of coffee, these conversations revealed the open reality of structural inequalities that go too often ignored. They empowered me to see the barriers to equal access to care—be they lack of insurance, health illiteracy, intimidating power dynamics, or poor care coordination between physicians that allowed some patients to fall through the cracks—that others simply did not or could not see, and guided me to be the kind of doctor who could help make those barriers vestiges of the past. Now, I think even more about the men and women whom I spoke to in those minority communities in Boston, and the language, cultural and socio-economic barriers that impede their access to health care.
Many of them are members of the cohort of 20 million who received insurance because of the Affordable Care Act (ACA). I wonder if they will be discouraged from seeking preventive care and speaking freely in their doctors’ offices due to uncertainty about the future of their health insurance, or fear of having no place in an America that has seen an upswing in anti-immigrant rhetoric and backlash against people like them. If care that once took place in primary care physicians’ offices is shifted to emergency rooms, I worry that we, the current crop of doctors-in-training, will never learn how to build relationships with the patients who, in many cases, are most in need of our support.

In the aftermath of the 2016 Presidential election, I worry about limitations in the kinds of exposure medical students will receive to patients from underrepresented backgrounds through their training. Indeed, in the Trump years, it is the patients whom I will not see who trouble me most. This is concerning for the health-care system as a whole because health care and its conditions are sewn through social networks as collective, and not individual, phenomena. One person’s ill health could very well impact the health of his neighbor. The altered health care-seeking behavior of a single patient who loses insurance if the ACA were to be repealed, or who feels alienated in Trump’s America, and is discouraged from seeking care, risks influencing the health care-seeking behaviors of members of his community, and solidifying as dogma the notion that health-care providers are not, or cannot, be considered allies. If this were the case, we all stand to lose because our health is linked.

Presidents impact policies, certainly, but ultimately I think the crucial question we must ask is if they impact the more quotidian aspects of our daily professional lives. Do we believe, for example, that they impact the way physicians practice? Despite the uncertainty that has arisen in the aftermath of the election, and the potential consequences for patients and physicians alike, I think medical students have reason to be optimistic that hospitals and their codes of ethics will survive the test of both time and this presidency. Atul Gawande writes in The New Yorker, “Our hospitals and schools didn’t suddenly have Reaganite values in the eighties, or Clintonian ones in the nineties. They have evolved their own ethics, in keeping with American ideals.” If the commitment that the medical profession has to treat all patients equally regardless of their background is a bellwether for the rest of society, then these “institutions of our daily lives” will become even more important in the Trump years.

This means, too, that medical students will have a greater responsibility to be attuned to changes in the health-care system that may be promulgated from the outside in the years to come. We will have to do more to engage with minority communities, to survey cost-cutting measures at the hospitals that employ us, and to fight for opportunities to engage in the policy decisions that may very well impact the patients who have access to our care—and those who do not. America’s medical students and physicians are, as ever, in powerful positions to advocate for those who feel excluded from the policies that may emerge. And for them, we fight even harder.
This week in health and medicine

Aaron van Dorn

Texas fetal burial regulation temporarily halted
A federal judge has temporarily halted implementation of Texas’ controversial “fetal burial” regulation following a legal challenge from a pro-abortion group, the Center for Reproductive Rights. The stay is only temporary until the legal challenge can be further adjudicated. The regulation, which would require fetuses from abortions and miscarriages to be cremated or buried at the expense of the mother, has raised numerous objections from abortion rights groups. (Huffington Post)

CMS scraps Medicare drug pricing changes
Proposed changes to the way Medicare reimburses doctors for drugs prescribed to patients has been dropped by the Center for Medicare and Medicaid Services in the wake of pushback from the pharmaceutical industry and doctor’s groups. Part of a number of experiments designed to lower health care costs, the Medicare Part B Drug Payment Model would have lowered reimbursement rates for doctors on drugs given to patients from 6% to 2.5%, with an added flat fee. There were concerns that the changes would prevent doctors from prescribing more expensive drugs for patients if it meant the costs were higher than the reimbursement. (The Hill)

Lifetimes of mice extended by reprogramming genome
According to a study in the journal Cell, scientists at the Salk Institute in La Jolla, California, were able to reverse the effects of aging on organs in mice and extend their lifespans by 30% by directly manipulating their genomes. While the techniques cannot be ethically be applied to humans, the scientists hope that they can show the way towards a better understanding of human aging and the possibility of other forms of treatment. (New York Times)

Healthcare.gov sign-up deadline extended
The Obama Administration has announced that they are extending the sign-up period for Healthcare.gov, the federal healthcare marketplace. The new extension is until 11:59pm Monday, December 19 Pacific time for plans beginning on January 1, 2017. The administration says that extension is needed due to the volume of interest. The original deadline was for Thursday. (NBC News)

Mumps outbreak at University of Missouri
A severe outbreak of the mumps has occurred at the University of Missouri in Columbia, Missouri this year, with 228 confirmed cases since the fall, out of a population of about 25,000 undergraduates. All infected students had received the two required measles, mumps and rubella vaccinations. The university is recommending that all students receive a third MMR booster. (Columbia Tribune)

Hawaii healthiest, Mississippi unhealthiest of the States
A new report from a non-profit health care group, United Health Foundation, has ranked US states according to how they do on a number of health indicators, including obesity level, insurance coverage, and smoking rates. According to the report, Hawaii is the healthiest state for the fifth year in a row, with Massachusetts in second. Mississippi is the unhealthiest state, with Louisiana second. (MarketWatch)
Biomedical research bill becomes law, but critics raise concerns over long-term implementation

Susan Jaffe

The overwhelming support for the law marks a stark contrast from the Affordable Care Act, another landmark health reform bill Obama signed in the second year of his presidency. Republicans promise to repeal it as soon as the new Congress convenes next month and Donald Trump is sworn in as president. But before the promised elimination of the ACA, Congress took $3·5 billion from its Prevention and Public Health Fund to pay for most of the new law.

The Cures Act passed with approval from 87 percent of the House of Representatives and 94 percent of the Senate. The vote came within a month of what many Americans consider one of the most unprecedented and divisive presidential elections in US history.

“This bipartisan law is a Christmas miracle,” said Sen. Lamar Alexander, a Tennessee Republican and the chairman of the Senate’s health committee, in an op-ed this week. The law “shows the government at its best,” said Vice President Joe Biden at the White House signing ceremony. “And it shows that our politics can still come together to do big, consequential things for the American people.” Obama appointed Biden to head his Cancer Moon Shot initiative to find ways to speed up cancer research, prevention, and cures.

“I believe that the United States of America should be the country that ends cancer once and for all,” Obama said before signing the law. “This bill will bring us even closer, investing in promising new therapies, developing vaccines, and improving cancer detection and prevention. Ultimately, it will help us reach our goal of getting a decade’s worth of research in half the time.”

Among the few dissenting lawmakers, was Sen. Elizabeth Warren, the progressive Massachusetts Democrat who argued that the bill would weaken oversight of pharmaceutical companies. “I will fight it because I know the difference between compromise and extortion,” she said shortly before the Senate voted last week.

Dr Michael Carome, director of Public Citizen’s Health Research Group, a consumer advocacy group, said the law could weaken the standards of evidence for drugs seeking FDA approval for new indications other their original approved use. However, the Pharmaceutical Research and Manufacturers of America, which represents many of the leading US biopharmaceutical research companies, said the law’s “pro-patient, science-based reforms” would promote competition and “the timely review and approval of new treatments.”

Connecticut Representative Rosa DeLauro, a Democrat, also criticized the bill because it failed to deal with the “excessive prices” of prescription drugs. And she is concerned that there is no guarantee that the Cures Act will get the money Congress promised.

The law gives the $4·8 billion to the National Institutes of Health over a ten-year period for Obama’s cancer, precision medicine and brain research initiatives. Another $500 million goes to the Food and Drug Administration, also spread out over a decade, and $1 billion will help state programs to treat opioid abuse. However, Congress must approve the funds every year before they can be spent.

Representative Diana DeGette, a Colorado Democrat who attended the bill signing is confident the money will be provided. She said there is a strong bipartisan commitment in Congress for the biomedical research the law targets. As a member of the House of Representatives Energy and Commerce Committee, she worked closely with the Republican chairman, Fred Upton of Michigan, for over three years to secure that support.

But some health advocates worry that as Congress faces mounting budget pressures in the next ten years, lawmakers could be tempted to use the Cures Act money to justify keeping NIH’s overall funding stagnant, or even make cuts. “It is going to be hard to find money to increase NIH’s base discretionary budget,” said Emily Holubowich, executive director of the Coalition for Health Funding, which includes healthcare provider, patient advocacy, public health, and scientist groups. “This new cures fund gives them a little bit more of an excuse to say we’re going to hold NIH flat because there are other priorities that need to be funded.”

This post was updated on December 16, 2016.
This week in health and medicine

Aaron van Dorn

Potential antidote to carbon monoxide poisoning developed
Researchers at the University of Pittsburgh have discovered a potential antidote to carbon monoxide poisoning. The study shows that the antidote can be used to cut the amount of carbon monoxide in the bloodstream by half within 25 seconds in mice. It can take over five hours for carbon monoxide in the bloodstream, and treatments at a hospital can reduce that to two hours or twenty minutes, depending on the severity of the intervention, but the new intervention could potentially be provided by first responders on the spot. If the same results hold true for humans, it could make an enormous difference in how a previously deadly affliction is treated. Carbon monoxide is odorless and colorless, and deaths due to carbon monoxide poisoning are split between accidental exposure from faulty stoves and gas leaks to intentional suicide. (Pittsburgh Post-Gazette)

US life expectancy falls for first time since 1993
2015 saw a fall in life expectancy, with the amount dropping by a bit more than a month to 78.8 years. This follows on from several years of flat life expectancy findings, although this is the first drop since 1993. Cancer and heart disease were major factors, although “unintentional deaths,” which included car crashes and accidental drug overdoses rose by 3%. The drop was stronger for men than women, with men falling from 76.5 years to 76.3 years. Women’s rates dropped less sharply, by less than a month to 81.2 years. (USA Today)

Surgeon General raises concerns over adolescent e-cigarette use
Virvek Murthy, US Surgeon General, has issued a report calling e-cigarette use among adolescents and young people a major public health concern. Use of tobacco cigarettes among young people has fallen, with e-cigarettes becoming the most commonly used form of tobacco among young people, tripling among middle and high school students, and doubling among those aged 18 to 24. While advocates for e-cigarette use claim that the products are less harmful than combustible tobacco, critics claim that they are being marketed towards young people, with various flavors like bubble gum and blueberry. (Washington Post)

Bristol-Myers Squibb settle allegations
Drug company Bristol-Myers Squibb have settled allegations over anti-psychotic drug Abilify. The company was accused of misleading doctors on the drugs dangers, as well as promoting it for off-label uses among children and elderly dementia patients. According to the settlement, which stemmed from an investigation by 42 states, the company admits no wrongdoing, but agreed to marketing restrictions and to pay $19.5m. (US News & World Report)

Drug overdose deaths highest ever in 2015
The US opioid crisis continues, with overdose deaths raising 11% to reach a new high of 52,404 in 2015 according to a new report from the Centers for Disease Control. Heroin was a main driver, with overdose deaths rising 23%, totaling nearly 13,000 deaths. Synthetic opioids like fentanyl had a striking rise, jumping 73% with nearly 10,000 deaths. Opioids Vicodin and Oxycontin also rose 4% and claimed more than 17,000 people. (Chicago Tribune)

CDC urges flu vaccinations
This week has been named by the CDC as the National Influenza Vaccination Week, in an effort to encourage people to go out and receive flu vaccinations. The program began in 2005. The CDC estimates that deaths from the flu ranged from 12,000 during the winter of 2011 to as many as 56,000 during the winter of 2012. Effects of the flu vary from year to year due to changes in the severity and duration of the outbreak. (News-Review)
This week in health and medicine

Aaron van Dorn

Texas rules miscarriages must be cremated, buried
New rules pushed by Texas Governor Greg Abbott would require that fetuses—whether from abortion, or do to miscarriage—would be required to be buried or cremated, and the cremated remains either scattered or buried. Cremation can cost up to $4000, and according to the National Funeral Directors Association, in 2014 the average funeral cost $7181. Previously, such remains were treated as medical waste and could be treated as medical waste disposed of in sanitary landfills. Critics view the new regulations as a punitive measure to make abortions too costly for many. The new rules follow the Supreme Court rejecting a Texas statute that would have closed half of Texas’ remaining abortion clinics. (Huffington Post)

Trump begins nominating health positions
President-Elect Donald Trump’s transition team has announced nominations for several health-focused positions. To run the Center for Medicare and Medicaid Services, Trump has chosen Seema Verma, who worked with Vice President-elect Mike Pence as Governor of Indiana in the expansion of Medicaid in the state. The expansion, which Verma helped to design, is more complicated and less generous than Medicaid expansions in other states, with a greater degree of paperwork and great expense to the patients, primarily poor and working class residents. For the Department of Health and Human Services, which oversees health care policy in the US, Trump has chosen orthopedic surgeon and Republican Congressman Tom Price of Georgia. Price is a strong critic of the Affordable Care Act, and has authored several bills aimed at repealing and replacing the health care law. (Washington Post, New York Times)

Virginia braces for outbreak of hep C, HIV
Virginia State Health Commissioner Dr Marissa Levine warns that the ongoing opioid epidemic might leave the state vulnerable to a large outbreak of hepatitis C and HIV infections. While HIV infections have remained stable, hepatitis C infections jumped from 6000 to 8000 between 2014 and 2015. In 2014 and 2015, Indiana faced similar outbreaks of hepatitis C and HIV following epidemic levels of opioid drug use in rural counties. (Richmond Times-Dispatch)

Billions of dollars in economic loss attributed to lack of sleep
While many successful people brag about how little sleep they need, a new report of the economic impact of sleep deprivation in five major countries argues that $411 billion, or 2.28% of GDP, is lost each year to the effects of sleep deprivation on American workers. The losses are attributed to productivity loss from fatigue, illness and depression, all of which can stem from sleep deprivation, and an increase in mortality. Japan had the highest loss in the report, at 2.92%, and Canada and Germany the lowest, at 1.35% and 1.56% respectively. (Washington Post)

Researchers believe Parkinson’s disease linked to microbiome
New research has found a link between the neurodegenerative disorder Parkinson’s disease and our body’s microbiome. While previous studies had suggested a link, this is the first direct indication of the link. Researchers found that mice with a microbiome accumulated the protein alpha-synuclein, build-up of which is a key factor in the development of Parkinson’s, while mice who lacked a microbiome did not. Further experiments indicated that certain bacteria in the microbiome of Parkinson’s patients could contribute to the condition. Researchers hope to further identify bacteria responsible, towards producing a treatment. (CNBC)
Emergence of the corporate palliative care sector

Larry Beresford

Aspire’s specialty-trained palliative care teams, which include nurse practitioners, social workers and chaplains, provide home visits and telephonic support to patients with serious, advanced or terminal illnesses in 42 cities across the United States. Since Aspire launched in 2013 with venture capital support, more than 20,000 patients and their families have received this team-based care, which incorporates emotional, spiritual and mental health support, attention to physical symptoms, and help in navigating a complex health care system. Aspire teams typically are engaged by managed care plans and health systems that have assumed financial risk for providing health care to defined populations of beneficiaries.

They buy the service because Aspire, like many other palliative care programs and services before it, has documented higher patient satisfaction scores, better management of pain and other symptoms, fewer unwanted or unnecessarily aggressive treatments, all at lower cost on average, without denying treatments desired by the patient. Palliative care teams in hospitals across the country have demonstrated the value of this service for more than a decade, but what’s new is mobilizing teams to provide it in patients’ homes.

“The interdisciplinary team approach is critical to our success,” Frist says. Some of these patients eventually may be referred to hospice care. But they don’t have to be terminally ill or hospice-eligible to qualify for Aspire’s support, which he describes as a wraparound or overlay on conventional medical care—one focused squarely on the patient’s comfort and quality of life.

Who needs advanced illness care?

Dr Brad Stuart, a pioneering hospice and palliative medicine physician who developed the Advanced Illness Management model of home-based palliative care for Sutter Health in Northern California, agrees that Aspire is providing a valuable service in a system struggling to get a handle on the costs of managing chronic, illness within an aging population. But Stuart says “serious illness” is not strong enough language for a group of patients who are experiencing a mounting set of incurable conditions eroding both their quality of life and prognosis. He prefers “advanced illness” to describe these high-need, high-cost outliers who are responsible for a disproportionate share of total health care costs. “How can we reengineer the system to place the needs of people with advanced illness at its center, giving care consistent with their goals and values—because somebody actually asked them—while helping to keep them out of the hospital?”

The true value of a person-centered, multi-disciplinary approach to caring for these patients is harder to recognize when providers are paid on a fee-for-service basis—with more fees paid for more services. Only when the health plan or health system is financially responsible for managing a population’s total health care in an efficient manner on a capitated coverage basis can it connect the dots and see the value of palliative care.

But Frist says he is working with “other key stakeholders” inside the Beltway to develop a sustainable proposal for how community-based palliative care services could be covered for patients under fee-for-service Medicare. Stuart is part of a national advocacy group called the Coalition to Transform Advanced Care that is pushing a similar agenda.

The true value of a person-centered, multi-disciplinary approach to caring for these patients is harder to recognize when providers are paid on a fee-for-service basis—with more fees paid for more services. Only when the health plan or health system is financially responsible for managing a population’s total health care in an efficient manner on a capitated coverage basis can it connect the dots and see the value of palliative care.

But Frist says he is working with “other key stakeholders” inside the Beltway to develop a sustainable proposal for how community-based palliative care services could be covered for patients under fee-for-service Medicare. Stuart is part of a national advocacy group called the Coalition to Transform Advanced Care that is pushing a similar agenda.

The federal Center for Medicare and Medicaid Innovations and a number of private foundations, notably the California Health Care Foundation, are also promoting this kind of care. Narus Health, based in Nashville, is a company that is trying to “revolutionize palliative care,” in the words of its chief medical officer, Dr Jim Meadows.

Demonstrating the soundness these concepts is a new retrospective study led by Dr Dana Lustbader, Chair of the Department of Palliative Care for ProHEALTH in New York State, published online August 30 in the Journal of Palliative Medicine. “We evaluated the impact of a home-based palliative care (HBPC) program implemented within
a Medicare Shared Savings Program Accountable Care Organization on cost and resource utilization,” Lustbader explains. The study looked at 651 patients who died, 82 of them enrolled in an HBPC program and 569 receiving usual care, comparing their hospital admissions and hospice utilization rates in the final months of life.

Total costs per patient during the final three months of life was $12,000 lower with HBPC than with usual care ($20,420 vs $32,420), largely driven by a 34 percent reduction in hospital admissions during the final month of life. “People receiving HBPC were protected from avoidable emergency room visits and hospital admissions because ProHEALTH provided 24/7 in-person home visits, telephone or telemedicine video calls,” she says.

**An upstart startup outsider in corporate palliative care**

Another entrant into this new and emerging field of community-based palliative care is ResolutionCare in Eureka on California’s rugged far North Coast. Medical Director Dr Michael Fratkin has negotiated contracts with managed care plans to provide individualized palliative care addressing medical and nonmedical needs of those with advanced illnesses within the plans’ covered populations. ResolutionCare mixes home visits and multi-disciplinary team management for its patients with a liberal dose of telemedicine from its digitally advanced video recording studio.

“In the past 18 months we have provided 4000 encounters to 500 unique patients, saving them at least 60,000 miles of driving to a doctor’s office,” Fratkin says. “We have created a social enterprise dedicated to the public benefit, legally structured as a Public Benefit company and seeking certification as a B corporation. Our nonprofit entity, ResolutionCare Institute, is dedicated to professional and public education and research. We are still small enough to be nimble and to deliver value to society and to our work force.”

Fratkin is now pursuing working capital to develop network capacity for his model, and ResolutionCare is about to launch its first remote tele-mentoring relationship supporting a palliative care team in a distant community with the palliative expertise assembled in Eureka. Along with the principles of team-based palliative care espoused by others in this growing field, he adds a couple of missing pieces.

Second is paying attention to the professional caregivers. “Can we make palliative care meaningful and life-sustaining work for a depleted, insufficient professional work force that is experiencing increasing demands for its expertise and burnout?” Fratkin asks. The American Academy of Hospice and Palliative Medicine and other groups have acknowledged the looming workforce shortage in palliative care and recommended that primary care physicians and other frontline providers learn how to provide “primary palliative care,” so that specialist teams can be held in reserve for the more difficult and complex cases.

“We have a broken system, misaligned with the needs of real people and in need of disruptive innovation,” Fratkin says. “The experience of serious illness in our country at this moment is burdened by extraordinary amounts of real physical, emotional and psycho-social symptoms and suffering. There are enormous challenges to living with multiple chronic illnesses.” Plus the challenges of navigating a fragmented health care system, he says.

“This is also what’s going to happen to most of us when our time comes, facing the challenge of our own mortality,” Fratkin says. “That’s the real elephant in the room. It is unfortunate that we needed a specialty like palliative care to help us as a society learn how to address these issues, but clearly, we do.”
This week in health and medicine

Aaron van Dorn

Surgeon General report on addiction
Surgeon General Vivek Murthy has released a comprehensive report on addiction in the United States, Facing Addiction in America. The report aims to be a general overview of the latest information on substance abuse and addiction, including opioids and alcohol. According to the report, alcohol abuse has an annual economic impact of $249 billion, and illegal drug use accounts for $193 billion. The report also looks into issues of prevention, treatment and recovery, as well as laying out a guideline for the future. (Washington Post)

Marijuana as a gateway drug to tobacco
After a series of marijuana legalization initiatives won in states across the US on election day, public health officials are concerned that marijuana might lead to a normalization of smoking and lead an increased number of people back into smoking tobacco. California’s tobacco smoking rate is one of the lowest in the country, at only 11.6%, following an over 50% reduction between 1988 and 2014. (NPR)

Yo-yo dieting may increase heart risk in women
A report from the American Heart Association has found that women who are not overweight whose weight has fluctuated more than ten pounds over ten years may be at increased risk of heart problems. The researchers found a 66% increase in risk of death by coronary heart disease. The study found that women who were overweight or obese did not show signs of the increased risk of heart disease from weight fluctuation. The study was based data from nearly 160,000 postmenopausal women from a longitudinal study begun in 1991. (Live Science)

Trump’s election causes surge in IUD popularity
The surprise election Donald Trump last week has caused a spike in requests for intrauterine devices and other LARCs or long-acting reversible contraception. Birth control, including LARCs, is covered under basic insurance coverage thanks to a mandate under the Affordable Care Act. While the fate of the ACA still unknown, with access to contraceptive services now under undivided Republican governance, many women are looking at IUDs before changes come into effect. (Five Thirty Eight)

Minnesota mother sues teenage child to halt transgender treatment
A mother in Minnesota is suing her 17 year old child to halt their efforts to transition from male to female. The teen, who has been living apart from their mother for six months, will be 18 in July. The lawsuit also includes the teen’s doctors, public health and school officials. The teen obtained a letter of emancipation from a lawyer, and claims that their mother has made no efforts to bring the teen home. Under Minnesota law, a child is emancipated if they are financially independent and is living apart from their parents. (Star Tribune)

WHO declares end of Zika emergency
The World Health Organization has declared an end to the immediate emergency over the Zika virus. The WHO’s Emergency Committee declared the spread of the Zika virus a “public health emergency of international concern” in February of this year. While the virus is still of major importance, it was no longer a PHEIC. (Reuters)
Where next for US health and health care?

Richard Lane

It was an extraordinary time to have visited the US, to feel the visceral views across the political spectrum, to listen in real time to Donald Trump and Mike Pence’s health care policy speeches on November 1 denouncing everything to do with the Affordable Care Act. One after another, every Republican speaker took it in turn to shout about the increases in health insurance premiums under Obamacare, amid loud declarations and cheers to the promise of repeal and replacement of the ACA within the first 100 days of a Trump presidency.

But that was two weeks ago—an eternity in US election timescales. We now know who the next President will be, though we know much less about his thinking on the future of US health and health care. It would seem that President Obama’s meeting with Donald Trump at the white House on November 10 may have tilted the course of Trump’s views— for the time being. Instead of the shrill calls to repeal and replace on the first day of the new presidency, we now hear how parts of the ACA may well be retained: preventing insurers from refusing coverage on pre-existing conditions, and possible retention of young people’s coverage on their parents’ insurance policies. In this fevered post-election whirlpool, all we can really do is speculate about what lies ahead, and to consider possible options, not just for the new presidency, but what this might mean for the wider US health policy and global health arenas.

A highlight in my recent US trip was a visit to Washington, DC, to meet with members of Kaiser Health News, partners in our coverage of the US election since early September. With our shared aim of trying to make sense of a complex US health and health care system, on Wednesday, November 16 we posted a roundtable podcast discussion of many key topics that will resonate in the US health community in the months ahead. Listen here to a nearly half-hour discussion with Julie Rovner and Mary Agnes Carey from Kaiser Health News, who were joined in KHN’s Washington, DC studio by Margot Sanger-Katz from the New York Times, in a link-up with myself in The Lancet’s London web studio. We look forward to future discussion as January 20, 2017 approaches, and with hopes that a dramatic change in political leadership will not bring about dramatic reductions in quality and reforms to US health efforts, at home and abroad.
This week in health and medicine

Aaron van Dorn

Utah teens die from synthetic opioid purchased online
Two thirteen year old boys in Utah have died following taking a synthetic opioid they purchased online. The synthetic drug, which currently has not been added the schedule of illegal drugs, is known as U-47700 or “pink,” and can be purchased for as little as $40. The drug, which is eight times stronger than morphine, has been responsible for at least 50 deaths in the US. (Mercury News)

Researchers look at polio drugs in treating acute flaccid myelitis
Researchers are looking at several classes of drugs used to treat polio in an effort to fight against acute flaccid myelitis, a polio-like condition that has been observed in a number of children and infants in the United States, beginning with an outbreak in Colorado in 2014. While no specific enterovirus has been identified as the cause of the condition, pocapavir, a drug being developed to help fight polio, was used in a compassionate use-case to fight the condition and showed some success. Cases of the condition have been on the rise, with the CDC having identified 89 so far, and a six year old boy in Seattle is believed to be the first to have died from the condition. (Washington Post)

Childhood obesity jumps over summer break
Researchers have found that childhood obesity rates jumped during summer breaks, according to a longitudinal study that tracked children from kindergarten through second grade. Rates of obesity rose from 8.9% to 11.5%, and cases of overweight children rose from 23.3% to 28.7% between the beginning and the end of the study. However, the jumps were not observed during school years, but in the period between school years. (Tech Times)

Women’s cancer deaths to rise 60% by 2030
Women’s rate of mortality due to cancer is expected to rise 60% by 2030, to 5.5 million, according to a report from the American Cancer Society. The rise is due to an increase in the total number and aging of the population. The increase is expected to be greatest in low- and middle-income countries, where populations are increasingly adopting unhealthy habits, such as an increase in red meat consumption and smoking. (KTLA)

FDA looks at Nutella usage
Nutella manufacturer Ferrero has been petitioning the Food and Drug Administration for several years to reduce the size of the “suggested serving” on the nutrition label on the back of a jar of Nutella. The manufacturer hopes that a smaller suggested serving—and a smaller calorie count—will make the chocolate hazelnut spread more attractive to consumers. The current suggested serving is two tablespoons (37 grams) and 200 calories. Ferrero claims that how people use Nutella has shifted over the years. The FDA will be opening a public comment period for consumers to share how—and how much—they use the spread. (CNN)

Time change can affect your health
Daylight Savings Time ends across the US this Sunday, and while an extra hour’s sleep might seem appealing, experts warn that it can cause problems down the road. The shift can disrupt your circadian rhythms, disturbing your sleep schedule, and the increased darkness in the evening can lead to an increase in traffic accidents for those unaccustomed to driving at night, and can cause many people to experience seasonal affective disorder. (ABC News)
This week in health and medicine

Aaron van Dorn

Measles complication potentially more common than previously thought
Subacute sclerosing panencephalitis (SSPE), a potential complication of the measles virus might be more common than previously thought, according to researchers at the David Geffen School of Medicine at the University of California, Los Angeles. Previously, it was believed that in about 1 out of 100 000 cases, after running its course, the measles virus can spread to the brain and become dormant—for ten years on average—which can lead to a progressive, debilitating brain condition. Researchers have found that 1400 children under five who contract measles contract SSPE, and one in 600 for those under twelve months. There is no cure for the condition, and the only way to prevent it is to vaccinate. MMR vaccination generally occurs between twelve and fifteen months. (US News & World Report)

Jury awards $70m in baby powder cancer case
A California woman has been awarded $70m by a jury in St Louis over claims that baby powder sold by Johnson & Johnson caused her ovarian cancer. While talc, the principle ingredient in Johnson & Johnson’s baby powder, has been linked by some studies to an increased risk of ovarian cancer when used for feminine hygiene, the American Cancer Society says that the results are mixed and there is little evidence of a direct link to cancer. Around 1700 cases accusing involving Johnson & Johnson and their baby powder are currently in the courts. (Bloomberg)

Placebo helps children with migraines as well as drugs
In a study comparing two medicines used to treat migraines in children, topiramate and amitriptyline, researchers found that sugar pills worked as well as the drugs, with fewer side effects. Topiramate is only approved for use in children above the age of twelve, and amitriptyline is not approved for use in children. Up to 10% of children in the US suffer from migraines, and the new study could have impacts on how doctors approach treatment. (NBC News)

Soylent stops sales of product after more consumers become ill
Soylent has discountinued sales of their meal replacement powder after several customers fell sick from consuming it. This follows Soylent discontinuing sales of its Soylent Bars, a snack bar formulation of its product, earlier this month. While Solent says that tests done on their product are negative for contaminants and toxins, they are reformulating their products to remove “likely ingredients.” They expect to have their products ready for sale again by the first quarter of 2017. (Business Insider)

Teal pumpkins to signal food allergies during Halloween
Halloween is just around the corner, and around the country children will be heading out for trick-or-treat, but for the one in thirteen children in the US with severe allergies, it can be a limiting experience. The Teal Pumpkin Project encourages households offering allergen-free treats to signal with a teal-painted pumpkin that children with food allergies are welcome. (CBS News)
This week in health and medicine

Aaron van Dorn

Sexually transmitted disease infections on the rise
The rates of sexually transmitted disease infections are at an all-time high, according to a newly released CDC report. Rates of chlamydia, gonorrhea and syphilis among young adults and teens are especially high, with over half of reported chlamydia and gonorrhea cases in those under the age of 25. Syphilis infections are especially high in men who have sex with men, representing 80% of cases, and 90% of syphilis infections in men. The report faults cuts to state and local budget for STD prevention programs, with half of programs facing budget cuts. (NPR)

Cigna ends preauthorization for opioid treatment medicine
Insurer Cigna has ended a policy that required doctors and patients to seek authorization prior to prescriptions of buprenorphine, a drug used to reduce cravings for opioids. The reversal results from a settlement agreement following inquiries into barriers to treatment by New York State Attorney General Eric Schneiderman. In a statement, Schneiderman called on other insurers to follow Cigna’s example in removing barriers for treatment of opioid addiction. (Wall Street Journal)

Placebos fool you, even when you’re in on it
Portuguese researchers have found that placebo sugar pills used to treat chronic back pain work, even when the patients know that the pills are placebos. Patients in the placebo group reported a great reduction in usual and maximum pain (30% in both) versus those who received a normal treatment consisting of pain medication (9% and 16%, respectively). The placebo group also reported a reduction in disability over the regular treatment group (29% vs none). The researchers said the reasons for the reaction are complex, but speculated that engendering hope for the outcome of the treatment contributed. (New York Times)

Screen time guidelines for children
A new guideline from the American Academy of Pediatrics suggests that children under 2 years avoid any screen time outside of video chatting, and between 2 and 5 years old, children should be limited to only one hour per day. The guideline also recommends that screens not be used as the only method to soothe children. The guidelines also suggest that while school age children can benefit from media usage, they should not be allowed to sleep with a TV, computer or smartphone in their bedrooms. It also suggests that school age children benefit from eight to twelve hours of sleep a night. (CBS News)

Judge blocks Mississippi law defunding planned parenthood
A federal judge blocked implementation of a state law that would have prevented the state’s Medicaid program from providing funding to organizations that provide abortions. The law was passed in the wake of a debunked viral video in 2015 that attacked the organization, part of a wave of similar laws there were passed in nearly two dozen states. The law went into effect in July, although neither of the two Planned Parenthood-affiliated organizations in Mississippi provides abortion services. (The Hill)

Hepatitis A cases linked to Detroit whole foods
Two cases of hepatitis A have been linked to the prepared foods section of the Detroit Whole Foods, according to the Detroit Department of Health on Friday. An employee who worked in the prepared foods section and a customer who ate there have both contracted hepatitis A. It is still unclear what if any link there is between the prepared foods and the two cases, the health department is encouraging anyone who worked or ate at the section to consult a doctor for preventative care. (Fortune)
A total of 25 states and the District of Columbia have legalized medical marijuana, with at least four others voting on it next month, *The Hill* reported on August 4. The evidence base for marijuana as a medical treatment remains scant, but tantalizing anecdotes suggest a variety of treatment applications calling out for further study. Those applications include the treatment of pain, anxiety, sleep disturbance, and gastro-intestinal symptoms such as nausea and anorexia, says Michael Fratkin, MD, medical director of Resolution Care, a palliative care service in Eureka, California.

Increasingly, America’s hospice and palliative care providers are hearing that their patients are interested in these applications for common symptoms of serious illness. But their responses to such requests are still being sorted out. Hospices strive to meet the needs of terminally ill patients at the end of life, supporting their ability to make choices and live out their remaining days in ways that are meaningful to them. But what if that includes cannabis—which remains a controversial choice in many settings and is not recognized as a legitimate medical therapy by the federal Drug Enforcement Administration (DEA)?

Hospice is an organized service of palliative or comfort-focused professional care and support for patients who have a prognosis of six months or less to live, and for their families. It aims to maximize quality of life when its quantity is in short supply, and to that end hospices mobilize therapies and services that are reasonable and necessary to manage the patient’s condition—but not curative treatment. In the United States, hospices are paid a daily all-inclusive rate for their services by Medicare, which covers about 85 percent of enrolled hospice patients. Out of that daily payment the hospice must provide all of the care patients need related to their terminal diagnoses.

So what is the promise of medical marijuana for hospice patients? Robert Cole, associate medical director of Hospice of the East Bay in Pleasant Hill, California, sees real value for cannabis as a palliative treatment for the symptoms experienced by his patients. One of its most promising potentials is as an adjuvant analgesic treatment, potentially reducing the need for high doses of opioid painkillers at a time when overdoses from prescribed opioids have become a national epidemic. “The bottom line is that cannabis is a remarkable drug that does not produce some of the negative effects of opioids. Its potential benefit as an analgesic needs to be studied further,” Dr Cole says.

The real question is whether hospices would be willing to consider it as a legitimate medical therapy, says Dr Fratkin, whose agency uses telemedicine and contracts with managed care organizations to provide community-based palliative care on California’s rugged North Coast. “Can hospices take responsibility for understanding some fundamental principles, for example between edible or smoked, THC [tetrahydrocannabinol] versus CBD [cannabidiol]?” he asks. “Are we willing, in California, where it is legal, to write prescriptions or medical recommendations? Is it safe? Yes it is.”

Resolution Care does not pay for medical marijuana for its patients because the compounds are so variable and not subject to pharmaceutical quality control. “But we have some very responsible and civic-minded pot dispensaries that will provide the substance and accompanying counseling free of cost to patients in our program or in the local hospice,” Dr Fratkin says.

A Supplement, Like St John’s Wort?

How are hospices responding to the spread of legal medical marijuana? “We’re working on this issue, but it’s definitely a work-in-progress,” reports Jeri Conboy, director of Blessing Hospice & Palliative Care in Quincy, Illinois, a state that is now running a statewide pilot of medical marijuana. “We are a small hospice, and a few of our patients have pursued medical marijuana,” Conboy says. “We have learned through them about the qualifying or certifying process in this state. As with St John’s Wort [an herbal remedy used to treat depression], we try to view it like a supplement. But not all of our physicians are on board with it.”
Conboy’s parent hospital system has a policy that it does not pay for medical marijuana or participate in the patient’s process to become qualified for it. “Basically, we have to stay at arm’s length,” she explains. “For the hospice team, we can’t be present when medical marijuana is consumed. It is not part of hospice benefit services. But we ask about it, just as we ask if patients are taking herbal medications, and we explain the hospice’s position on the issue,” she says. “Our staff report frustration at their inability to control the situation. Yet isn’t this just one of many things we don’t have control over and must learn to co-exist with?”

Reportedly, a few hospices have gotten more involved in recommending, ordering or prescribing medical marijuana, and an article in the quarterly newsletter of the American Academy of Hospice and Palliative Medicine suggests that other hospice providers quietly view it as a viable palliative care treatment option. Hospice physician David Casarett, MD, professor of medicine at the University of Pennsylvania, last year authored a book called Stoned: A Doctor’s Case for Medical Marijuana.

Brian Jones, director of hospice and palliative care at St Elizabeth Healthcare in Edgewood, Kentucky, acknowledges the need for hospices to proceed with caution on medical marijuana, attuned to public relations concerns. “We also want to be advocates for evidence-based medicine at the end of life. Clearly, there’s not enough research about medical marijuana,” he says. If it were acknowledged as part of the patient’s palliative treatment, he poses, would that make it related and thus the hospice’s responsibility to pay for it?

Frequently, hospice and palliative care patients look to their health practitioner to give them some direction, Dr Cole notes. But many hospices don’t yet have policies or procedures on the subject. “As a hospice practitioner, I want to be able to enter into a conversation with my patients openly about all of the options available,” he says. “I don’t want to overstate the benefits. The effects of high-THC cannabis can be disturbing to some patients. But we should be able to lay it all out there for our patients without being worried about the response of the DEA.”

Hospices are also concerned about turning off their referral community. “There is a quandary here; there may be real risks from the government. But we’re not serving our patient community as well as we might,” Dr Cole says. Dr Fratkin finds it outrageous that this potentially beneficial treatment can’t be adequately studied because of the government’s biases. “We should be looking at dosages, at in-vivo studies,” he says. But it’s clearly just a matter of time before regulators open the door for scientific researchers to give it the closer look it deserves.
Making children’s dental health part of primary care

Nadia Laniado

The very vulnerable children and adults we see each day in the clinic mirror the Centers for Disease Control and Prevention’s sobering statistics that more than 100 million Americans are missing one or more of their teeth and that the most common chronic disease of childhood remains dental decay.

The most vulnerable populations are at the highest risk. The overwhelming majority of these children and their parents do not have health insurance, let alone any type of dental insurance or benefit. Many the children that come to our hospital for dental care have never seen a dentist before. Their parents do not have dental homes, their mouths are diseased and reflect years of neglect. Contributing to this are cultural habits and diet that are extremely harmful to their children’s oral health. Many do not believe baby teeth require care because they are going to fall out.

The majority of bad things that happen in our mouths are preventable, yet if not cared for properly, it threatens our overall health. There is evidence that having periodontal disease is a risk factor for type 2 diabetes, cardiovascular disease, rheumatoid arthritis, and other inflammatory disorders. Furthermore, on a more basic level, having a smile that you’re self-conscious about can negatively impact self-esteem and ultimately the ability to succeed.

Yet the message that oral health is an integral part of overall health and well-being is just not reaching the public or health care practitioners. For too many years, dental care has been the stepchild of overall health care. It’s time for that to stop.

The answer is to move dental screening into primary care, because children see their pediatricians more during the first year of life than at any other time. Dental care must be a critical component of overall wellness care, and primary care doctors have a unique opportunity to participate and support this concept. A convenient and effective way to address this issue is a basic dental screening in the doctor’s office followed by the establishment of a dental home by a child’s first birthday.

At the North Bronx Healthcare Network, we have instituted an interdisciplinary education and prevention program where pediatric dental residents are in primary care settings teaching physicians how to do oral exams and apply fluoride varnish. The pediatricians and internists we are training have welcomed us. They acknowledge that they feel poorly trained in oral examination and uncomfortable assessing oral health risk. We can only hope that this can be done in many other hospitals, clinics and offices, particularly those serving the most vulnerable.

It shouldn’t surprise me, but according to a recent report by Delta Dental, more than a third of young adults aged between 18 and 24 have gone two or more days without brushing their teeth. It is highly unlikely they would go that long without using their cellphone. Yet a toothbrush is a device that is efficient, inexpensive, and has a proven outcome. Our children and their caregivers need to understand that brushing twice a day with a toothbrush is by far more important than the expensive cell phones in their hands. And hopefully we can do more than encourage, but instead require, that pediatricians and frontline doctors emphasize the importance of this simple task.
This week in health and medicine

Aaron van Dorn

Brain implant restores sense of touch to man with paralyzed hands
Scientists at the University of Pennsylvania have been able to restore a sense of touch to a man with paralysed hands in a medical first. Through an implant in his brain, the patient is able to feel sensations from a robotic hand that he is able to control with his mind. He is able to tell which finger is being touched and whether the object is hard or soft. While finer-grained sensations—such as telling the difference between types of fabric—are not yet possible, the researchers see this as being a critical step towards more functional prosthetics. (NPR)

Over half a million heart surgery patients at risk for bacterial infections
More than half a million heart surgery patients in the US are at risk from a bacterial infection stemming from the use of a particular device in surgery, according to the CDC. The device, called a “heater-cooler unit,” is used to keep organs and blood at a specified temperature during heart-bypass surgery. Around 250,000 such surgeries are performed in the US each year, and 60% of those surgeries utilized a particular model manufactured in Germany linked to the infections. The infections are from nontuberculous mycobacterium, which is common and not normally harmful, but can cause problems for those with weakened immune systems. The infections can be asymptomatic for months, and can in rare instances lead to death. The FDA strongly suspects that the cause of the infection comes from contamination at the devices’ factory. (Washington Post)

FDA warns childrens’ deaths linked to homeopathic teething treatment
The FDA has issued a warning to parents that a homeopathic teething treatment has been associated with the deaths of ten children, and four hundred other adverse events. The manufacturer of the teething tablets and gels, Hyland’s, said in a statement that the FDA has not yet made them aware of any data linking their product to the adverse events. However, they ceased sale of the products in the US this week. They have not, however, issued a recall. The FDA reported that repeated lab testing had shown inconsistent amounts of belladonna, or deadly nightshade, in the product. (CNN)

DEA holds off on rescheduling kratom
Following an announced intention to list the herbal drug kratom as a Schedule I substance in September (covered here), the DEA has announced that it will be opening a public comment period. In addition to public feedback, the DEA has requested scientific research from the FDA. The announcement of the rescheduling brought a lot of public feedback and petitions against the move. The drug, which can be used as both a stimulant and a sedative at different doses, has been used for a number of medical treatments, from diarrhea to anesthetic, as well as a treatment for opioid withdrawal. (Huffington Post)

Soylent Bars recalled after consumers became sick
Soylent has issued a recall for their latest product, Soylent Bars, after customers reported that they became violently ill after consuming them. Customers complained of nausea and diarrhea. Soylent, a company that aims to tear people away from the tyranny of sitting down to eat, raised $22 million dollars in crowd-funding in 2013. Their signature product is a meal replacement system consisting of a nutrient powder that is mixed with vegetable oil and water to create a full day’s nutrition in a drinkable slurry. (Tech Crunch)
The election is stressing us out

According to a new survey from the American Psychological Association, half of respondents reported that the upcoming presidential election between Democrat Hillary Clinton and Republican Donald Trump is a major cause of stress. In the survey of over 3500 adult Americans, 52% reported the election as a major source of stress. Those with political affiliations were similarly stressed, with 55% of Democrats and 59% of Republicans reporting the election as somewhat or very stressful. However, the election wasn’t the only thing on our minds: the top three stressors were money, work and family responsibility. (APA)
The Global Burden of Disease 2015

Aaron van Dorn

It provides researchers, policy makers and development agencies with a tool to help in allocating resources and see where interventions have had the greatest effect. Instead of spending money blindly and hoping for the best, we can now see what provides the greatest return on investment and replicate its success elsewhere.

While the average voter in the US greatly overestimates the amount the US government spends on foreign aid in general, and health-focused aid in particular, in 2014, USAID spent $3·1 billion on the global fight against HIV and AIDS and around half a billion dollars each on both maternal and child health and malaria reduction. As of 2014, the Bill and Melinda Gates Foundation had an endowment of $44·3 billion. But ensuring that that funding is used in the most efficient and effective manner possible ensures that it does the most good for people who need it, and the GBD ensures that we can see where those investments are most effective.

During a launch event in Washington, DC Friday, The Lancet Editor-in-Chief and Publisher Dr Richard Horton called upon the audience to use the information provided by the GBD to identify areas that have unmet needs, under the title “Development is Not Destiny.” While previous measures of world health and causes of death divided the world into categories like “developed” and “developing,” or broke countries down only along terms of income level, the new GBD breaks down countries by Socio-demographic Index or SDI. Use of the SDI allows the GBD to compare and contrast countries and regions that have similarity along a number of different dimensions: average income, education and fertility rates.

The IHME site contains an extensive array of visualization tools that allow you to break down the findings in an intuitive, visual way. One of the major comments from the release event was the need for researchers to be able to find a way to present these findings to people in a comprehensible way, and the visualizations help to make complex relationships in the data more understandable. The current issue of The Lancet with the GBD report is a massive document, with over 400 pages of commentary, visualization and reports.

The blog has been edited. The original post misidentified IHME—they are based at the University of Washington in Seattle.
This week in health and medicine

Aaron van Dorn

Indiana declares public health emergency, begins needle share program

The Indiana State Department of Health has declared a public health emergency and begun a temporary emergency needle exchange program in northeastern Allen County due to an increase in the spread of HIV and hepatitis C among opioid drug users. Indiana faced a similar outbreak in 2015 in southern Scott County, which was ended in part with a temporary needle exchange program. However, current Governor and Republican Vice Presidential candidate Mike Pence is morally opposed to needle exchange programs. As a Congressman, he voted for a 21-year ban on federal funding for needle exchange programs. (WISH TV)

Cases of polio-like illness on the rise

The CDC reports that reported cases of acute flaccid myelitis have risen after falling in 2015. Fifty cases have been reported so far in 2016, with 90% of those cases in children. Only 21 cases were reported in 2015, significantly down from 121 cases reported in 2014. Causes of the illness are unknown, but it causes weakness in the limbs and loss of reflexes and muscle tone. Severe cases can cause respiratory failure of the muscles involved in breathing are involved. (CBS News)

Theranos closes blood testing facilities, lays off workers

Theranos, the company that wowed Silicon Valley investors with its promise of multiple diagnostic blood tests from a single finger-pricked drop of blood, has closed its blood testing facilities and laid off 40% of its workforce. Theranos’ fall has been as precipitous as its rise, with federal regulators recently banning its founder, 32-year-old Elizabeth Holmes from owning or operating a laboratory for two years. The troubles were compounded when the drug store chain Walgreen’s canceled a lucrative contract with Theranos to provide diagnostic services, after Theranos was unable to demonstrate that its central technology actually worked. (NPR)

Marijuana legalization moves forward

Four more states appear poised to approve ballot initiatives that would legalize recreational marijuana according to recent polls, with voters in a fifth state split. California, Maine, Massachusetts and Arizona all seem poised to approve the measures. Nevada is the closest of the states, with polling on the question currently split 47/46 for. If all of the measures were to pass, a quarter of Americans would live in states with legal marijuana. (The Hill)

A ripe old age

A study in the journal Nature suggests that humans may have already reached our maximum viable life span. While vaccines, better nutrition, antibiotics and increases in medical knowledge and ability have greatly increased human lifespans over the last two centuries, the report suggests that it would be extremely difficult for any human to live past the mid-120s. They suggest that accumulated damage from living, including exposure to the sun and other forms of radiation and mutations in individual cells might limit further lifespan increases. (Huffington Post)

Ohio bridal shop sues Texas hospital

An Ohio bridal shop is suing a Texas hospital for damages after one of its nurses shopped for wedding dresses there shortly after treating a patient with Ebola in 2014. Nurse Amber Vinson shopped after helping to treat Thomas Eric Duncan, the first US Ebola patient. Two days after Duncan’s death, Vinson returned to Ohio to shop for a wedding dress. After Vinson was diagnosed with Ebola after her return to Texas, and authorities closed the the boutique to prevent further transmission. The owners of the boutique claim that business has not recovered since the closure in 2014. (Tech Times)
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

CMS rules against binding arbitration clauses
The Centers for Medicare & Medicaid Services has issued a ruling prohibiting binding arbitration clauses in nursing home contracts for nursing homes that accept Medicare and Medicaid funds, which includes nearly all nursing facilities. Binding arbitration clauses prevent patients and their guardians from suing nursing home corporations, instead forcing them into privately adjudicated arbitration systems, which critics have accused of being overly favorably to the corporations that choose them. (NPR)

Congress approves funding for Zika, flooding relief
Congress has approved a continuing resolution to fund the government through December 9, avoiding a potential government shutdown. Included in the spending bill are $1.1 billion for Zika research and mitigation, $500 million for flooding relief in Louisiana and other states and $37 million for the opioid crisis. Funding intended to address the amount of lead in the water of Flint, Michigan, was withdrawn at the last minute after an agreement was reached to attach funding for that to an infrastructure bill in the lame duck session after the election. (CNN)

Teen pregnancy continues downward trend
According to a new report from the CDC, the teen pregnancy rate continues to trend downwards, with 2015 being the seventh straight year of the lowest on record, 22.3 births for every thousand women between 15 and 19, an 8% decrease from 2014, and 64% lower than it was in 1991. However, that rate is still much higher than in other developed nations. In Switzerland, the rate is only 3 in 1000. (LA Times)

Artificial pancreas receives FDA approval
The FDA has approved the first "artificial pancreas" system for sale in the US, in a surprise move. Approval of the device was not expected until sometime next year. The system consists of a reader, which is kept at the doctor's office, and a small disk with a filament sensor applied with adhesive to the patient's skin. The patient does not need to stick their finger or interact with the device at all, and returns to the doctor's office to have the results read and interpreted, reducing user error from inconsistent self-monitoring. (Medscape)

Leprosy in California
Officials in California have reported a child has contracted leprosy, and another child is suspected of having it. Leprosy, also known as Hansen's Disease, is rare and extremely difficult to contract, and can remain dormant in the body for up to ten years. Officials do not believe that others are at risk, and the origin of the infection is under investigation. (ABC News)

CDC urges Americans to get flu vaccination
Amid declining rates of vaccination, the CDC is urging all Americans to get vaccinated against the flu as soon as possible. While the flu is generally mild for most adults, it can be deadly for children, the elderly and those with weakened immune systems. Around 45% of Americans were vaccinated last year, a 1.5% drop from the previous year. The sharpest drops were seen among elderly, where the rate dropped by 3.5%. (NPR)
EpiPen’s price-gouging response “sickens” Congressional panel

Susan Jaffe

But after a nearly four-hour congressional hearing last week investigating spikes in Mylan’s EpiPen prices, Maryland Democrat Elijah Cummings told Mylan CEO Heather Bresch, “You might as well have taken the Fifth, too, with the kind of information that we’ve gotten here today.”

The EpiPen provides an automatic injection of epinephrine used to treat anaphylactic shock caused by a severe allergic reaction. “Roughly four people a day will die if they don’t get the proper dosage of epinephrine,” said Jason Chaffetz, a Utah Republican and chairman of the House of Representatives Committee on Oversight and Government Reform. “It’s not optional for somebody who has severe allergic reactions to a whole variety of things.”

The committee wanted to know why the price of an EpiPen two-pack was about $100 when Milan bought it in 2007, but after five price increases, it now costs $608.

Bresch failed to assuage concerns by explaining that the company receives $274 per EpiPen and makes a profit of only about $50 after paying for the drug, the materials to make the auto-injector, and marketing. The remainder of the $608 price tag goes to pharmacists, insurers, pharmacy benefit managers, and other middlemen.

Bresch also described her company’s plans to introduce its own generic version of the EpiPen at half the price and to expand its patient assistance program that offers it at a significant discount. The panel responded with skepticism.

“Nobody here has any clue as to whether or not you’re charging too much or too little,” said South Carolina Republican Mick Mulvaney. “The same exact thing from the same exact manufacturer costs $100 to $150 in Europe.”

Dr Douglas Throckmorton, deputy director for Regulatory Programs in the Center for Drug Evaluation and Research also testified, reminding the panel that FDA does not regulate drug pricing. But he said the FDA is reducing the backlog of generic drugs waiting for approval: “When more than one version of a drug, especially a generic version, is approved, it can improve marketplace competition and help to provide additional options for consumers.”

Even though Mylan has 96 percent of the market for auto-injected epinephrine, Bresch claimed the company has competition, which also did not reassure the lawmakers.

“I am a very conservative, pro-business Republican, said John Duncan, a Tennessee Republican. “But I am really sickened by what I’ve heard here today.”
Mental health and the White House

Rebecca Cooney

Editor's note. This podcast has been transcribed and edited for clarity.

Niall Boyce: I’d like to start off with a bit of a chat about US politics in general. I mean, I quite enjoy politics as a spectator sport, do you have a long-term interest in US politics, Bek?

Rebecca Cooney: I go in and out. But I think this election in particular has made it almost impossible for people not to get engaged somewhat as there seems to be a rather lot at stake.

Niall Boyce: Yes, I’ve always seen UK elections as being sort of black-and-white Ealing comedies and US elections as being grand, wide-screen 3D events. But this year just seems to be a bit darker, a bit stranger perhaps than it’s been before. This is something which the president of the American Psychiatric Association (APA), Maria Oquendo, picked up on in a blog she wrote recently where she said that the election seems like anything but a normal contest that has at times devolved into outright vitriol. She adds something which I thought we could talk about because it’s quite interesting. She says that the unique atmosphere of this year’s election cycle may lead some to want to psychoanalyze the candidates, but to do so would not only be unethical, it would be irresponsible. She’s talking about something called the Goldwater Rule—is that something you’re familiar with, Bek?

Rebecca Cooney: It is. To give some historical context, the Goldwater Rule is somewhat interesting in that it wasn’t enacted until almost 10 years after the sort of defining moment related to his campaign. A magazine, that’s now defunct, surveyed psychiatrists asking whether, at the time, Goldwater was fit for office. It’s very interesting to think that something of that nature would have happened then, back in 1964. I think there are a lot of parallels to what people are currently discussing. Barry Goldwater was really sort of a bombastic figure—lots of off the cuff speaking, lots of big claims, and so there are a lot of parallels with Donald Trump. But what’s also interesting, I think, is putting it into more of the context of how the United States treats both mental and physical ailments in terms of how we evaluate the fitness of candidates. And what I thought was really interesting was thinking back to Abraham Lincoln, who was sort of a textbook melancholic figure. At the time that may have actually been to his benefit as a candidate in that it made him somewhat more approachable, people felt sort of a kinship with him, something about the 19th century zeitgeist, a sympathy that they had with him. That same dimension probably is not something that would work out in the candidates favor these days.

Then sort of fast-forwarding to, for example, Franklin Delano Roosevelt. Though there aren’t a lot of accounts about his mental health, clearly he was someone who had physical ailments. He contracted polio at 39, and during his candidacy and presidency, there were many pains taken to control the optics of his situation and to make him seem sort of impervious. Making sure that photographs of him weren’t taken as he was entering cars or exiting and so forth. So somehow during the time that elapsed this ableist narrative emerged that presidential candidates should be these impervious people who don’t have any sort of physical or mental ailments.

Considering that with something like the Goldwater Rule is really interesting because not only is there kind of this top-down gag order not to discuss it, but it also puts a lens up to the stigma around it. Another really notable example, somewhat different but related, was Thomas Eagleton, who in 1972 was the democratic vice presidential candidate with George McGovern, who was running against Richard Nixon at the time. Eagleton had been hospitalized for a depression several times during his life, something that wasn’t disclosed to George McGovern. Eagleton hadn’t...
been the first choice and there was a lot of pressure to find a suitable candidate for the vice presidential spot. So once the whisperings of this came out and talk of shock therapy, Eagleton withdrew himself from being the candidate. Even though there seem to have been some expressions in popular media, like Time magazine, where people said they were not sure that this would impinge at all on his ability to be a leader.

There’s both a precedent that having a mental health history could be a detriment to a candidate’s viability, but it is also really interesting that the APA would take such a strong stance with the Goldwater Rule.

**Niall Boyce:** One thing that interests me for the election in question, was that in the early 1960s, it was really an election at a point in time where the whole issue of nuclear war was clearly very foremost in the American people’s minds. And in the aftermath of the Cuban missile crisis, I wonder if it’s this power which the American president is perceived to have, of really having immense sort of global destructive capability at his or her fingertips which has maybe fed into this, as you put it, ablest narrative. The idea that the president has to be superhuman, to be physically and mentally healthy.

**Rebecca Cooney:** Right, I think it’s who has the finger on the button. In a way, that behooves a question of mental health fitness as opposed to physical health fitness, yet there has been just as much discussion about physical health in this election cycle especially. Particularly a lot of the right-wing conservative groups poring through evidence trying to suggest that Hillary Clinton has some neurological problems and things like that. But there is something too about this election in particular that is making these issues more salient and I think that has a lot to do with the global climate with terrorism and also potentially changing relations with Russia and involvement there.

So it is really interesting to think about, but clearly you know talking about health is not new at all in election cycles. In fact, when John McCain, for example, was running for office, he had had a melanoma diagnosis and that was an issue. He was also 72 at the time. Now we have two candidates who are either 70 or on the precipice of 70. Obama was only 47 when he started his presidency. These are really different components of health, so is it more legitimate to ask a psychiatrist not to speak on someone’s mental health? Is that a more legitimate requirement than having physicians not comment on health more generally? I’m not sure that it absolutely makes sense to do that, but it’s definitely something interesting to think about and an unusual election in that sense.

**Niall Boyce:** It’s probably worth reminding ourselves here of what the Goldwater Rule actually says, which is that psychiatrists can be asked for opinions about an individual who is in the light of public attention or who has disclosed information about himself/herself through public media. Now the advice is that a psychiatrist may share with the public his or her expertise about psychiatric issues in general, but it’s unethical for a psychiatrist to offer a professional opinion unless he or she has conducted an examination and has been granted proper authorization for such a statement. Which is a way of saying, if you do know the person in question and you’ve talked to them, it’s unethical to disclose information without their consent. And if you don’t, it’s very ill advised and probably unethical gossip.

**Rebecca Cooney:** And there has been fallout, not necessarily with the Goldwater Rule in particular, but, for example, physicians with TV shows in the US making suggestions about the candidates’ health. There have been some implications of doing that without having had any sort of contact with the candidate.

**Niall Boyce:** This, as you said, is a particularly fraught election considering the global situation at the moment, but of course, a great deal hangs on the domestic situation as well. Of which, mental health is I think increasingly a big issue. In fact, a few years ago when I was at APA, the guest speaker was Bill Clinton. He didn’t actually turn up in the room as I don’t think he was well at the time, so he communicated over a video link, and the impression I got is that for the Clinton’s, mental health issues are seen as being something of priority. Now I’m not sure that Donald Trump has really spoken much about health care at all and especially about mental health care, is that correct?

**Rebecca Cooney:** That is absolutely correct. As of this last week, Hillary Clinton put out her comprehensive agenda on mental health, which has received some pretty good support from high profile groups like the National Alliance of Mental Health (NAMI). But on the other side, Donald Trump’s website has three mentions of mental health, one in the context of gun control, or gun rights, rather. So there is a mention of it, but there is clearly not the same developed sort of offering in terms of something that can be evaluated in terms of policy.

What is really interesting and typifies this unusual election is that you do have fairly strong bipartisan support for some sort of mental health reform in the country. Most of that being sponsored by people that you would consider Washington insiders, which is the antithesis of how Donald Trump is portraying himself. So within Congress, you have both in the House and the Senate, plans that have been put out in the last year. The Senate has the Mental Health Reform Act, and in the House, the Helping Families in Mental Health Crisis Act, which passed overwhelmingly. I think there were only two votes against that.

So both Republicans and Democrats are in support of doing something. I think where a breakdown comes is in the actual implementation of a plan where we have “pie in the sky” ways of overhauling mental health care in the US.
But it still remains to be seen where the funding will come from and how we might actually translate policy changes into care. But with regard to Hillary Clinton’s specific plan, some other areas that she has called attention to, for example, have been the idea of more community-based treatment options, also using psychiatric liaisons, and training police officers in crisis intervention, doing more supportive housing models, that sort of thing.

There are a lot of interesting pieces to the plan and it is probably the most comprehensive mental health care proposal that has been put forth by a candidate ever. I can’t imagine anything more comprehensive than that in the past. Another point though that is common to both parties that has become more of an issue is suicide prevention. In the NBC forum, there was mention about suicide prevention for our military persons. Hillary Clinton’s plan also talks about beefing up suicide prevention at colleges and universities, a $50 million dollar initiative there. But this also harkens back to the difficulties with the two parties very, very different stances on gun control issues.

Niall Boyce: That’s something which I thought we were going to get back to that sooner or later. I think that this is a really big issue, a very controversial one. And one of the concerns is that when one of these terrible mass shootings occurs, it seems that turning the conversation to mental health is almost a way of diverting from harm reduction measures, such as gun control, and actually risks scapegoating people with mental health problems by identifying all people with mental health problems as potentially being very dangerous.

Rebecca Cooney: It is a very fine line that people walk. I would think that that the majority of Democrats who have weighed in on the issue have not tried to push it into the realm of being a mental health issue per se. But again, you historically have people who want to defend gun rights, but they also don’t want to have their personal liberties taken away. But when you invoke the spirit of mental health as being more of a problem, you are doing exactly that. There hasn’t been good traction with proposals for example to track people via a federal database registry where information could get fed into that system across state lines. We’ve had proposals that typically, pardon the pun, get shot down and nothing really happens.

Niall Boyce: The other issue which has come up a lot in this election is the idea of immigration to the States and specifically immigration from what we could very broadly term the Hispanic population. Now we published a review recently in The Lancet Psychiatry, of which Maria Oquendo was one of the authors actually, specifically looking at the resilience and the challenges that the Hispanic immigrant population in the United States face in terms of their mental health and there are a few mentions of health issues in general. Is this a big deal as far as either of the candidates are concerned and can you see it being a big deal with the American public in this election?

Rebecca Cooney: Immigration is obviously an issue for people on the right. It’s definitely been a common refrain, but it gets muddled somewhat in this more global conflict and talking about immigration more broadly because of, for example, Syria. But in terms of domestic borders, people who are coming from Mexico or Central America are probably the most likely immigrants. In terms of illegal immigration, things have really dropped off, so it is odd that it has become a hot point issue even though peak immigration was 10 years ago or something.

The statistics about how many Hispanic people in the US who have mental health issues is really pretty staggering. We know that about 30% of people who are Hispanic don’t currently have health care which is an issue. But then also, for females who are Hispanic, 50% have some diagnosable depressive disorder which is, as you know, well above average. There is a double whammy of issues—people who are more likely not to have access to health care, but who might be more likely to need mental health treatment. And even under the Affordable Care Act, those people who are not here legally are not currently eligible for health-care access.

It brings up the issue more generally, of impairment and the capacity of our system to treat people with mental problems. Not having adequate access to health care is even more of a barrier that someone would have to face when they are seeking treatment.

There are also some important aspects of the Mental Health Parity and Addiction Equity Act, which was passed in 2008, and interestingly, Hillary Clinton was a co-sponsor of that, that bear on this. Treating mental health issues on par with physical health issues. And that health insurers are supposed to treat illness in the same way. There are still a lot of issues with that in practice, for example, insurers finding ways around it like using “fail first” requirements or making it that much more difficult for providers to be able to participate, so that a lot of them end up opting out of networks and doing private pay because the system itself is so complex and challenging. So not only are people who are here as immigrants having difficulties seeking mental health resources, but those who were born here encounter the same challenges though probably not quite at the same scale. But to be sure there are some major issues.

Niall Boyce: One problem with tackling any complex issue, of which mental health provision in the States is one, is that when you have a deadlocked political system, everything’s very difficult. Now we spoke about Maria Oquendo earlier, referring to this as being a vitriolic campaign. Certainly from my perspective in the UK, the polarization is really quite incredible. Can you see any way to walk back from this to a more sort of cooperative, maybe respectful,
turn in US politics or is this just what we’re all going to have to learn to live with?

Rebecca Cooney: I think it comes down to how well—and this is me off the cuff—that if Donald Trump were to win, how well the Republicans and Congress manage him and his influence. Clearly, his kind of wavering stance on what seems to be important to him depending on the day, or the region of country he’s visiting, is going to matter in terms of moving things on the agenda up or down.

Because of the work that’s gone on on both sides of the aisle through these new large scale mental health reform acts, there is some reason to be optimistic that it will still remain high on the agenda. And really as frustrating and awful as it is, all that it takes is another mass shooting for this kind of resurgence of interest in “what we are doing to help people to cope better”. With 20% of Americans having some diagnosable disorder, it’s something that affects everyone regardless of their political stance. Even for people who are very hard-core conservative or very supportive of the military, they see the same mental health problems occurring within military personnel. Treating that is a priority, trying to figure out new ways of treatment through the VA, for example.

It’s enough of an issue that I think everyone has a horse in the race so to speak, and that it is something that will continue to be a priority. That said, if Hillary Clinton becomes president, I think that there is a much better shot of some of these reforms coming to pass sooner and probably without incident. And that’s probably to everyone’s benefit.

Niall Boyce: We will be watching things very closely between now and November. But for now, Rebecca Cooney, thank you very much for joining us.

Rebecca Cooney: Thank you.

Niall Boyce: Thanks also to you the listener for downloading this podcast, and I hope that you’ll join us again next time, goodbye.
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

The cost of opioids
Researchers have calculated that the total economic burden of the ongoing opioid abuse epidemic is $78.5 billion dollars. Health care costs, cost of substance abuse treatment and nonfatal loss in productivity represent nearly two thirds of the total cost. Slightly less than ten percent of the total was due to criminal justice costs, mostly at the state and local level. (Science Daily)

Potential changes at the Clinton charities
The Clinton Health Access Initiative, headquartered in Boston, has announced plans to distance itself from the Clinton family should Hillary Clinton win the presidential election in November. The Clinton family and several closely linked members would step down from the board of directors, and the organization would be known as CHAI, with the C standing for something else. Close Clinton aide Ira Magaziner would continue on as the organization’s chief executive. CHAI operates in more than 30 countries and negotiates lower prices for HIV/AIDS drugs and is the largest of the Clintons’ charity endeavors. (Boston Globe)

Children hospitalized with infection from dental procedure
Seven children who all underwent the same procedure at a California dental clinic have been hospitalized with severe bacterial infections. The children all underwent pulpotomy, a common procedure for children who still have their primary teeth. The cause of the infection is currently unclear, and officials are contacting children who underwent the procedure back to May. (CBS News)

Suicide in New York City
The rate of suicide in New York City has risen nearly 15% since 2000, but still remains only half of the national average. While the rate of suicide among men has remained stable, the suicide rate among women has risen 56% since 2000. Experts credit part of the lower rate with tighter gun control laws. While guns are use in half of all suicides nationwide, they only accounted for 10% in New York City. (PIX 11)

Pediatricians and gun safety
According to a recent survey conducted by the Journal of Pediatrics of 1200 parents around St Louis, pediatricians rarely broach the issue of gun safety with patients, even though many parents would welcome it. The survey found that 77% of pediatricians had not asked about gun safety, while 75% of respondents would welcome a discussion of safely storing guns. However, parents who actually reported owning guns were less interested in gun safety discussions with their pediatricians. (Kaiser Health News)

Under (blood) pressure
According to a new report from the CDC, 70% of Americans over 65 have high blood pressure, and almost half of those under 65 do not have their blood pressure under control. For a quarter of Americans over 65 enrolled in the Medicare Part D prescription drug insurance program are not taking their blood pressure medication as directed. The CDC also calls for larger refill schedules for blood pressure medication, and coordination of drugs onto a single refill day. (CDC)
The kratom bomb—DEA moves to fast-track scheduling herbal drug

Rebecca Cooney

The DEA has indicated that it is working to expedite the temporary classification of the alkaloids mitragynine and 7-hydroxymitragynine, two of the main active constituents of the plant kratom, as schedule 1 drugs under the Controlled Substances Act. Substances in schedule 1 are considered those which have a high potential for abuse and which are not accepted as safe or effective for medical treatment or under medical supervision.

With the expedited classification targeted for September 30, 2016, the backlash from kratom users and supporters has begun to intensify. This week, proponents of the herb held a rally in Washington, DC and submitted a 120 000-signature petition to the White House opposing the DEA’s plans and asking for an open comment period that would allow experts and the public to weigh in.

Kratom, like many other unregulated herbal supplements, has the cache of east meets west. Used as a folk remedy in countries such as Thailand, kratom leaves are harvested from a tree in the coffee family and commonly steeped as tea or consumed in capsules. In small amounts, kratom is purported to have a stimulant effect, but in larger amounts, it works as a sedative.

Although kratom is still used in traditional medicine in Southeast Asia where it is grown, such as for the treatment of diarrhea or as a local anesthetic, its popularity in the west has primarily been recreational or as an opioid substitute to ease withdrawal symptoms or for chronic pain. It is in that capacity that kratom has risen to notoriety and flagged the attention of the DEA as well as the CDC. In a Morbidity and Mortality Weekly Report issued earlier this summer, a CDC study found that from 2000 to 2015, US poison centers received 660 calls related to kratom, with nearly a half of reported cases requiring medical attention for either moderate or more severe symptoms, including tachycardia and nausea. Two deaths were reported. The report concludes with the suggestion that kratom use is an emerging public health threat—a sentiment echoed by the DEA.

Supporters of the use of kratom for easing opioid addiction or withdrawal allege that that it is an unfair characterization, especially in light of the serious opioid epidemic in the US. For perspective, about 28 000 people died from opioid overdoses in 2014 alone. Critically, there is little clinical evidence to support a legitimate medicinal role for kratom. But, as the case has been with marijuana, there is also the difficulty of obtaining high-quality evidence with the impending schedule 1 designation, which will make studies investigating kratom that much more difficult to conduct. Without clinical support for the safety and efficacy of kratom, it is unlikely that the DEA’s decision will be circumvented. For many kratom users who have espoused the protest, “We are the ones in pain”, after this decision, relief may remain out of reach.
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

Cancer moonshot blue ribbon panel delivers its report
The Obama Administration’s ambitious new cancer research initiative, dubbed the Cancer Moonshot, has delivered its report to the National Cancer Advisory Board this week. Among some of the recommendations are building a national cancer data ecosystem to allow broader sharing of massive amounts of patient data that until now has remained siloed, streamlining the process for patients to find relevant trials and expansion of proven prevention and early detection strategies. (Cancer.gov)

Court blocks gun purchases for medical marijuana users
The 9th Circuit Court of Appeals in San Francisco has ruled against a Nevada woman complaining she was denied the purchase of a firearm due to her medical marijuana card. While many states recognize medical marijuana in some form, it is still illegal under federal law, and federal rule prohibits gun sales to known users of illegal drugs. The ruling only applies in the area of the 9th Circuit, which covers the western United States, including California, Washington and Nevada, all of which have some form of medical marijuana sales. (NBC News)

Shot not spray
Bad news for parents of kids who hate shots: the Centers for Disease Control and the American Academy of Pediatrics are recommending that the nasal spray version of the annual flu shot not be used for children, as the nasal spray version of the vaccine has proven less effective than the traditional shot. Scientists are unclear on why the nasal version has proven less effective than the shot. (South Bend Tribune)

Exercise can partially offset the effects of alcohol
According to a new study that aimed to look at the effects of alcohol in the context of a broader examination of health, exercise and diet, researchers found that the higher rates of mortality associated with moderate alcohol consumption were only evident in those who do not exercise. People who drank moderately (one to two drinks per day) and exercised the recommended amount (150 minutes of moderate-to-intense physical activity per week) were slightly lower than average. People who consumed alcohol beyond those levels still showed higher levels of death, regardless of exercise level. (Time)

Young, wild and gluten-free
While the number of people who have celiac disease has remained steady, the number of people following gluten-free diets has risen steadily. 1.76 million people in the US have celiac disease, while 2.7 million without the disease are ascribing to a gluten-free diet. A gluten-free diet is recommended for those with celiac disease, a disorder that prevents people from digesting gluten and can lead to a variety of digestive complaints, from diarrhea to weight loss. Researchers said that gluten-free diets among those without celiac disease were especially popular with younger adults under thirty, women and non-Hispanic whites. (Huffington Post)

Apple updates guidelines for health and health research apps
Apple has updated the guidelines for developers making health and health research apps for sale in the App Store. According to the new guidelines, apps will not be able to store personal health information on iCloud or disclose health data to third parties or for use in advertising. Apps that conduct research on humans must also contain consent from users and any apps conducting human subject research must obtain approval from an independent ethics review board, producible upon request. (Apple)
Hillary Clinton proposes mental health care reforms

Susan Jaffe

“Too many Americans are being left to face mental health problems on their own, and too many individuals are dying prematurely from associated health conditions,” according to her proposal. “The next generation must grow up knowing that mental health is a key component of overall health and there is no shame, stigma, or barriers to seeking out care.”

Her multi-faceted strategy includes:

- improving early diagnosis and intervention, emphasizing the needs of children and students;
- boosting investments in brain and behavioral research to discover new mental health treatments;
- $50 million annually for suicide prevention at colleges and universities;
- increasing community-based treatment options;
- enforcing federal laws requiring health insurers offer mental health coverage that is on par with other benefits;
- increase housing and job opportunities; and
- training police officers in crisis intervention for people with mental health problems, and offering treatment for non-violent, low-level offenders instead of jail.

In developing her plan, Clinton campaign staff sought input from a number of sources, including the National Alliance on Mental Illness, an advocacy group for Americans affected by mental illness. In a memo to the group’s state leaders, Angela Kimball, NAMI national director for advocacy and public policy said, “The Clinton plan creates a new bar for candidates for the Oval Office” and praised its emphasis on early intervention and mental health parity. (Were Clinton’s opponent, Republican Donald Trump, to release a mental health reform plan, Kimball said NAMI would provide a detailed analysis.)

Clinton’s call for better housing is also important, said Jennifer Mathis, director of policy and legal advocacy at the Bazelon Center for Mental Health Law, a legal advocacy group that represents people with mental disabilities.

“People with serious mental illness are cycling back and forth between the streets, the emergency room, jails, shelters and psych hospitals,” she said. “Without a place to live, it is very hard for people to address their mental health issues.”

Congress has also signaled its willingness to improve mental health care. In July, the US House of Representatives passed the Helping Families in Mental Health Crisis Act. The Senate health committee passed the Mental Health Reform Act in March and committee chairman Lamar Alexander, a Tennessee Republican, is optimistic that the Senate will vote on it this year. “Chairman Alexander thinks members should be able to finish their work soon and pass legislation to address America’s mental health crisis—which affects one in five adults in our country, with 60 percent not getting the help that they need,” said an Alexander spokesperson.
Palliative care seeks its place in managed care

Larry Beresford

So says a recent blog posting at the Center to Advance Palliative Care (CAPC), an organization formed to promote this medical specialty. Palliative care focuses on relieving suffering in patients with serious or advanced illnesses, maximizing their quality of life, helping them cope with manifestations of illness—whether physical, psychosocial, spiritual, or practical—and giving voice to their goals and preferences for treatment.

CAPC started out promoting palliative care teams in acute care hospitals—with considerable success. Two-thirds of US hospitals with more than 50 beds now have such programs, according to a 2015 CAPC survey. But patients need to go home from the hospital as soon as they are able, and palliative care needs to follow them to their home or residential setting—whether through home visits from professionals, coordinating phone calls, or a combination of these. CAPC, too, is highlighting the transition home through education, with a planned pre-conference “boot camp” on how to develop palliative care in home, medical office/clinic, and long-term care settings at its upcoming national seminar in Orlando, FL, October 26.

Conventional fee-for-service reimbursement generally only covers the physician’s visits in community-based palliative care, not the services of the full interdisciplinary team. But more than 30 percent of Medicare payments are now made to health systems that reward quality and cost-effectiveness over volume of services provided, CAPC’s blog post notes. This should grow to more than half by the end of 2018. “Value-based payments are an unprecedented opportunity to assure access to palliative care.”

Accountable care organizations (ACOs) are defined as groups of doctors, hospitals, and other health-care providers that come together voluntarily to share financial and medical responsibility for coordinated, high-quality care to Medicare patients. Over six million Medicare beneficiaries are already in ACOs, which number more than 700 nationally. ACOs, medical homes, and other new models of care coordination—many of them brought into being by the 2010 Affordable Care Act’s incentives for building coordinated networks of health care—emphasize bundled payments, shared savings, capitation, and value-based purchasing of health services. These are aimed at increasing the provider’s responsibility for maximizing quality and controlling unnecessary care.

But if they are to achieve reform’s “triple aim” of improved patient experience, quality and satisfaction; reduced per capita spending on health care; and improved health of populations, they need to find efficient, effective, person-centered ways to care for those beneficiaries who have advanced illnesses and multiple care needs. Medicare Advantage plans also have incentives to figure out how to care for these complex patients—the minority of beneficiaries who eat up the majority of health-care resources and costs.

Wrap around like a blanket

At ProHEALTH Care Associates in Lake Success, NY, a palliative care program based within an ACO, is making home visits and telehealth connections to help patients cope with the significant needs of advanced illness, improving quality of care and outcomes, and reducing wasteful spending. It has documented savings of $12 000 per patient in the final three months of life, compared with matched patients receiving “usual care” but not palliative care, according to research just published in the Journal of Palliative Medicine.

ProHEALTH’s chair of palliative care, Dana Lustbader, MD, a former critical care specialist, calls palliative care in an ACO an example of perfect alignment: better care costs less. The staff of nurses, social workers, and physicians makes house and clinic calls for patients who have tremendous needs that conventional health care does not address. “We wrap around them like a blanket. We support their caregivers, and send nurses, social workers and volunteers into the home,” Dr Lustbader explains. “We’re doing it from within a high-performing ACO. We’re paid out of shared savings. We get claims data on eligible patients using an
algorithm to identify the high-need, high-risk, high-cost patients," based on intensity of care, disease burden, frailty, and history of hospital admissions and ER visits.

Eighty percent of the patients served by ProHEALTH’s palliative care team have multiple chronic conditions, and 57 percent of them are referred to hospice care before they die. “We refer to hospice for end-of-life care, although some patients don’t fit hospice eligibility criteria and others don’t want to discontinue active treatment,” Dr Lustbader says.

Hospice care is a defined benefit under Medicare that requires eligible patients to have a terminal prognosis of less than six months to live—certified by two physicians. The hospice can get in trouble with Medicare auditors if the grounds for that prognosis aren’t clearly documented on the insurance claim. But hospice agencies have skills and resources that might be helpful to patients who have advanced illnesses and complex care needs, but have not yet been given a six-month prognosis—in other words, candidates for palliative care.

**Where does hospice enter?**

A number of hospices have tried to get on the palliative care bandwagon through relationships with ACOs or participation in a new Medicare Innovations demonstration project called the Medicare Care Choices Model, which is testing concurrent care—both hospice-like supportive services and conventional disease-modifying treatments at the same time.

Hospice and Palliative Care of the Bluegrass, based in Lexington, KY, has a Centers for Medicare and Medicaid Services (CMS) Innovations grant to provide post-hospital nurse coaching and transitional support to managed care patients in order to prevent avoidable hospital readmissions. “We have to think about partnering with MCOs, ACOs, and the like because the consumer is going to be ‘navigated’ through these scenarios by patient navigators employed by health systems,” says the hospice’s chief medical officer, Todd Cote, MD.

Four Seasons, a hospice and palliative care provider based in Flat Rock, NC, has a CMS Innovations grant for a three-year pilot project enrolling palliative care patients across the continuum of care settings and following them with a 24-hour interdisciplinary model of care. Four Seasons is using a data collection tool to track how well it manages symptoms, care planning, costs, and outcomes of care such as reducing pain scores and increasing patient satisfaction.

“I think the time is now for palliative care,” says its chief medical officer, Janet Bull, MD, “Once reimbursement starts shifting in the direction of value-based care, then palliative care will be a great solution for addressing the triple aim.” But hospices need to understand that payment reform is here to stay, and start aligning their services with value-based managed care systems.

Eventually, Dr Bull says, the carved out hospice benefit that is now paid separately by Medicare, even for Medicare Advantage patients, is expected to go away. Hospices will need to demonstrate their ability to care for patients “farther upstream” in the disease progression if they want to continue to have a major role in caring for the sickest of the sick.
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

**FDA warnings on opioid and benzodiazepine mixing**
The Food and Drug Administration will issue new warnings on the boxes of opioids warning of the dangers of mixing the pain medications with benzodiazepines, used to treat anxiety, insomnia and seizure disorders. The number of people prescribed both classes of medicine—2·5 million people—has increased by 41% between 2002 and 2014. ([Washington Post](https://www.washingtonpost.com))

**WHO issues antibiotic-conscious treatment guidelines**
The World Health Organization has released guidelines aimed at fighting the growing threat of antibiotic resistance in the treatment of three common sexually transmitted infections. Antibiotic resistant bacteria have been increasing rapidly over the last few years. According to the report, worldwide there are currently 131 million people infected with chlamydia, 78 million with gonorrhea, and 5·6 million with syphilis. ([WHO](https://www.who.int))

**Looking for existing drugs to fight Zika**
Researchers looking for drugs with the shortest path to clinical use have identified two groups of compounds that can be used to fight the Zika virus, according to a report in *Nature Medicine*. One stops the virus from replicating inside the body, and the other prevents the virus from effecting fetal brain cells. ([Medical News Today](https://www.medicalnewstoday.com))

**Don’t push kids into sports specialization too early**
New guidelines from the American Academy of Pediatrics call for parents to avoid pushing children into sports specialization too early. The AAP suggests that avoiding specialization can help prevent overuse injuries and stress. The guidelines also call for an end of ranking child athletes prior to high school. ([Med Page Today](https://www.medpagetoday.com))

**Hepatitis A outbreak in Virginia**
Fifty-eight people have currently been identified in a hepatitis A outbreak in Virginia. The Bureau of Public Health has identified the cause as infected strawberries from Egypt that were used in smoothies at a smoothie chain. Officials are investigating whether the outbreak is linked to hepatitis A outbreaks in five other states. ([ABC](https://www.abcnews.com))

**Clinton Foundation earns high marks from charity watchdog**
While political questions continue to be raised about Democratic Presidential candidate Hillary Clinton’s association with her family’s Clinton Foundation, Charity Navigator, a leading charity watchdog organization, gave the foundation its highest rating of four out of four stars. The evaluation was determined by a close look at the Clinton Foundation’s finances, tax records and an objective algorithm. ([Seattle Times](https://www.seattletimes.com))
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

Opioid crisis continues in Ohio
Ohio saw eight overdose deaths a day, for a total of 3050 people in 2015, a 20% increase over 2014. Deaths from every drug category with the exception of prescription pills, alcohol and “unspecified” rose in 2015. Deaths from fentanyl, a synthetic narcotic 30 to 50 times more potent than heroin more than doubled. (Columbus Dispatch)

Some ACA insurance rates to see sharp increase in 2017
Plans in the Affordable Care Act exchanges are expected to see some sharp increases over previous rates, as insurers continue to adjust to the new marketplace. Obama Administration officials stressed that many of the increases would be offset by tax subsidies for qualified enrollees. (Wall Street Journal)

Sonic stimulation used on coma patients
Researchers at University of California, Los Angeles, have used sonic waves to stimulate the thalamus, a small, egg-shaped structure in the brain in a successful effort to bring a 25-year-old coma patient to full consciousness within days. The thalamus is often diminished in those with severe brain injuries and those in a coma. Researchers hope to expand the treatment to other patients. (UPI)

Guidelines for children and added sugar
The American Heart Association has release a first-ever guideline for parents on the amount of added sugar children should be consuming. The AHA recommends that sugars make up no more than 10% of daily calories for children. The average child currently consumes around 16% of their daily calories in sugar. (CBS)

Orlando hospital won’t bill Pulse Nightclub shooting survivors
Orlando Health won’t seek remuneration from survivors of the Pulse Nightclub Shooting. Orlando Health said that the expenses could total more than $5 million. Orlando Regional Medical Center, Orlando Health’s main hospital, treated 44 of the victims of the shooting, including nine who died at the hospital. (KTLA)

Face transplant patient feels hope
Patrick Hardison, a volunteer firefighter whose face was severely disfigured responding to a house fire fifteen years ago reports that he feels hopeful for a normal life one year after undergoing face transplant surgery. Hardison said that wanted to come forward and tell his story to help others effected come forward and consider the extensive surgery. (CNN)
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

Aetna reduces presence in ACA exchanges
Following the Justice Department’s blocking of a merger between Aetna, one of the nation’s five largest insurance companies and insurer Humana, Aetna has announced that they will reduce the number of counties they offer insurance products on the exchanges by more than two thirds. The Obama Administration claims that the move is in retaliation for the Justice Department’s decision to oppose the merger on anti-trust grounds. Aetna claims the move is based on the unprofitable nature of some of the exchanges. (New York Times)

Out-of-pocket medical expenses in retirement continue to rise
Retirees need to set aside $130 000 on average to cover medical expenses over the course of their retirement, according to a study from Fidelity Investments. The expenses stem from Medicare premiums and prescription drug costs. (Bloomberg)

Cost of EpiPens rise dramatically
The cost of EpiPens—a self-contained epinephrine delivery system, which can help counter act a life-threatening allergic reaction—has risen dramatically since the medicine was purchased by Mylan, who have raised the cost from around $100 for a pack of two in 2009 to current price of more than $600. This change has especially impacted families on high deductible insurance plans, who have little recourse but to pay for the potentially life-saving medicine. (CBS)

Local opposition halts trial release of genetically modified mosquitoes
An FDA approved trial release of genetically modified mosquitoes in the Florida Keys has been halted due to local opposition. The genetically modified mosquitoes, intended to help fight the spread of the Zika virus. The modified mosquitoes mate with local mosquitoes, but their offspring do not mature to adulthood. Locals opposed the testing of what they see as an “untested” technology. (NPR)

Traumatic brain injuries from strollers on the rise
The ratio of traumatic brain injuries stemming from children in strollers is on the rise, according to a report published in Academic Pediatrics. TBIs made up 19% of stroller injuries and 18% of carrier injuries in 1990, and 42% and 53% respectively in 2010. Researchers believe the rate of injury hasn’t increased, but the new results reflect an increased understanding and detection of traumatic brain injury. (Live Science)

More people leaving their bodies to science
Research universities are seeing an upswing in the number of people donating their bodies to science. Experts are attributing the increase in part to rising funeral expenses and a lessening of religious and cultural objections to dissection and cremation. Donated bodies are used by medical students to practice surgical procedures and to test new technologies. (Houston Chronicle)
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

**First Zika-related death in the US**
An infant with Zika virus-related birth defects has died in Texas, making it the first death in the US stemming from the virus. The infant was born with microcephaly and died shortly after birth. The mother had traveled to Latin America during her pregnancy. ([US Today](https://www.usatoday.com))

**FDA bans sales of e-cigarettes to minors**
Filling a regulatory hole, the FDA has used its regulatory power of tobacco products to ban the sales of electronic cigarettes to minors. E-cigarettes, which deliver a nicotine and flavor-containing aerosol to users, can now only be sold to those over 18 years old, with a photo ID. ([WebMD](https://www.webmd.com))

**Social media abuse of nursing home residents**
The Centers for Medicare and Medicaid Services have called on state regulators to ensure that nursing home operators prevent employees from posting demeaning and dehumanizing photos and videos of residents on social media. The move comes after reporting from [ProPublica](https://www.propublica.org), which documented instances of posts on social media platforms by nursing home staff showing residents nude, covered in feces and after death. ([ProPublica](https://www.propublica.org))

**Affordable Care Act making people healthier**
A study of low-income residents of Kentucky and Arkansas, states that accepted the Medicaid expansion built into the Affordable Care Act (or Obamacare), has found that residents are more likely to report better health than similar residents in Texas, which refused the expansion. ([KMOV](https://www.kmov.com))

**Hospitals concerned over transplant ratings impact**
Hospitals are leery of conducting transplant operations with imperfect organs and extremely sick patients, for fear that poor outcomes will reduce their federal hospital ratings, which help determine a hospital’s standing and funding levels. While the Centers for Medicare and Medicaid Services eased the standards in April in response to a study, hospitals are still reluctant to put their reputations at risk. ([Stat News](https://www.statnews.com))

**Life long library-lingerers live longer**
According to a longitudinal study from Yale University, those who read more than three and a half hours a week were 23% less likely to die during a follow-up period in the study, even accounting for factors like health, income and education. The benefits also only stemmed from reading books, not newspapers or magazines. ([Christian Science Monitor](https://www.csmonitor.com))
Zika virus continues to spread, CDC issues Florida travel advisory

Susan Jaffe

Dr Tom Frieden, director of the Centers for Disease Control and Prevention (CDC), said last week that recent “aggressive” mosquito control efforts have been disappointing. The Aedes aegyptimosquito that can spread Zika may be resistant to some insecticides or may breed in “cryptic” places insecticides cannot reach, he said.

Since four out of five individuals with the virus will have no symptoms, Frieden said there could be thousands more “people who have actually had the disease in the US because most asymptomatic people aren’t tested.” The virus can cause microcephaly and other congenital abnormalities in the fetuses of Zika-infected mothers. As of August 4, 15 infants in the US have been born with microcephaly to mothers with laboratory evidence of possible Zika infection, the CDC reports.

The CDC has issued a travel advisory recommending that pregnant women avoid a one-square-mile north Miami, FL neighborhood after state officials confirmed that several people in the area—17 as of August 8—got the virus from Zika-infected mosquitoes.

“It’s the first time in modern history that we have issued a travel advisory about the continental United States,” CDC director Tom Frieden told reporters in Miami last week.

But a travel advisory from Public Health England goes even further than the CDC, warning pregnant women to “consider postponing non-essential travel to the rest of Florida until after the pregnancy.”

The CDC also encourages pregnant women who live or work in the area to try to avoid mosquito bites and urges all pregnant women in the United States be tested for possible Zika virus exposure during each prenatal care visit.

Congress has not yet approved President Barack Obama’s request for $1.9 billion to help local officials respond to the Zika threat. “There is an overwhelming cry for more help and more resources,” said Dr LaMar Hasbrouck, executive director, National Association of County and City Health Officials. The CDC is borrowing money from other public health accounts to help local responders with mosquito control, Zika detection, and other efforts, which could reduce their overall response capacity, a recent survey showed.

When aid does come, it could “be too little, too late,” Hasbrouck fears. “A fire house doesn’t wait until a three-alarm fire to buy fire trucks, to gas them up and recruit and train firefighters.”
Congress, contracts, and cancer: challenges in Native American health

Rebecca Cooney

The Lancet United States of Health Blog recently had the opportunity to speak with Donald K Warne, MD, MPH about the state of Native American health in the US. Dr Warne is a family physician and the chair of the Department of Public Health at North Dakota State University, which oversees the only Masters program in the nation that includes an American Indian public health specialization.

Rebecca Cooney: Thank you so much for taking the time to talk with us today. To start, tell us a bit about your background and how that has brought you into contact with some of the issues facing Native American health right now.

Donald Warne: I'm an enrolled member of the Oglala Sioux tribe from Plain Ridge, South Dakota. So my first exposure was birth. I've been closely connected to my community and certainly to their health issues. I grew up in a family with a lot of medicine men and traditional healers. It's been very fortunate to grow up closely connected to health and healing from a cultural perspective.

I went to medical school at Stanford University and I became a family physician. Later in my career, I went back to school to get my Masters in Public Health from Harvard University with a focus on health policy. But I went into my medical career a little bit naively. I thought I would have an impact on Indian health as a primary care doctor. What I found was that you can have an impact on one patient at a time. But in truth the health issues occur long before you get to the doctor or to the clinic or hospital.

So with that experience and working full time as a family doctor in the mid-1990s, I found myself getting frustrated with the fact that almost everything I was dealing with was preventable. Looking at conditions like diabetes and heart disease, it is very difficult, if not impossible, to prevent those things in the clinic. It really has to be done at the community level. It changed my career path and trajectory and I decided to go back to get more training in public health so I could work further upstream.

Over the years, I worked with tribal health departments. I was on faculty at Arizona State University for a time as a professor focusing on Masters in Public Health line policy. I was also a staff clinician with the National Institutes of Health conducting diabetes research primarily with the Southwestern tribes.

Following my MPH and training in health policy, I became the health policy research director at the Intertribal Council of Arizona. In 2008, I became the executive director of the Great Plains Tribal Chairman’s Health Board, which is a four-state regional public health agency that is a consortium of 18 tribes in what is now the Great Plains area of the Indian Health Service. I’ve served as chair of the Department of Public Health at North Dakota State University in Fargo for the last five years.

Cooney: One of the other distinctions that you hold is being the first Native American doctor to serve on the national board of directors of the American Cancer Society.

Warne: I’ve been involved in multiple disease issues, and particularly here in the Northern Plain where we have significant cancer disparities. We have higher rates, unfortunately, of cigarette smoking and lower rates of cancer screening. So one of the outcomes is that we have among the worst cancer mortality rates in the world when you look at American Indians of the Northern Plain. I started my advocacy work when I was in South Dakota as a member of the Mid-West region of the American Cancer Society. Unfortunately, although the American Cancer Society has been around for now over a hundred years, I’m the first American Indian physician to serve on the national board.

Cooney: For those of our readers who didn’t see it, there was a piece in Newsweek recently where they delve into poor cancer care for Native Americans and the broader...
constitutional issues and potential treaty violations that underpin that lack of care. What should people know about the services that Indian Health Service provides and, importantly, the chronic funding shortages?

**Warne:** It is a little known fact that American Indians are the only population in this country that is born with a legal right to health services. Nationally, people are not born with a legal right to healthcare in the US. Either we purchase insurance or we qualify for public assistance programs like Medicaid. That’s true for everyone except American Indians. The basis for that is primarily routed in our treaties. There were hundreds of treaties signed with the tribal nations and the US government. Typically the treaties would exchange land and natural resources for various social services including housing, education, and healthcare. So that’s why there is a Bureau of Indian Affairs, a Bureau of Indian Education, and an Indian Health Service—the federal government has a trust to respond early to provide those services.

Even among lawmakers and policy makers, unfortunately, it’s a little known fact. The truth is that the majority of people, even lawmakers, don’t really understand the legal or historical basis for provision of health services to American Indians.

When you look at the funding of Indian Health Service it is nowhere near what would be considered proper care. For many generations now, Indian Health Services has been underfunded relative to other health systems. We are still somewhere around 40-60% level of need funded.

The challenge there is that with limited resources, we can provide only limited services. One example, specifically, is colonoscopy for screening for colon cancer. We do not have gastroenterologists or surgeons working within the Indian Health Service. We are dependent on referrals to the private sector and wind up unfortunately going through that budget relatively quickly because the referrals cost more money than taking care of patients in-house.

**Cooney:** Speaking of the lack of a preventative care component, in relation to cancer screening that can be especially disastrous.

**Warne:** When you look at national data sets, we are seeing decreases in colorectal cancer mortality rates in every population in this country except American Indians. We are the only ones either with leveling off or still in some cases increasing mortality from colorectal cancer. Quite honestly, most of that can be traced back to inadequate screening. Congress likes to point the finger at Indian Health Services and blame them for terrible health services. But in truth this is Congress’ fault—they don’t put enough resources into the agency and they are the first ones to criticize the agency for underperforming. Congress is in direct violation of its treaty responsibilities.

**Cooney:** I’m curious to get your impression of the impact that the Affordable Care Act (ACA) has had on Native American health in general.

**Warne:** Overall, the ACA is definitely a step in the right direction looking at it from a national perspective. But it’s important to consider that the ACA is not truly health care reform. It is health insurance reform in many ways. Indian Health Service (IHS) is not health insurance. One provision in the ACA is to include the requirement to pay for preventative care. That’s great if you are insured, but if you are dependent on IHS, those provisions actually don’t apply—that’s one of the reasons why we have less access to higher levels of preventive care and screening like colonoscopy.

But in general, we should be looking at the ACA as the largest expansion of Indian health in our generation. Particularly in states that have expanded Medicaid. For example, in North Dakota, we estimate that about 50-60% of the American Indian population in the state is at or below 138% of the federal poverty level. So what that means is that at least half if not a little more of the American Indian population is eligible for Medicaid and Medicaid expansion. So once you are on Medicaid or Medicaid expansion, you do have access to things like cancer screening. The challenge there is that not every state has expanded Medicaid, including South Dakota.

We are seeing a natural experiment play out in that North Dakota has expanded Medicaid and South Dakota has not. We are amassing some preliminary evidence of disparities and access to services based on South Dakota choosing not to expand Medicaid. American Indians can participate in the marketplace at no cost for up to 300% of federal parity level. Now 300% of the federal parity level for a family of four is about $72,000 dollars a year. In the Dakotas we have very few American Indian families making that much money. So we estimate that another 30-40% of the American Indian population is between 138% of poverty, which is applicable for the Medicaid expansion, and 300% of poverty. So we should be able to provide health insurance to about 90% of the American Indian population in North Dakota just by taking advantage of existing ACA opportunities.

So we should look at the ACA as an opportunity to provide health insurance to the vast majority of American Indians in North Dakota and other states with expanded Medicaid. Then hopefully we can get the same types of outcomes in places like South Dakota that have not yet expanded.

**Cooney:** In your estimation, what do you think should be the top priorities or where should we be directing our efforts most?

**Warne:** I think there are two main fronts. One, we should hold Congress’ feet to the fire. They need to live up to their treaty responsibilities. The treaties that we have are our...
contracts with the federal government, and the US government is in breach of contract when you look at the funding of Indian Health Service.

One of our challenges politically is that we have federally recognized tribes in only 35 states. So therefore 15 states and 30% of the Senate have no tribes in their constituencies. We need advocacy partners from both within Indian country and non-Indian advocacy partners. We have to get partners from outside Indian country that take us on as a priority and recognize that the US government is really committing civil rights violation and social injustice.

On the other hand, at the state level, particularly in states like South Dakota that have a significant number of American Indians living in poverty, we need to expand Medicaid. We need better outreach enrolment and, in states that have not yet done so, we need to advocate for Medicaid expansion. Then ultimately, long-term, we need Congress to live up to its responsibilities.
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

Zika in Miami
The CDC has taken the extraordinary step of issuing a travel warning for an area within the continental United States. The CDC advisory suggests pregnant women or those who may become pregnant refrain from traveling to Wynwood, a neighborhood north of downtown Miami that includes some of the most popular beaches in the US. (CNN)

Zika vaccine enters human trials
A DNA vaccine for the Zika virus has entered into human trials in a phase 1 study run by the National Institute of Allergy and Infectious Diseases. The study contains 80 people between the ages of 18 and 35. DNA vaccines work by using a circular piece of DNA called a plasmid that helps the body create proteins similar to the Zika virus that help the body create an immune response to the virus. Similar techniques have been used in vaccines for the West Nile virus. Researchers indicate that it would be several years before the vaccine would be ready to use outside of a clinical trial. (Live Science)

Sickle cell trait not linked to premature death
A recent study of nearly 50,000 African Americans in the US Army has found that people who have the trait for sickle cell—only present in one gene, not two, one from each parent as required for symptomatic sickle cell disease—does not put carriers at risk for early death. Previous studies have indicated that carrying the trait might put young African Americans, especially military recruits and athletes, at risk for early death, due to factors like heat stroke and heat stress from physical exertion. (US News & World Report)

Americans are wider, but not taller
A recent study by the CDC looking at weight trends over the last twenty years has found that the average American has put on about fifteen to seventeen pounds during that period, but hasn’t gotten any taller. The average woman went from 152 to 169, and the average man went from 181 to 196. (CBS)

Evidence For Flossing’s Benefits Thin as Floss
Following an Associated Press Freedom of Information Act request on evidence of flossing’s health benefit, the recommendations for flossing have been removed from the new Dietary Guidelines for Americans, prepared by the Departments of Health and Human Services and Agriculture. (NPR)
Democrats back Clinton, progressive platform at DNC in Philadelphia

Susan Jaffe

Sanders also stressed the need for unity when he addressed the convention on its first day, citing the Democratic party platform as evidence of the gains his supporters have achieved. The platform is a blueprint explaining the goals a Democratic president would pursue if elected. Past conventions, regardless of party, have usually been so scripted that reporters were often desperate for something to do and the platform document was the last place to find actual news—not so this year.

“It is no secret that Hillary Clinton and I disagree on a number of issues...that’s what democracy is about,” Sanders told the convention. “But I am happy to tell you that at the Democratic Platform Committee, there was a significant coming together between the two campaigns and we produced, by far, the most progressive platform in the history of the Democratic Party.”

Instead of scrapping the Affordable Care Act as Republicans have promised, provisions in the platform would expand the health insurance marketplaces by adding a “public option,” a non-profit health plan run by the government instead of insurance companies, similar to the federal Medicare program. As a non-profit with low administrative costs—and no shareholders seeking a profitable return on their investments—it would offer a cheaper alternative and reduce consumers’ premiums as insurers compete to offer similar value, supporters say. Democrats would also create a Medicare “buy-in,” allowing people ages 55 to 64 to pay to join Medicare, until they turn 65 and become eligible for the health care program. The platform would also allow Medicare to negotiate drugs prices with pharmaceutical companies on behalf of some 55 million—and rising—beneficiaries who use most of the prescription drugs in the US.

“206

“...it would be like Wal-Mart having each of its stores negotiate prices but the reason why Wal-Mart’s prices are so low is because they negotiate on behalf of all of its stores,” she said.

The Democratic platform also calls for a “fully funded National Institutes of Health to accelerate the pace of medical progress.” It would provide funding to study gun violence, and also addresses opioid abuse, mental health, autism and other health issues. The platform also supports funding to respond the Zika threat by developing diagnostic tests, a vaccine and treatment.

When Clinton’s running mate, Virginia Sen. Tim Kaine, mentioned Alzheimer’s disease in his speech accepting the vice presidential nomination, “he didn’t just say it’s a problem,” said Mary Woolley, president of Research!America. “He also said what we need is research to defeat it.”

Clinton “has a long-time track record of talking about and putting research to work to defeat HIV-AID and...has a very strong commitment to the research that it takes to combat diseases that particularly affect women and children,” said Woolley. “She understands the importance of the government’s role in fueling research and she understands public-private partnerships.”

But a Democratic president cannot accomplish the platform goals alone, Sanders reminded the delegates. “Our job now is to see that platform implemented by a Democratic Senate, a Democratic House and a Hillary Clinton presidency—and I am going to do everything I can to make that happen.”
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

ALS "Ice Bucket Challenge" gets results
The “Ice Bucket Challenge,” a viral sensation during the hot summer of 2014 actually ended up helping researchers discover a new gene related to amyotrophic lateral sclerosis, or ALS. The challenge ended up raising more than $115 million. (New York Times)

US blood supply shortage
According to the Red Cross, a major shortage in the US blood supply is looming, with only five days of supply left. The shortage comes while the FDA is formally reconsidering the thirty year ban on blood donations from all men who have sex with men. (WebMD, Scientific American)

Recommended changes in postpartum counselling
The American College of Obstetricians and Gynecologists’ Committee on Obstetric Practice has issued an opinion recommending that women should be counseled and offered long-acting, reversible contraception immediately postpartum in order to reduce the rate of subsequent unintended pregnancies. (ACOG)

Age differences between sexes in Alzheimer’s onset
A new study suggests that men tend to experience the onset of Alzheimer’s disease earlier than women, with men seeing the beginning of the disease most often in their 60s, and women experience onset beginning in their 70s, 80s and 90s. (UPI)

Anti-biotic research gets up your nose
Researchers in Germany are investigating a strain of bacteria (Staphylococcus lugdunensis) that lives in the nasal cavities of humans which has been show to destroy the drug-resistant strain of Staphylococcus aureus known as MRSA. (NPR)

Heat dome sticking around, is awful
The current “heat dome” that’s making life miserable in the eastern United States isn’t going anywhere through the end of the week, with temperatures in cities 10–15 degrees higher than average. Doctors recommend staying hydrated and out of the sun. (Medline Plus)
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

**Norovirus strike convention**
An outbreak of norovirus has been plaguing the 2016 Republican National Convention in Cleveland this week. (Washington Post)

**Gonorrhea bacteria developing resistance**
The bacteria that causes gonorrhea is developing resistance to the two main treatments for the STI, azithromycin and ceftriaxone, according to the CDC. While the rates are still low, resistance can develop quickly. (Huffington Post)

**Possible Zika transmission in Florida**
Public health officials in Florida are investigating the first possible locally transmitted case of Zika virus. (Reuters)

**Medicaid in North Carolina**
North Carolina’s Democratic Congressional delegation is urging the federal government to reject a restructuring of North Carolina’s Medicaid program being pushed by the Republican governor and state legislature. (NPR)

**Prostate cancer rates in the US grow**
New study reports that new prostate cancer cases in the US have grown by 72 percent. (Medline Plus)

**CTE and the WWE**
Dozens of retired professional wrestlers sue World Wrestling Entertainment Inc. alleging lack of care for neurological damage stemming from repeat brain injuries sustained in the ring. (CBS)
Republican Party lays out platform for Election 2016

Susan Jaffe

Editor’s note. Susan Jaffe reports from this week from the Republican Party’s platform committee meeting. The health provisions of the Democrats’ platform will be featured next week.

Several delegates said they don’t expect the presumptive Republican presidential nominee, Donald Trump, to agree with every point and that’s OK.

"With Mr. Trump, on a lot of these issues, he’s with us,” said Melody Potter, a member of the Republican National Committee from Charleston, West Virginia. “We know for a fact that Hillary Clinton is not with us.”

Potter, who was on the healthcare, education, and crime subcommittee, said the “very conservative” platform helps define her party for American voters.

“The Republican Party stands for something,” she said. “We have to draw a sharp contrast between our principles and the progressive, liberal, Marxist principles of the Democrats.”

Reporters attending the platform committee meetings this week were not allowed to see copies of the roughly 50-page document delegates discussed. But some delegates were willing to mention some health care provisions.

One section promises that a Republican president, on the first day in office, will halt the programs created by the Affordable Care Act and then sign legislation passed by congressional Republicans to repeal it.

However, the platform would retain the law’s requirement that health insurers sell coverage to people with pre-existing health problems, said Darcie Johnston from Vermont.

The platform also focuses on religious freedom and health care, assuring that medical professionals would not have to provide services, such as abortion, that conflicted with their religious faith. Other provisions would affirm the constitutional right to life of the unborn, and call for a permanent ban on federal funding and subsidies for abortion and health insurance policies, including Obamacare, the insurance program set up by the Affordable Care Act.

During the health subcommittee meeting, delegates were eager to restrict what they believed were the most objectionable parts of the law. “I thought we are repealing Obamacare,” its chairwoman, Carolyn McLarty of Oklahoma, reminded the group.

The platform would also prohibit the use of taxpayers’ money to fund organizations, like Planned Parenthood that delegates said “sell aborted baby body parts.”

Eric Brakey, a state lawmaker from Maine, proposed an amendment which was approved that would give the terminally ill a “right to try” investigational drugs not approved by the US Food and Drug Administration (FDA). It can take FDA 10 years to approve some medications, and that’s too long for dying patients, he said.

Although the platform recognizes the role of government and private investment in biomedical research, delegates said the document does not specifically call for increasing federal funding for the National Institutes of Health.

“Medical research is important,” the platform committee chairman, US Sen. John Barrasso of Wyoming, who is also a physician, said during a short break. “I would like to see it in the platform.” It should include a “call for additional focus on medical research,” he said, but did not provide details before calling the committee back to order.

Republican party officials said the platform would be available to the public after it is approved at next week’s convention which begins next week. They did not expect convention delegates to make changes, despite a fledgling effort to replace it with a two-page statement of principles.
This week in health and medicine

Rebecca Cooney and Aaron van Dorn

**CDC and gun violence**
With African Americans twice as likely to die from gun violence, African American public health leaders are calling on CDC Director Thomas Frieden to break his silence on gun violence. (CNN)

**Opioid law passes Senate**
US Senate passes bill with bipartisan support targeting opioid addiction; critics argue that the slated funding is insufficient. (New York Times)

**On the front lines of Zika**
Health departments in Texas are shifting focus to a new species of mosquito in an effort control the spread of the Zika virus. (NBC)

**Investigation of physician abuse**
An investigation by the Atlanta Journal-Constitution newspaper finds a troubling pattern of widespread and unchecked sexual abuse by physicians in the US. (Atlanta Journal-Constitution)

**Concussions among kids**
A new report suggests that concussion rates among American children have doubled. (Medline Plus)

**Eastbound and down**
Scientists at the University of Maryland believe they have discovered why eastbound jetlag is so much worse. (Gizmodo)
Obama rejects Zika funding approved during Democrats’ sit-in

Susan Jaffe

White House spokesman Eric Schultz called the House measure “woefully inadequate.” So even though the number of Zika cases in the US continues to rise as summer weather—and peak mosquito season—spreads across the United States, the president intends to veto the legislation, Schultz said.

House Speaker Rep. Paul Ryan, a Wisconsin Republican, called the bill “a significant step forward in the fight against Zika...that assures the administration will continue to have the needed resources to protect the public.”

The Zika shortfall is just one of the problems Democrats have with the legislation. It also cuts money for Obama’s signature health law, the Affordable Care Act, and for the Ebola response. It would also restrict women’s access to contraception and eliminate some provisions of the Clean Air Act, Schultz said.

The timing of the House vote was unusual. House Republican Speaker Paul Ryan brought the legislation to a vote at 3am last Thursday morning, during the remarkable sit-in by Democrats demanding a vote on gun control legislation. Democrats waved signs bearing the names and photos of people who died as a result of gun violence. The protest had been going strong for more than 15 hours, with some Democrats sitting on the floor, and some prepared to camp out with pillows and blankets.

They also used their cell phones—prohibited on the floor by House rules—to send photos and live video via social media to the outside world when Republican majority ended official business and turned off the House TV cameras and microphones C-Span uses to broadcast congressional proceedings. Instead, C-Span picked up the amateur video feed of Democrats explaining why they had taken over the chamber (Michigan Democrat Debbie Dingell revealed very personal reasons).

After Republicans returned to the House floor and approved the legislation over Democrat quite loud objections, Speaker Ryan adjourned the meeting and sent members home for the July 4 holiday. The sit-in ended too, but its leader, civil rights icon Rep. John Lewis, a Georgia Democrat, promised “when we come back here on July the 5th, we’re going to continue to push, to pull, to stand up, and if necessary, to sit down.”

Updated to reflect the status of the bill, Tuesday, June 28, 2016.
TUESDAY, MAY 10, 2016—15:24

Biden pleads for open data for cancer moonshot

Susan Jaffe

"Why can’t we do the same kind of thing in the fight against cancer?" Biden asked the seventh annual “Health Datapalooza” conference on Monday. The meeting brought nearly 1500 health researchers, entrepreneurs, patient advocates, health insurance representatives, and health care providers to Washington, DC this week, in addition to health officials from Australia, Canada, France, Israel, and the United Kingdom.

“Big data and computer power” can explain how genomics, medical history, lifestyles and genetic changes could trigger cancer, Biden said. But first this data must be standardized in compatible formats, so that it can be shared.

“Today different technology systems can’t talk to each other," he said. “Most major cancer centers don’t have an easy way—and in many cases the motivation—to share data, including patient records, test results, family histories, and treatment responses.”

Biden called for an “open national network that allows any researcher, physician or patient access to raw data in a privacy-protected manner.”

Under President Barack Obama, the federal government has released vast amounts of data about the care provided by hospitals, doctors and other health care providers to millions of older Americans in the Medicare program, along with patient outcomes and cost. The data has enabled federal officials to measure and rate Medicare providers and even penalize them for poor quality of care.

Previous “Health Datapalooza” conferences focused on the need to identify and release health data and make it accessible, said Niall Brennan, Medicare’s chief data officer and director of its Office of Enterprise Data and Analytics. “We have made a significant amount of progress, so now the question becomes not what can we release, but what people should be doing with the data,” he said.

Biden wants researchers and entrepreneurs to do more than analyze health care data to measure the quality of care or spending patterns. “I desperately need your input,” said Biden, whose son died last year of brain cancer. “Every day thousands of people are dying, and millions more are desperately looking for hope, for another day, one more month, maybe another year.”
Paris Climate Change agreement to be signed in New York

Susan Jaffe

Representatives of some 155 countries are expected at the signing ceremony, including President François Hollande of France, Canadian Prime Minister Justin Trudeau and other heads of state. President Barack Obama will be in Europe but he “is proud the United States will join the historic Paris Agreement this week, on the first day it is open for signature,” White House spokesman Frank Benenati said.

UN Secretary-General Ban Ki-moon has urged all countries to ratify the agreement as soon as possible. “It is in their national interest to implement the agreement and reap the benefits of sustainable global climate action,” he said in an email to The Lancet.

The signing ceremony “is a significant milestone and demonstrates the continued momentum for climate action,” said Nat Keohane, who directs the Environmental Defense Fund’s global climate program.

After 195 nations adopted the agreement last December, signing the agreement indicates the countries’ willingness to take the next step to ratify it. When 55 countries responsible for at least 55 percent of global emissions do so, the agreement takes effect. That could happen this year said UN spokeswoman Devi Palanivelu, noting that several countries are coming to New York with ratification documents they will submit after signing the agreement.

But things are not moving as swiftly in the US. Responding to a lawsuit by 27 states, a federal court temporarily barred the Obama Administration’s Environmental Protection Agency from implementing its Clean Power Plan, which seeks cuts in carbon emissions from coal plants.

It could threaten electric power reliability and increase costs, said Cynthia Meyer, spokeswoman for Attorney General Ken Paxton of Texas, one of the states suing EPA.

The plan is considered essential to meeting the US climate change pledge of a 26–28 percent cut in 2005-level greenhouse gas emissions by 2025.

The climate agreement also comes amid the most contentious and unpredictable presidential campaign in decades. While Democratic candidates support it, Republicans oppose the president’s global warming efforts. “I think there’s a change in weather,” Donald Trump, the leading Republican contender told the Washington Post last month. But he added, “I am not a great believer in man-made climate change.”
In the weeks since the president’s request, the number of cases of the mosquito-borne virus among people who traveled to countries where transmission has been confirmed has almost quadrupled to 193, as of March 9. It is in nearly twice as many states—32 and the District of Columbia—with Florida, New York and Texas topping the list. In Puerto Rico, the US Virgin Islands, and American Samoa, the number of cases is 174, or 19 times higher, reports the US Centers for Disease Control and Prevention.

“We are scraping together every dime we can to respond to this,” CDC director Dr Tom Frieden said last week in a conference call with reporters. “But it makes it very difficult to do things like plan for large-scale mosquito-control activities in Puerto Rico [and] establish and support rapid response teams to respond to clusters in the United States.”

Zika virus has been linked with microcephaly, a rare birth defect among newborns that causes brain deformities. But Dr Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, who joined Frieden on the call, cited recent studies linking Zika to other fetal abnormalities and Guillain-Barre syndrome, which causes paralysis.

“As the weeks and months go by, we learn more and more and realize how much we don’t know,” Fauci said. “And unfortunately, the more we learn, the worse things seem to get.”

He is “cautiously optimistic” about developing a vaccine for Zika and expects to begin a phase one trial to determine the drug’s safety and immunogenicity by early fall, with results possibly by the end of 2017. But without emergency funding from Congress, “we may find ourselves halfway through a phase one trial and not being able to take that next immediate step” to phase two, he said.

Meanwhile, the threat of mosquitoes spreading the virus may increase with the rainy season in Puerto Rico and warmer weather in the continental US. Since mosquito control is usually the job of local government, Frieden said state and local officials have been invited to a day-long “Zika Action Summit” at CDC’s Atlanta headquarters April 1 to help them prepare battle plans.
Congress wrangles over funding for Zika research

Susan Jaffe

While such Capitol Hill visits are part of the budget process, the looming virus adds a new urgency to the proceedings—though not necessarily enough to deter controversy.

Senator Roy Blunt, a Missouri Republican and chairman of the Senate Committee on Appropriations health subcommittee, began Thursday’s hearing by asking about emergency funding Congress provided to address the Ebola crisis.

“After the Department of Health and Human Services received $2.7 billion to spend on Ebola and other infectious diseases, more than half remains unspent, and none of the remaining funding thus far has been used for the current Zika outbreak,” he said. “This shows the fundamental problem in our public health system: it has a short attention span. We immediately forget about the outbreak that came before and do not adequately plan for the ones on the horizon.”

“Ebola isn’t over,” said Dr Tom Frieden, director of the Centers for Disease Control and Prevention, who explained the Administration’s Zika funding request along with Dr Anthony S Fauci, director of the National Institutes of Health’s National Institute of Allergy and Infectious Diseases (NIAID).

Frieden said about 100 CDC staff stationed in West Africa conducted 10,000 tests for Ebola last month and discovered a new case that required an intensive investigation in “a very challenging environment.” He told the committee that the Ebola funds are “fully committed” and funding for Zika is a separate matter.

“This is about finding things like Zika before they become problems,” he said. “We do need urgently to both not let down our guard against the threats we know and strengthen the systems so that we don’t always have to address things that we might have been able to find earlier.”

About $200 million of the $1.8 billion requested would go to the NIH and Food and Drug Administration to develop a Zika vaccine. When Tennessee Republican Lamar Alexander asked how long that could take, Dr Fauci said the agency is “engaging pharmaceutical companies right now.”

Last month, NIAID notified researchers of its interest in supporting research and product development to combat the virus.

Phase 1 trials could begin by the end of the summer to determine if a vaccine is safe and if it triggers a protective immune response, Fauci said. By the end of 2016, phase 2 trial could start if there are still enough people at risk for infection, with results expected in six to eight months.

Frieden confirmed that the mosquito-borne virus has been detected in the brain tissue of infants who died after developing microcephaly, a usually rare birth defect among newborns that causes an abnormally small head and can result in developmental delays, seizures, hearing loss and other problems. However, only about 20 percent of people infected show symptoms of the illness, which typically include fever, rash, joint pain, and conjunctivitis.

As of February 10, 52 cases of the virus have been reported in 18 states and Puerto Rico among US travelers who visited countries where transmission has been confirmed, according to the CDC. Another nine cases of locally-acquired cases have been confirmed in Puerto Rico and the US Virgin Islands.
Shkreli pleads the Fifth on drug price hikes

Susan Jaffe

The unwilling star witness was Martin Shkreli, the former head of Turing Pharmaceuticals who was responsible for the company’s decision to raise the price of Daraprim, used to treat toxoplasmosis, a parasitic infection that affects HIV patients, from $13.50 to $750 a pill. Shkreli appeared before the US House of Representatives Committee on Oversight and Government Reform in response to a subpoena, and “respectfully declined” to answer the committee’s questions by invoking his Fifth Amendment right against self-incrimination. Although he left Turing after he was charged in an unrelated securities fraud case, he is still a major Turing shareholder.

“What do you say to that single pregnant woman who might have AIDS, no income, and she needs Daraprim in order to survive?” asked Jason Chaffetz, a Utah Republican who chairs oversight committee. When Shkreli didn’t answer, Chaffetz said, “Do you think you’ve done anything wrong?”

As Maryland Democrat Elijah Cummings tried a different tact, Shkreli turned to photographers and smiled. “I want to ask you to—no, I want plead with you to use any remaining influence you have over your former company to press them to lower the price of these drugs,” Cummings said. “You can look away if you like but I wish you could see the faces of people...who cannot get the drugs that they need.”

Within minutes after he was dismissed from the hearing, Shkreli sent a response via Twitter: “Hard to accept that these imbeciles represent the people in our government.”

The committee then sought input on controlling drug prices from the chief commercial officer of Turing, Nancy Retzlaff, Howard Schiller, interim CEO at Valeant Pharmaceuticals—which raised the price of Isuprel for heart arrhythmia from $251 to $1346 a vial—Mark Meritt CEO of a trade group representing pharmacy benefit managers and Dr Janet Woodcock Director of the Center for Drug Evaluation and Research at the Food and Drug Administration.

When asked about drug prices, Woodcock reminded the committee that FDA doesn’t regulate them. But since competition helps lower prices, she was asked about the delays in getting new cheaper generic drugs onto the market. FDA takes about 10 to 15 months to approve new drug applications, under the Generic Drug User Fee Act but there is a backlog of about 3000 applications that pre-date the 2012 law. The latter are already 40 months old “and they’re not getting any younger,” she said.

Retzlaff said she was “comfortable” with 5000 percent increase in Daraprim because the company was offering discounts to some patients and reinvesting the revenue to develop better treatments for toxoplasmosis. Several committee members reacted with skepticism, especially since the company had hoped—according to internal emails the committee obtained—that the increase wouldn’t attract public attention.

But the Daraprim and other huge drug price increases attracted more than just public attention. Committee members called the practice “disgraceful,” “outrageous,” “repulsive,” and “absolutely disgusting.” And they promised to take action to solve the problem.
Increasing access to mental health services—a sensible strategy for reducing gun violence

Ron Honberg

Mental illness has been associated with a number of highly publicized mass shootings in recent years, including Virginia Tech, Tucson, and Aurora. Yet, mass tragedies occur relatively infrequently, accounting for less than one percent of all gun related deaths. Mental illness is infrequently associated with acts of gun violence that do not involve mass shootings.

Research shows that most people with mental illness pose no greater risk of violence towards others than anyone else. In fact, people with mental illness are more often victimized by violence than the perpetrators of violence.

There are small subgroups of people with mental illness who do pose higher risks for violence such as people with co-occurring substance use or untreated symptoms of psychosis. While the link between mental illness and gun violence toward others is relatively small, the link between guns and completed suicides is quite high. More than 90% of persons who take their lives through suicide have mental illness and between 2000 and 2010, firearms accounted for 50% or more of all deaths by suicide.

How can sensible solutions be crafted for reducing gun violence associated with mental illness?

In NAMI’s view, these solutions must involve a two-fold approach. First, federal and state firearms reporting laws must be based on research evidence. Second, access to quality mental health treatment and supportive services much be increased and barriers to participating in needed mental health care must be eliminated.

Current federal law includes eleven categories of people who are prohibited from possessing firearms. One of these categories is “persons adjudicated mentally defective or involuntarily committed to a mental institution or incompetent to handle their own affairs, including dispositions to criminal charges of found not guilty by reason of insanity or found incompetent to stand trial.”

Putting aside this highly offensive and outdated terminology, not all of these criteria have a clear nexus with heightened risks for violence. This is particularly true for individuals deemed incompetent to manage their own affairs. There is no research evidence showing that a person temporarily assigned a guardian or assigned a Representative Payee by the Social Security Administration (SSA) for managing Supplemental Security Income (SSI) or Social Security Disability Insurance (SSDI) benefits poses a greater risk of gun violence than anyone else. The nexus between involuntary civil commitment and the risk of violence may be clearer, since legal standards for commitment in all states include dangerousness to self or others.

Proposals to further expand criteria for mental health reporting to federal or state databases, while well intentioned, may have unintended negative consequences. Consider for example Connecticut, which in 2014 passed a law to include people who voluntarily enter psychiatric hospitals in state reporting criteria. Although no studies have been done on the impact of this new law, there are concerns that it could have a deterring impact on the willingness of people to seek mental health treatment when they need it the most for fear of negative consequences. Stigma and prejudice towards people with mental illness is still unfortunately alive and well in 21st century America.

Keeping guns out of the hands of violent or potentially violent people, whether or not they have mental illness, is a laudable and important goal. However, for people with mental illness, the best solutions may lie in increasing access to mental health care. During the height of the recession, more than $4 billion was cut from state mental health budgets, leaving severe gaps in access to mental health services. Only 41% of adults in the USA with a mental health condition received mental health services in the past year. Among adults with a serious mental illness, 62.9% received mental health services.

The package of proposals by President Obama to address gun violence earlier this month included a recommendation to increase federal funding of mental health services by $500 million in 2016. The infusion of more federal resources into mental health services would represent a significant step forward. There are also multiple bills in the US House of Representative and the Senate to improve mental health care.

The current focus on mental illness and the need for better mental health services has been largely driven by concerns about violent tragedies. It is important to recognize that people with mental illness and their families experience tragedies that fall under the radar screen every day. These include homelessness, overrepresentation in criminal justice systems, and high rates of suicides. Perhaps 2016 will be the year we finally commit to fixing the broken mental health system in America.
Black and white and gray all over

Rebecca Cooney

On January 4, 2016, the White House announced President Obama’s executive actions for reducing gun violence in the USA. As expected, the announcement was met with an array of responses, from exultation to excoriation. The Administration’s roadmap to curbing gun-related assaults and deaths and improving safety comprises four plainly worded actions: keep guns out of the wrong hands through background checks; make our communities safer from gun violence; increase mental health treatment and reporting to the background check system; and shape the future of gun safety and technology. But the linguistic simplicity of the actions belies a much more complicated struggle between employing some common sense measures to keep guns “out of the wrong hands” and the role that mental health should have in that discussion.

Gun rights advocates have been quick to claim that mental illness is the catalyst for increasing rates of gun violence and mass shootings. While there is no doubt that the perpetrators of several high-profile shootings have been individuals with emotional disturbances, to suggest that mental illness is the primary precipitant in gun violence is patently incorrect. The relationship between mental illness and violence, and gun violence in particular, is one that is far more nuanced. And in order to respond to the epidemic of violence, gun policy reform must take a thoughtful and deliberate approach to the way in which mental illness is addressed and incorporated.

The most substantive piece of the executive action is the expansion of background checks. In addition to making clear that, regardless of the location of the point of sale, be it the internet, a gun show, or a store, anyone purchasing a firearm must go through a background check. When a background check is conducted, records in the National Instant Criminal Background Check System (NICS) are searched and indicate whether an individual is prohibited from possessing a firearm because of a felony, being addicted to a controlled substance, the subject of a restraining order, or having been adjudicated to the anachronistic category of “mentally defective”.

Previously, the information fed into NICS came from criminal courts. States were not required to provide mental health information, nor was the FBI permitted to investigate specific individual’s mental health capacity—a major loophole that allowed individuals who posed a serious mental health threat, but who did not have a criminal history, from legally purchasing firearms. But a Department of Health and Human Services (HHS) modification to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule expands reporting entities to include organizations that make mental health determinations. More specifically, healthcare agencies that were unable to report to NICS will now be able to report health records that could have an impact on an individual’s ability to purchase guns. Mental health adjudications could have wider reach than feeding into NICS and there has been little indication that adequate oversight will protect the health records of Americans who have had contact with mental health professionals and those who are not necessarily in the group of individuals with the highest risk of violence. Thus, physicians and mental health professionals in the USA should have an essential and well-defined role in making such adjudications, a function which stands in stark contrast to the current position of pro-gun lobbyists and politicians who would restrict that role.

Two weeks after the executive actions were announced, we are still in the earliest stages of the HIPAA modification and NICS reporting developments, which gives us a rare opportunity for the medical and health community to become more vocal agents of change. Instead of a chorus reiterating that guns are indeed a public health issue, it is a prime moment to recognize that those who work to protect health should have a say in when, how, and with whom we intervene. It’s time to make the “gray” part of gun control reform matter.
Some Congress members say a 1980 law may curb rising drug prices

Susan Jaffe

No single federal agency reviews US drug prices, but 51 members of the US House of Representatives have discovered a 35-year-old law that allows the government to control huge hikes in drug costs. And they want the Department of Health and Human Services and National Institutes of Health (HHS) to use it.

Earlier this week the group led by Texas Democrat Lloyd Doggett wrote to HHS Secretary Sylvia Matthews Burwell and NIH director Dr Francis Collins to explain why.

Under an obscure provision in the 1980 Bayh-Dole Act, federal agencies retain some patent rights to the drugs produced through government-funded research. These rights include sharing the patents with drug makers so that no single company controls the price of a drug. The law says the government can assert what are called “march-in” rights when “action is necessary to alleviate health and safety needs which are not being reasonably satisfied” or when the benefits of a patented product are not “available to the public on reasonable terms.”

“When drugs are developed with taxpayer funds, the government can and should act to bring relief from out-of-control drug pricing,” says Doggett. “The [Obama] Administration should use every tool it has to rein in the practice of pricing a drug at whatever the sick, suffering, or dying will pay.”

This is not the first time NIH has been asked to intervene. When consumer groups urged NIH in 2012 to use the Bayh-Dole Act to open access to an HIV/AIDS drug, NIH director Francis Collins declined.

“The general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of the NIH’s march-in authorities,” he wrote in a 2013 decision.

That was before HHS, which includes NIH, hosted an unprecedented day-long public forum last November on drug price hikes to find ways to help patients. Burwell told the forum that HHS had asked drug companies for information about their “pricing arrangements.”

NIH and HHS spokeswomen acknowledged receiving the congressional letter and said the agencies would respond directly to the senders.

“We share a focus on ensuring access and affordability for people across the country, while encouraging drug development and innovation,” said HHS spokesman Benjamin Wakana.

But drug costs should not singled out, said Holly Campbell, a spokeswoman for the Pharmaceutical Research and Manufacturers of America, which represents 56 major drug companies.

“Conversations about cost need to look at spending across the health care system and not just at the share of spending that goes toward life-changing medicines,” she said. “The share of spending on medicines has been consistent for more than 50 years.”
Budget boon for biomedical research

Susan Jaffe

The US Congress has become famous for political gridlock but shortly before going home for the holidays, members approved a 2009-page budget for fiscal year 2016 with generous increases for some key health and science agencies, most notably the ailing National Institutes of Health (NIH).

Congress doubled President Barack Obama’s $1 billion request for the NIH, providing a total of $32.1 billion, more than the agency has received since 2003. It includes $935 million—a 60 percent increase—for Alzheimer’s Disease research, and increases of $200 million for the president’s Precision Medicine Initiative, $85 million more for the BRAIN Initiative, and an additional $100 million to fight antibiotic resistance.

“This increase comes at just the right time to take advantage of remarkable opportunities to improve human health, powered by dramatic advances in scientific knowledge and technological innovation,” said NIH director Francis Collins. In addition to thanking congressional leaders, he also acknowledged the agency’s supporters.

“It has taken a lot of effort on the part of many voices—patients, advocates, scientists, our many colleagues in the public and private sectors—to make the case for biomedical research,” he said.

“After years of what felt like beating our heads against the wall, we finally got through,” said Jennifer Zeitzer of the Federation of American Societies for Experimental Biology, which represents 27 associations of professional scientists. More members of Congress began to recognize that “biomedical research is critical to the economy and saves lives,” she said, including some conservative Republicans in the House of Representatives who spoke publicly about their willingness to support a substantial increase for NIH.

Other budget highlights include $21.5 billion for the Food and Drug Administration, a 5% increase which was nearly all of what the president requested and also more than the House of Representatives and the Senate had separately approved. It includes a 9% boost to implement the Food Safety Modernization Act to ensure that imported food meets US standards, as well as increases for the president’s precision medicine and brain initiatives.

Steven Grossman, deputy executive director of the Alliance for a Stronger FDA, was “pleased but not surprised” by the new funding. Because congressional leaders understood that “the needs at FDA are quite pressing,” he said they were able to give the agency more than what the House and Senate had appropriated.

Congress set the stage for the budget increases after agreeing in October to raise federal discretionary spending limits, a deal negotiated by House Speaker Rep. John Boehner, only after he had announced he was resigning. Paul Ryan, who reluctantly took over Boehner’s position, was widely credited for helping to rally Republicans behind the proposal after only seven weeks as House leader.

“It was a good win,” said President Obama, in his year-end press conference after signing the budget into law. “There are some things in there that I don’t like, but that’s the nature of legislation and—and compromise. And I think the system worked.”

But the budget wars are far from over as the US enters a presidential election year. All but one of the US senators running for president voted against the budget, including Independent Bernie Sanders. (Florida Republican Marco Rubio missed the vote.)
Paris climate change agreement faces hurdles in the USA

Susan Jaffe

But the international consensus to reduce global warming failed to move the Republican candidates competing for Obama’s job. It merited just two brief asides during their debate two days later and is unlikely to win over Republicans in Congress.

“When I see they have a climate conference over in Paris, they should have been talking about destroying ISIS,” said Ohio Governor John Kasich, to much applause.

And Donald Trump, the businessman-turned-politician at the head of Republican pack seeking the presidency, said it was “inconceivable” that Obama thinks that global warming “is the biggest problem this world has today.”

While the Paris negotiators were at work, the US House of Representatives easily passed a Republican-backed bill to repeal the Administration’s Clean Coal Plan, which seeks dramatic reductions in carbon pollution from coal-fired power plants that are essential if the USA is going keep its commitment to control greenhouse gases. Two weeks earlier, the Senate passed similar legislation.

Opponents of the Clean Power Plan are also fighting it in federal court, where 27 states filed lawsuits to block the regulations, claiming that the Environmental Protection Agency (EPA), which issued the plan, doesn’t have the authority to force states to reduce carbon emissions.

“It’s going to cost hundreds of billions of dollars and hurt consumers and businesses,” said Jack Mozloom, Media Communications Director, National Federation of Independent Businesses, one of 16 business and manufacturing groups also suing the EPA.

But in climate change skirmishes two weeks ago, opponents suffered losses.

Obama vetoed two joint congressional resolutions condemning the Clean Coal Plan. And Democrats defeated Republican efforts to include similar measures in the budget legislation the president signed into law before heading to Hawaii for vacation earlier this month. Republicans also failed to block funds for helping poorer countries adapt to climate change.

It may be possible to avoid another congressional confrontation on the issue, said Alex Hanafi, a senior attorney at the Environment Defense Fund’s global health program who attended the Paris climate negotiations. The president can use something called “executive agreement” to approve the climate change accord, he said. “The provisions in the agreement are consistent with US law and thus the pathway for US participation won’t require a stop in the US Senate.”
Gene editing—a revolution from stem to stern

Rebecca Cooney

With the entrance of CRISPR (clustered regularly interspaced short palindromic repeats), a technique using the Cas9 enzyme to cut strands of the genome at precisely targeted locations to insert, replace, or remove DNA, the manipulation of the genetic basis of human disease has once again come to the fore.

Much of the excitement comes from the sheer versatility of the yet little explored technique as a possible way to preempt, for example, diseases such as Tay-Sachs or sickle cell anemia. But that promise may not come without unforeseen consequences, prompting leaders in the world of genetics to question what the scientific and ethical boundaries of this technology should be.

December 1–3, 2015, experts from the leading international scientific groups in this domain at the Gene Editing Summit held at the National Academy of Sciences and the National, co-hosted with the Academy of Medicine Chinese Academy of Sciences and the UK’s Royal Society. The summit brought together researchers and stakeholders from around the world to discuss the scientific, ethical, and legal issues surrounding the current state of gene editing. After days of discussion, the group released a statement to summarize the consensus.

The statement highlighted four areas where caution must be exercised and where continued work is necessary to clarify and quantify the clinical utility of gene editing. The first area is to better elucidate where there is strong basic and preclinical evidence for editing gene sequences in human cells. Of note, the statement makes clear that germline cell editing should not be used for establishing pregnancy. Second, at the somatic cell level, a greater understanding of the risks involved in the individual receiving genetic modification therapy is necessary. Currently, there is little to no regulation for somatic genetic editing. Similarly, there is little oversight with respect to germline cell editing. Here, there is considerable ambiguity around the circumstances where editing might be appropriate. In particular, the capacity of editing to “enhance” human traits or capacities is of great concern. Finally, the statement points to the urgent need to continue the conversation within the international community about regulation around the human genome.

Coming to a consensus on some aspects of science and ethics, though at a crossroads, is far from the end of the story. In fact, the consensus statement serves as a foundation for the next epoch of discussion. On December 8, 2015, it was announced that the second wave of the Academies’ Human Gene Editing Initiative was set to commence. Alta Charo, a professor of Law and Bioethics at the University of Wisconsin, Madison, and Richard Hynes, of MIT and Howard Hughes Medical Institute investigator, are set to co-chair the study committee that will steer that next wave of information gathering and buy-in from the scientific community, policy makers, patient advocacy groups, and the public. This is a monumental step in determining the way in which gene editing can and will be employed for human disease. More specifically, the committee is tasked with evaluating the scientific evidence around several weighty issues, including the clinical applications of gene editing in specific human disease states; what the specific risks of gene editing may be in humans and what steps can be taken to mitigate those risks; and what the appropriate ethical, scientific, and legal oversight bodies should be in the USA and internationally.

It is a pivotal time to move forward with gene editing. But to do so will require a firm accounting of what has been accomplished and what might be accomplished through the judicious and thoughtful clinical application of our latest scientific developments.
As drug prices go up, some point consumers up north

Susan Jaffe

Many Americans and even government health programs are feeling squeezed by rising drug costs, with federal officials reporting last week that US health care spending in 2014 rose at the fastest rate since 2002 “in part due to the introduction of new drug treatments for hepatitis C as well as of those used to treat cancer and multiple sclerosis.”

Treatments for hepatitis C, which affects around 3 million people in the USA, can cost more than $100 000, Health and Human Services Secretary Sylvia Matthews Burwell said at an unprecedented day-long conference on drug pricing HHS hosted last month.

“And that’s an issue for both patients and the organizations and governments that serve them. Since more than three out of four infected adults are baby boomers, this disease has become one of the main cost drivers for Medicare’s prescription program. Impacts have also been significant in state Medicaid programs.”

To ease the financial pain, Democratic presidential candidates Hillary Rodham Clinton, former Secretary of State, and Vermont Senator Bernie Sanders would allow individuals to buy drugs for personal use from other countries. When he was in the House of Representatives, Sanders was the first of a handful of congressmembers who accompanied constituents to Canadian pharmacies to fill prescriptions.

Prompted by the HHS conference and recent price hikes, two leading Senate Republicans, Charles Grassley of Iowa and John McCain of Arizona want Burwell to use a provision of a 2003 law to certify that drug importation is safe and would significantly reduce drug prices. That step would permit pharmacies and wholesale retailers to import prescription drugs from Canada, the senators wrote in a letter to Burwell. They also want the FDA, which is part of HHS, to waive any prohibitions against individuals who import drugs for personal use. However, the senators recommend that Burwell limit the waiver to Canadian drugs no longer under patent in the USA, that have had “significant and unexplained” price hikes, and have no competitor, among other things.

Although FDA spokesman Christopher Kelly would not discuss the senators’ letter, he said importing drugs is risky and—with some exceptions—illegal.

“Drugs from foreign sources that are not FDA-approved do not have the same assurance of safety, effectiveness, and quality as drugs subject to FDA oversight,” said Kelly. “Such drugs have been found to be contaminated, counterfeit, contain varying amounts of active ingredients or none at all, or contain different ingredients altogether.”

FDA rules allow individuals to buy foreign-made drugs for personal use, which are not available in the US and are considered safe, along with other conditions.

Although individual US customers have relied on Canadian pharmacies for years, Canada is not the solution to high drug prices, said John Rother, president of the National Coalition on Health Care and former chief policy adviser for AARP, an advocacy group for older Americans with more than 37 million members.

“It is a way for individuals to save sometimes very substantial amounts of money,” he said. “But Canada has the population of California and they can’t supply the whole United States market.”
Resistance to antimicrobial drugs has become a health threat of epidemic proportions worldwide. The long list of drug-resistant bacteria continues to expand at an accelerated rate, highlighted yet again by the recent Commission published in The Lancet. Author Ramanan Laxminarayan, from the Center for Disease Dynamics, Economics & Policy, and colleagues wrote:

“Antibiotic resistance is a nuanced and multisectoral problem that threatens to erase decades of progress in medicine, food security, and public health. Like climate change, the issue of antimicrobial resistance is worldwide, and connects priorities across the globe regardless of a country’s level of development.”

Of significant concern is that antibiotic resistance is most challenging for our most vulnerable—children and older adults and the residents of heavily populated urban areas. As a practicing and investigative dermatologist, I have witnessed this problem first hand in the lab, clinics, and in hospitals, and have seen how easily it is to fuel the fire of antibiotic resistance.

Topical antibiotics were historically applied to all procedure sites, from biopsies to skin cancer surgeries. Studies have shown that doing so does not reduce the incidence of infections, but does increase the risk of creating resistant strains of bacteria. To help stop antibacterial resistance, we need to address what is happening every day in hospitals, emergency rooms, and clinics. And we need to address the over-prescription and over-use by health-care providers and patients.

Bacterial drug resistance has many negative consequences. Drug-resistant bacterial infections result in higher doses of drugs and the addition of treatments, with greater risk for side effects, longer hospital stays, and increased risk of permanent injury and even death. In the USA, infections due to antibiotic-resistant bacteria add $20 billion to total health care costs, plus $35 billion in costs to society.

Unfortunately, it is relatively easy for bacteria to develop drug resistance. These bugs are very good at passing around the tools they need—genes—to resist the weapons we have available. Poor patient compliance or taking an antibiotic for too long, such as can be the case with the use of antibiotics for acne, increase the likelihood of bacterial resistance.

In addition, drugs that inhibit but do not kill microbes are more likely to allow some microbial cells to survive and therefore develop resistance when exposed to that drug in the future. This process accounts for the majority of antibiotics in our armament.

The abuse of broad-spectrum antibiotics by physicians and patients alike has also impressively fueled the emergence of many dangerous antibiotic-resistant strains.

We also have to consider the environmental factors that play a role in resistance. Urban living—close quarters, public transportation, and the stressful pace of life—not only bring these organisms together, but increase our susceptibility. It can be considered another aspect of the high cost of living that comes with city life.

Many Americans may not understand the depth of this public health challenge, nor roles we all must play in the fight against microbial resistance. In the same way we have adopted recycling, wearing seat belts for safety, and reduced smoking, we need to adopt new behaviors around antibiotics.

What can we do?

• Think twice about using an antibiotic and ask your doctor to be sure it is necessary.

• Do not use an over-the-counter antibiotic ointment every time you have a scrape or a cut. Washing with soap and water, applying petroleum jelly and a bandage is typically more than enough to avoid infections, without encouraging bacteria to develop resistance.

• Wash your hands frequently with soap and water, and especially before eating, but also fortify your skin barrier by applying a moisturizer to damp skin. Dry, brittle skin can allow bacteria to enter and cause trouble.

• Oral and topical antibiotics for inflammatory skin diseases, such as acne, rosacea, and hidradenitis, should be used only temporarily and at a dose so low that it only imparts an anti-inflammatory effect.

Personal prevention, like the steps outlined here, will help to strengthen the efforts of governments and health experts worldwide that have moved this issue up the priority chain for the sake of public health. We can all play our part in the fight against antimicrobial resistance. There is no question about it, we need to begin now.
FRIDAY, NOVEMBER 20, 2015—02:41

No bones about it

Rebecca Cooney

Listen to a new podcast with Dr Douglas Kiel, President of the American Society for Bone and Mineral Research (ASBMR) about some fundamental changes that are being advocated to overhaul the process and requirements for osteoporosis clinical trials. Dr Kiel spoke on behalf of the ASBMR at a recent FDA Scientific Workshop: Osteoporosis Drug Development—Moving Forward.

One promising area for improving the drug development pipeline is through the substantial advances in bone biology and the identification of biomarkers. For more information on the use of biomarkers in drug development, read more about the Biomarkers Consortium, a bridge between public and private sectors to support the discovery and development of biological markers, under the auspices of the Foundation for the National Institutes of Health.
Can you hear me now?

Susan Jaffe

Almost 30 million Americans over 60 years old have difficulty hearing, but less than a third can afford hearing aids, according to a report to President Barack Obama by his Council of Advisors on Science and Technology two weeks ago. Even though hearing loss is often part of the natural aging process, the council did not recommend that Medicare—the federal health insurance program covering 55 million older adults—pay for hearing aids, which can cost an average of $5000 to $6000 for a pair.

When Congress created Medicare 50 years ago, hearing aids were among the services specifically excluded from coverage. “So it is going to take an act of Congress to change that rule,” said Dr Christine Cassel, president of the National Quality Forum and co-author of the report, “Aging America & Hearing Loss: Imperative of Improved Hearing Technologies.” But the cost of such legislation would likely “break the bank,” she said.

Instead, the council focused on solutions for people with mild-to-moderate age-related hearing loss and recommended how the federal government can “open up the hearing technology market to lower cost and increased innovation.”

For example, the US Food and Drug Administration should allow the sale without a prescription of “personal sound amplification products,” or what the report calls “basic” non-surgical, air-conduction hearing aids, a cheaper alternative to prescription hearing aids that would be similar to over-the-counter reading glasses. The Federal Trade Commission should permit consumers to get free copies of their diagnostic hearing tests and hearing aid fittings in order buy hearing aids from any company in person as well as through the mail, phone, or the internet.

While such steps may increase older adults’ access to some hearing care, they are no substitute for Medicare coverage of prescription hearing aids, said Joe Baker, president of the Medicare Rights Center, a consumer advocacy group. “Fulfilling the promise of the Medicare program requires its eventual expansion to cover all needed services, like hearing aids and other care,” he said.

Dr Peter DeGolia, a geriatrician at University Hospitals Case Medical Center in Cleveland, Ohio argues that treating hearing loss is an essential part of beneficiaries’ medical care. He is also medical director for the McGregor Program of All-Inclusive Care of the Elderly, which serves older adults who receive both Medicare and Medicaid—and covers prescription hearing aids. “Hearing loss can absolutely cause increased social isolation and can contribute to the appearance of memory loss and dementia,” he said. Hearing aids can improve patients’ understanding, cognition, and interaction with other people. “Fix the hearing and they do a lot better, they’re not demented.”

Last March, Rep. Debbie Dingell, a Michigan Democrat, introduced legislation to add hearing aid coverage to Medicare, after an ENT physician told Dingell that half her patients who needed a hearing aid couldn’t afford one. But in yet another reminder that Congress is hardly in a mood to raise Medicare spending, the legislation has won support so far from only six members.
Drug pricing—the bitter pill

Rebecca Cooney

Prescription medication is on the rise, with nearly 60% of American adults taking at least one. But what drives the cost of certain medications?

Listen to our podcast with Dr Peter Bach on the mechanics of drug pricing and why Americans are paying more.
Precision medicine and smartphones

Susan Jaffe

Not all of the one million volunteers needed for the research group that is the centerpiece for President Barack Obama’s Precision Medicine Initiative (PMI) will have smartphones to send data to researchers investigating genetically tailored medical treatments. But that’s no reason to keep them out of the study, said Kathy Hudson, Deputy Director for Science, Outreach and Policy at the National Institutes of Health.

“It would be my expectation absolutely that we would provide people with the gadgetry they need,” she said. “We don’t want technology to be a barrier.”

A working group co-chaired by Hudson presented recommendations three weeks ago to NIH director Francis Collins, which he immediately accepted, on how to begin assembling the one-million-member cohort expected next year. One of the top recommendations would ensure that the cohort reflects the diversity of the US population, including racial and ethnic minorities, and elderly and low-income people.

“Critically, the PMI cohort will be designed to ensure that people historically underrepresented in biomedical research are included in sufficient numbers to allow robust inferences in these groups,” the report says.

About 64 percent of Americans own smartphones with Internet access, according to an April report from the Pew Research Center. However, ownership is concentrated among younger Americans and people with relatively high income and education levels. And about 14 percent of adults surveyed in 2013 said they do not use the Internet, including 41 percent of those 65 years old or older.

In addition to providing smartphones or electronic activity trackers, Hudson said it may be necessary to supplement the data plans for volunteers who have the devices but lack sufficient connectivity.

Who pays the bill hasn’t been determined yet. The working group will be exploring “whether or not we can come up with interesting partnerships with the manufacturers of these various devices or if we can just purchase them and provide them to the participants during the course of their participation,” Hudson said.

In a survey of 2600 adults conducted by the Foundation for the NIH last spring, Hudson said slightly more than half said they would be interested in participating in the study, even without the offer of a free smartphone or data plan.

And the offer may not attract some people to sign up, since it comes with a catch. Study participants may have to donate blood, tissue samples and other biospecimens, share data from their electronic health records, as well as divulge information about their environmental exposures, lifestyle, and family background. Anyone afraid of needles should probably not apply.
US House of Representatives possibly “injured” by ACA spending, judge OKs lawsuit

Susan Jaffe

Only the US House and Senate, “acting together, can pass laws—including the laws necessary to spend public money,” wrote United States District Court Judge Rosemary Collyer, providing the first of several civic lessons in her decision. The House claims “that it has been injured in several concrete ways, none of which can be ameliorated through the usual political processes.”

The House of Representatives has voted more than 50 times to repeal the ACA, despite Obama’s promised veto. Frustrated in the political realm, the House last year approved a resolution to sue the president. No Democrats supported it.

The money in question—about $4 billion so far, says a House Republican staffer—goes to health insurance plans to lower what members qualifying for financial assistance contribute toward the cost of deductibles, drugs, and medical care.

In June, the US Supreme Court upheld another type of subsidy—reducing the cost of members’ monthly premiums—in states where the federal government operated online health insurance exchanges. Opponents claimed that only policies purchased through state-run exchanges were eligible for premium subsidies.

The House argues that the ACA provides a permanent appropriation for the premium subsidies but cost-sharing reductions spending must be approved each year. Administration officials say annual approval is unnecessary. Although about 5·6 million low-income Americans could lose this financial assistance if the court eventually upholds the House claim, experts have said that is not enough to significantly dismantle the law.

While Judge Collyer did not take sides on funding question, she concluded that “The House of Representatives as an institution would suffer a concrete, particularized injury if the Executive were able to draw funds from the Treasury without a valid appropriation.”

However, she dismissed another complaint that the Administration acted without congressional approval by delayed enforcement of the requirement that most large employers provide workers with health insurance.

“Spending this money is one of the most lawless things this Administration has done,” said Rep. Paul Ryan, the House Committee on Ways and Means chairman and former Republican vice-presidential candidate. “It is a perfect symbol of the president’s disregard for Congress’s authority.”

But the Department of Justice, representing the Administration, plans to appeal the decision, which White House Deputy Press Secretary Jen Friedman called “unprecedented.”

“The law is clear that Congress cannot try to settle garden variety disputes with the Executive Branch in the courts,” she said. “This case is just another partisan attack—this one, paid for by the taxpayers—and we believe the courts will ultimately dismiss it.”
Billions served but Cleveland Clinic says no thanks to McDonald’s

Susan Jaffe

After 20 years of serving patients, visitors, and Clinic employees in Cleveland, Ohio, the restaurant’s last day will be September 18. The world renowned hospital is not renewing its contract with McDonald’s.

“As a part of Cleveland Clinic’s commitment to health and wellness, we have made a number of changes across our health system over the past ten years that promote healthy food choices, exercise, and a smoke free environment,” said Eileen Sheil, the Clinic’s executive director for corporate communications, explaining why McDonald’s had to go. “Our goal is to reduce the risk factors that contribute significantly to chronic diseases.”

Hospital officials have talked about banning McDonald’s for at least a dozen years, as part of their growing interest in promoting—and practicing—healthy lifestyles. In 2007, the hospital system stopped hiring people who smoke.

In 2011, the American Hospital Association, which represents about 5000 hospitals, issued “A Call to Action: Creating a Culture of Health.” Its top recommendation declared: “As part of fulfilling their mission, hospitals are beacons of trust in the community. Hospitals must create robust health and wellness programs as examples to the communities that they serve.” Another of the report’s recommendations suggested that hospitals “remove environmental inconsistencies, such as unhealthy foods at meetings, in vending machines, or in the cafeteria.”

The Clinic becomes the seventh US hospital to shut down its McDonald’s, following hospitals in Texas, Tennessee, Pennsylvania, Illinois, Kansas, and Indiana, said Sriram Madhusoodanan, who directs the “Value [The] Meal” project at Corporate Accountability International, a watchdog group based in Boston that has urged hospitals to get rid of fast food, particularly from McDonald’s.

A hospital that allows McDonald’s to operate within its facility is providing “a tacit endorsement” of the restaurant’s “junk food,” he said. The introduction of salads, egg white breakfasts, sandwich wraps, and other menu options is just an effort to deflect criticism, he added.

McDonald’s has a quite different view: “You told us you’re trying harder to be more nutrition-minded for yourself and for your family,” the company’s nutrition website says. “That’s why we have been accelerating our efforts to serve food you feel better about eating and to help you make informed nutrition choices...We’re committed to giving you more delicious choices to feel good about now and in the months and years to come.”
Making gun violence an open target

Rebecca Cooney

According to the most recent estimates from the CDC, influenza kills anywhere from 3300 to 49 000 Americans. With a comparable number of deaths to the perennial challenge of the flu, why then is there so much resistance to the idea that gun violence is a public health issue?

Much of it comes down to ideology—the evocation of personal freedom and the constitutional protection of one’s rights. Somehow, over the last few decades, the notion of gun ownership has become a sort of proxy for civil liberties. And unlike the flu, where we can stress practicing good hygiene, targeting the vulnerable with seasonal campaigns, and encouraging vaccination, openly talking about firearm-related injuries in the context of health has been subject to restrictions. In 2011, Florida passed what essentially served as a “doctor gag order”, prohibiting physicians from inquiring about gun ownership or documenting any information related to gun ownership or the presence of guns in the home in medical records. Since then, a Miami circuit court struck the law down as a violation of free speech, but the ruling was appealed by Florida governor Rick Scott and is still pending. It is not a phenomenon singular to Florida. Similar bills have been introduced—but not passed—in at least 9 states. It is a frightening trend highlighting the massive force of special interests to impinge on the doctor-patient relationship and an example of suppressing open discussion about guns.

How can we discuss the strategies to reduce this massive number of needless deaths when certain forces are actively working to keep us from talking—even behind closed doors?

The conversation about gun violence in the USA needs to happen openly, it needs to be inclusive, and it needs to happen now. That means putting aside the reductionist arguments from either camp—those who are concerned about preserving gun rights and those who favor stricter gun control—and actually looking at data to shape evidence-based policy. Everytown for Gun Safety is one such organization that is working to close the gap between the previous lack of comprehensive data and the implications for public health and policy to reduce gun violence. In our latest United States of Health Blog podcast, I spoke with Ted Alcorn, Lancet contributor and the Research Director for Everytown for Gun Safety, about gun violence, public health, and how gun control measures can be improved.

In efforts to increase access to research, Everytown for Gun Safety has also recently launched a new website dedicated to data and analysis to aid in the conversation about curbing gun violence.

Pulling these pieces together is a start and it brings with it a modicum of hope that there are ways in which to uphold the 2nd Amendment, while putting gun safety first. But it can’t and won’t be done without an open discussion.
Home-care workers

Susan Jaffe

Home-care workers are excluded from the federal law requiring most employees to receive a minimum wage—currently $7·25 an hour—and 150% of that pay when they work overtime. After 40 years, the US Department of Labor (DOL) issued rules eliminating that exemption. The new rule was supposed to take effect last January but it was blocked by a lawsuit filed by associations representing companies that hire these workers. (Sixteen states, however, do have their own minimum wage rules that also apply home-care workers.)

Home-care workers provide help to older people or those with disabilities with dressing, eating, and other daily activities. This assistance is often the only reason many can stay out of more expensive nursing homes, said Deane Beebe, spokeswoman for the Paraprofessional Healthcare Institute, an advocacy group for home-care workers. Home care is also one of the fastest-growing industries in the country, yet she said for every two workers who are hired each year, one leaves.

“How are we going to build the workforce we need if this occupation doesn’t provide a decent wage?” Beebe said. “Who’s going to take these jobs? They are difficult emotionally, physically and they are socially isolating.”

After a federal judge in December sided with employer groups, the labor department appealed and last week won a decision upholding the new pay rules. On Tuesday, the employers announced they would appeal again, this time to the US Supreme Court. They argue that individual families and home-care agencies won’t be able to afford the higher pay. The rule also applies to state Medicaid programs, which provide health insurance for low-income families, and several states had filed legal papers in supporting the employers’ challenge.

“Left standing, the decision will hurt consumers, particularly patients with disabilities and home-care workers, as well as the home-care agencies that both employ and serve them,” said Denise Schrader, chairman of the National Association for Home Care & Hospice, which represents about 33 000 US home-care and hospice organizations. Consumers will have less access to care and workers will receive less pay—not more—as employers cut back services, she said.

Even as the legal fight continues, labor officials are “strongly encouraging employers to prepare for thoughtful implementation [of the rule] now,” a DOL spokesman said.

---

Watch Illinois Congresswoman Jan Schakowsky shadowing home care worker Gilda Pipersburgh last summer, pictured on the right with her client.

The video is part of the “Come Care with Me” series produced by the Paraprofessional Healthcare Institute, an advocacy group for home care workers.
TUESDAY, AUGUST 25, 2015—20:00

Clean Power Plan

Susan Jaffe

The Clean Power Plan, which includes regulations issued under the Clean Air Act, requires existing power plants across the country to slash 2005-level carbon emissions by 32 percent over the next 15 years. Utility companies would also ensure that at least 28 percent of their electricity generation comes from wind, solar, or other renewable sources. By 2030, the new rules would prevent up to 3600 premature deaths, 1700 non-fatal heart attacks, 90 000 asthma attacks in children and avoid 300 000 missed work and school days, according to the Administration’s estimates.

“It also shows the world that the United States is committed to leading global efforts to address climate change,” says the Administration’s summary. And the plan is essential if the USA is going to carry out its climate change plan submitted to the UN Framework Convention on Climate Change in preparation for December’s global conference in Paris.

Each state has been assigned a reduction target based on their current carbon pollution levels. They must start by 2022, and if not, the federal government can step in to do it for them, setting the stage for a barrage of lawsuits. But the last time Obama left it to the states to carry out a major legacy-making domestic policy, everyone ended up at the Supreme Court, arguing over the Affordable Care Act. Twenty-six states filed lawsuits to overturn the law. As readers may remember, the court ruled that Medicaid expansion was optional, and as of last month, 20 states have opted out. And 27 states have declined to set up their own health insurance exchanges, the Internet-based system that enables individuals and families to purchase private insurance policies. They left that job to the federal Department of Health and Human Services (HHS), which had a terrible time rolling out the exchanges last year. This year was much improved. (Another 10 run exchanges either in partnership with or with support from HHS, while 14 states operate their own exchanges.)

States can tailor their own carbon-reduction plans to their unique circumstances, EPA chief Gina McCarthy wrote in the agency’s blog three weeks ago. “States can run their more efficient plants more often, switch to cleaner fuels, use more renewable energy, and take advantage of emissions trading and energy efficiency options,” she said. EPA also has model plan they can adopt that’s guaranteed to meet the requirements.

“But states don’t have to use our plan—they can cut carbon pollution in whatever way makes the most sense for them,” McCarthy. And if it doesn’t?

On August 5, two days after the EPA announced the final rules, West Virginia and 15 other states asked the agency for a delay. “Absent an immediate stay, the [rules] will coerce the States to expend enormous public resources and to put aside sovereign priorities to prepare State Plans of unprecedented scope and complexity. In addition, the States’ citizens will be forced to pay higher energy bills as power plants shut down.”

While EPA considers the request, the states filed a lawsuit August 13 asking a federal court to order a postponement. On Monday, the US Court of Appeals for the District of Columbia told EPA to respond by August 31.
Faulty towers

Rebecca Cooney

The culprit is *L pneumophilia*, a species of Legionella bacteria, which causes pneumonia-like symptoms and flourishes in cooling towers—heat rejection devices used for air conditioning—that are heavily relied on in the summer months. Narrowing the skyline down to a handful of units is no small task. The exact number of cooling towers in New York City is well into the thousands and includes all shapes, sizes, makes, and models. But unlike previous years where sporadic infections have been reported around the city, this outbreak has been traced to roof-top cooling towers in a geographically clustered area. Five buildings in the South Bronx, including a hotel and a medical center, have tested positive for the bacteria and hundreds of spots have been inspected.

The incubation period from Legionella infection to disease is about 2–10 days. With the first positive tests for the bacteria having been identified in mid-July and city sources reporting no new cases after August 3, it is likely that the worst has passed. Enter the next set of hurdles. Although, the “ground zero” contaminated cooling tower is probably one of the five in the high-impact South Bronx cluster previously detected, to make that determination, genetic testing is under way.

Industry standards suggest that cooling towers should be maintained and cleaned twice a year. But in response to the magnitude of the current outbreak and number of deaths, on Thursday, August 13, 2015, the City Council of New York passed aggressive new legislation governing cooling tower upkeep. Ratcheting up the urgency for building owners, all cooling towers must now be registered within 30 days of the law’s enactment (by mid-September). But the law does not stop there. Building owners must also perform quarterly inspections for Legionella bacteria and provide the Department of Health and Mental Hygiene (DOHMH) with annual certification that cooling towers have been tested, cleaned, and disinfected. Failure to comply could result in penalties of $2000 for an initial infraction to up to a year in prison and a $25 000 fine for disobeying maintenance orders from the DOHMH. While some critics have decried the new measures as being overly punitive, safety governance of cooling towers should be on par with other building-wide regulations, such as fire codes.

It is surprising that such precautions have not already been enacted in a city of skyscrapers, where air conditioning runs for months, electric bills peak, and people bring sweaters to wear in chilly offices. But before New Yorkers can breathe deeply and welcome cooler fall weather, the new measure must be firmly enforced to align building owners with the public health needs of the city. That means greater vigilance and diligence, even with a hefty price tag. There is simply no room to be complacent. We’ve already seen the tragic effects this summer of giving cooling towers a cold shoulder.
Republicans and Democrats in the US House of Representatives last month overwhelmingly passed the 21st Century Cures Act aimed at speeding up drug development. But the Senate is not expected to vote on its version until next year.

More than 80 percent of the House backed the legislation after it was unanimously—a word rarely heard on Capitol Hill—approved by the House Committee on Energy and Commerce. In the process, the bill was revised to address concerns that drug approvals would happen a little too quickly, circumventing safety and efficacy standards.

The massive 362-page bill would streamline clinical trials, incorporate patient experience data, improve electronic health records, promote the discovery of new biomarkers for precision medicine, and encourage the use of new antibiotics, among other things. Supporters say it would also ultimately save taxpayers money in avoided health care costs: a fact sheet on the bill produced by the House Committee on Energy and Commerce cites the example of the polio vaccine, which has saved an estimated $800 billion since 1955.

The legislation also provides temporary funding of $8.75 billion to the National Institutes of Health, after years of cuts, and $550 million to the FDA over a five-year period. In order to spend that money, lawmakers had to reduce spending elsewhere, supplemented by an unusual source of new revenue—the sale of oil in the government’s Strategic Petroleum Reserve, which falls under the energy and commerce committee’s jurisdiction.

A handful of Democrats, including New Yorker Jerrold Nadler voted against the 21st Century Cures Act because it maintains the ban against federal funding for abortion, after an amendment offered by California Democrat Barbara Lee to eliminate it was rejected.

When the Senate’s Committee on Health, Education, Labor and Pensions (otherwise known as HELP) begins work drafting its version of the bill, several issues could slow things down. President Barack Obama and others have raised concerns about tapping the petroleum reserve and extending patent protection for some brand-name drugs. They also doubt whether the FDA funding is enough to get the job done.

“The new responsibilities for FDA outlined in H.R. 6 [the 21st Century Cures Act] exceed the resources provided in the bill,” according to a White House statement issued two days before the House approved it. “FDA will be unable to fully implement the programs established in the bill, while maintaining its current performance levels.”

The HELP committee has had eight hearings on FDA and NIH innovation and electronic health records and five staff working groups are developing legislation, said a spokeswoman. More hearings are planned, and its legislation should be drafted by the end of the year.

Debate on the Senate bill and an eventual vote would come next year, HELP committee chairman and Tennessee Republican Sen. Lamar Alexander said at an event held by the Bipartisan Policy Center two weeks ago.

But that’s also an election year, when nearly a third of the Senate will also be out on the campaign trail and the race for the White House will be in full swing.

Still, Mary Woolley, president and CEO of Research! America, thinks the Senate could pass a bill early in the new year.

“We know there is a strong determination in the Senate to craft and pass legislation that will modernize our research ecosystem and assure that science is serving the public’s interest,” she said. “Senator Alexander has his finger on the pulse of the concerns of Americans and understands the critical need to accelerate the discovery, development and delivery of new therapies to patients.”
World Hepatitis Day 2015

Rebecca Cooney

July 28, 2015 marks World Hepatitis Day to raise awareness about how to prevent viral hepatitis. But how we work to control and prevent hepatitis is very much reliant on how good our estimates are. Today, *The Lancet* published a paper including the first ever national-level prevalence estimates of chronic hepatitis B virus.

To hear more on these important new findings, listen to our latest podcast with principal investigator Jördis Ott.
In a statement released last Thursday, the AIDS Healthcare Foundation, one of the leading voices in the movement to introduce mandatory condom use in porn films, indicated that it had collected more than the 366,880 signatures needed to qualify a ballot measure. Los Angeles County passed similar legislation in 2012, “Safer Sex in the Adult Industry Act”, but the current push would extend a measure to the entire state—one of only two states where adult films are legal to produce (the other is New Hampshire).

Although the collection of thousands of signatures is far from a mandate by Californians, is there really substantial reticence to reduce the likelihood of transmission of HIV in a group of people who are at elevated risk because of the nature of their work? Indeed, the friction surrounding the potential legislation comes from porn producers who maintain that viewers are turned off by condoms and the demand for protection-less porn will move production to states without such legislation, which could be a blow to the financial security of the San Fernando Valley-based industry. The critics of the legislation are correct in certain respects. The number of shooting permits in Los Angeles County sharply declined after the enactment of the safer sex measure. And, in some cases, producers have moved production to other states such as Nevada, but with dire negative consequences directly attributable to laxer regulation. In September 2014, for example, at least two adult actors contracted HIV during unprotected sex at film shoots in Nevada. Interestingly, neither California nor Nevada require porn actors to undergo mandatory testing for HIV, although many companies will do their own testing on set. In the event of a confirmed HIV case, shooting is suspended, and public health authorities must then go about identifying and testing scene partners.

Much like the struggles for safe work environments in other inherently physically risky and demanding fields, in the world of porn, there continues to be tension between the financial health of the industry itself, which has been pitted against the health of the workers. It is understandable that porn producers and certain segments of California commerce are dismayed at the potential costs of implementing a common sense measure, but the human cost of pressuring adult film actors to work under conditions that continually make them vulnerable to transmission of a preventable infection is unconscionable. Not only are these workers exposed to greater risk, but a positive status can also render them without a livelihood. Performing without a condom is performing between a rock and a hard place.

The latest development in California’s regulation of the porn industry is well timed with the 8th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2015) taking place July 19–22, 2015 in Vancouver, British Columbia, Canada. It may not be a center stage issue in the global discussion about HIV prevention, nevertheless, the story unfolding in California is a topic that needs to be addressed. As part of the group of sex workers around the world, porn actors tread the line of marginalization and stigma all while being part of big business, estimated as a nearly $100 billion industry ($10–12 billion from the USA alone). The fact remains that allowing the porn industry to call the shots when it comes to basic workplace protection propagates further discrimination of and health risks for its workers. When it comes to satisfying the qualifications of fundamental public health risk reduction for porn actors, it is time that the rubber meets the road.
Immunotherapy comes of age

Rebecca Cooney

Reflected by the reception of eagerly awaited trial results at the 2015 annual meeting of the American Society of Clinical Oncologists (ASCO), which took place in Chicago, Illinois, March 29–June 2, immunotherapy has reached what might be considered a first critical stage of maturity. The approach is particularly encouraging in that it has shown early success across a range of tumor types and refractory cancers. And, with new trials exploring multiple pathways and in combination with chemotherapy, the role of immunotherapy in cancer treatment is destined to expand.

To hear more, listen to a podcast recorded at ASCO 2015 where Dr Mohammed Dar of MedImmune outlines the basic mechanisms that underlie immunotherapy, some of the new immunotherapy developments, and where the field is likely to move next.
WHO takes a big step to promote cancer treatment worldwide

Jordan Jarvis and Sandeep Kishore

Everyday, people around the world living with cancer go without life-saving treatment despite the fact that, for many of these conditions, effective treatments exist. The reality is that large populations in low income and high income countries alike are unable to gain access to these treatments at prices they can afford. This will soon begin to change.

On May 8th the World Health Organization added 16 new anti-cancer medicines to the Model List of Essential Medicines (WHO EML). The list is used by governments worldwide as a guide to set their own policies on which medicines should be “essential” and by UN organizations and philanthropic groups as a global standard to guide drug donations. Essential medicines are those that should be available and affordable at all times.

Experts who gathered to update the WHO list affirmed that there is “urgent need to take action to promote equitable access and use of several new highly effective medicines, some of which are currently too costly even for high-income countries.”

In 2012, two teams of experts petitioned the WHO to include imatinib for the treatment of chronic myeloid leukemia and trastuzumab for the treatment of HER2+ breast cancer on the WHO EML. The consideration of these applications for two highly effective cancer treatments kick-started a rigorous review process of the cancer section of the WHO EML through the Union for International Cancer Control (UICC) and its partners.

Our view, as petitioners for the addition of trastuzumab and imatinib to the WHO EML, is that this is a watershed moment for the global NCD community, including patients and front-line providers. The move by the WHO helps re-define essentiality based on clinical need—and not cost or cost-effectiveness alone.

People living with cancer have celebrated the additions of life-saving cancer medications to the WHO EML as a basic human right. Manon Ress, with the Union for Affordable Cancer Treatment (UACT), offered, “As a breast cancer patient whose life was saved for the last four years thanks to access to trastuzumab, the addition of this drug on the WHO EML was wonderful news. Twenty percent of breast cancer patients, those who are HER2+, could have had the same luck! However, the WHO needs to take this type of action much sooner, and not wait until the end of the patent term. In the future, we need to delink the price of all new drugs from the cost of R&D, from the beginning.”

The addition of high-priced cancer medications—along with patented medicines for hepatitis C and tuberculosis—on the same day is reminiscent of decisive moves by the WHO to add anti-retrovirals (ARVs) for treatment of HIV/AIDS in 2002, despite their cost.

The tension on whether to add expensive medications has largely centered on the debate of addressing the individual’s right to health versus population health—that is, on a limited health budget, should the government assist high-cost breast cancer patients to receive life-saving treatment, or should the cost of that treatment be spent on interventions that benefit a larger population? Jonathan Mann and AIDS advocates demonstrated that these are mutually reinforcing. Although definitions vary, the right to health is defined in the WHO constitution as “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” Repeatedly, national courts have affirmed the right to AIDS treatment, leading to government provision of HIV treatment in Venezuela and Argentina, for example. The WHO EML serves as a lever for national change.

“The EML is an essential tool for countries, regulators and procurers—such as Médecins Sans Frontières (MSF)—alike,” says Dr Jennifer Cohn, Medical Director, MSF Access Campaign. “The inclusion of medicines just added to the EML sends an important signal that initial high prices should not be a barrier preventing countries from considering use of medicines that can have an important public health impact.”

But, there is still much work to be done. Governments must align their own national essential medicines list (NEMLs) with the global standards endorsed by the WHO, bearing in mind national disease burdens. And, this will involve, where needed, spurring generic competition and invoking flexibilities enshrined in the World Trade Organization’s Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement.

The Young Professionals Chronic Disease Network (YP-CDN) has begun a next generation movement to do just that. In late March, we partnered with the American Cancer Society to host a workshop at Harvard University that focused on equipping young, passionate advocates from India, Rwanda, Kenya, Nigeria and the US with
evidence-based advocacy skills and knowledge to work toward improved cancer care and control policies. YP-CDN members are now focused on aligning national essential drug priorities with WHO standards for cancer treatment, to ensure inequalities are minimized. Our efforts involve pressure for government accountability, changes to financing and pre-payment structures, and other initiatives to enable all people with cancer (high or low prevalence) the chance of survival without pain or suffering. Emmanuel Sanwuok, a YP-CDN member in Ghana, remarked that those “opportuned to be in positions should be proactive and lead efforts and push the necessary knobs to ensure governments act accordingly.”

Oluwafunmilola James, a YP-CDN local leader and breast cancer advocate with the organization Breast Without Spot (BWS) in Lagos, Nigeria, says, “Even though a high proportion of the cancer medicines in the former WHO EML have not been included in the Nigerian EML yet, it’s at least very heart-warming to know that when the Nigerian Government eventually comes round to paying more attention to cancer control, one of our very first tasks will definitely be to advocate for the need to follow the WHO example by updating the Nigerian EML to include these cancer medicines.”

We believe that the rare alliance of people living with NCDs, next generation technical experts and advocates in a modern grassroots NCD movement will help embolden governments to follow the WHO’s lead. Advocates on the ground are leading the way. Dr Kalyani Menon-Sen, the Indian-based Coordinator for the Campaign for Affordable Trastuzumab explains: “Access to so-called “designer drugs” like Trastuzumab has so far been restricted to those who are able to pay the ridiculous prices demanded by patent-holders. That must change. Now that it is declared an “essential medicine”, it strengthens our hands in demanding that it be provided through the public health system.”
HIV in the heartland

Rebecca Cooney and Aaron van Dorn

Previously, the small, rural county in southeastern Indiana had seen no more than five cases of HIV infection in a given year—and often far fewer, with only three cases being reported between 2009 and 2013. According to the Morbidity and Mortality Report released by the CDC May 1, 2015, there have now been 135 new confirmed cases, many in the small town of Austin, IN which has a population of around 4200. Since that report has been released, that number has swollen to nearly 150 new cases since December.

Small and isolated, Scott County is typical of a lot of small towns in Appalachia and along the Ohio River valley. The second half of the 20th century has brought economic decline and, with it, persistent, multi-generational poverty, few employment opportunities, and lack of access to health care. Compounding the socio-economic issues has been a surge in the abuse of prescription opioid painkillers, which has left the region ripe for complications and infections acquired from injection drug use, such as HIV and hepatitis C (HCV).

One of the main means of transmission in Scott County is the sharing of needles among users. In response, Indiana Department of Health (ISDH) has set up a unique “one stop shop” system for containing the outbreak and providing treatment to those who have been infected. Treatments and services offered include a temporary needle exchange program, on the spot HIV testing for users, assistance filling out applications for health insurance, and addiction counseling.

Is it possible that a model treatment program could emerge from what has been one of the most notable public health crises in the USA in the last few decades? There is some reason to be optimistic. The concerted efforts of the ISDH and other partners, such as the CDC and the Indiana University School of Public Health, along with local health workers and law enforcement have been valiant. It is a rare demonstration of coordination among agencies and alignment of actions and goals. But Scott County and other similar areas across the country are at continued risk for HIV and HCV outbreaks. At root are some of the most entrenched social and health inequities—long-term regional challenges that can threaten to overwhelm even the most effective public health defenses. The outbreak response has, by necessity, been focused on fighting fires. But, we are hardly out of the woods.

Listen to a podcast featuring Dr Jennifer Walthall of the ISHD and Rebecca Cooney discussing the public health response in Indiana.
American College of Physicians at 100

Rebecca Cooney

In recognition of a century of leadership in internal medicine and health care, The Lancet acknowledges the dedication and commitment of the ACP to improving the practice of medicine.

Perspectives
Osler redux: the American College of Physicians at 100
In this Perspectives piece Charles S Bryan brings his unique historical view to the evolution of the ACP over the last century.

Profile
Wayne Riley: energetic new President for century-old ACP
Geoff Watts profiles Wayne Riley, the remarkable and passionate new ACP president who assumed office on May 2, 2015.

Podcast
ACP at 100
Steven Weinberger, EVP & CEO of the American College of Physicians talks with Rebecca Cooney about its mission, advocacy, and some new initiatives.
It was an elaborate and patriotic event, from the rousing performance of the US Public Health Service Music Ensemble to the boatswain’s call announcing the arrival and departure of the Official Party. It was an historic event too, but perhaps not for the most obvious reasons. Murthy is the first person of Indian descent to hold the position and the youngest at age 37. But he is not the first to hold an MBA in addition to an MD degree, nor the first minority. And he is not the first to bring some level of controversy to the role. His confirmation and commission is especially noteworthy, however, because it illuminates the continued struggling that the USA has had in making health a priority and in doing so has raised the profile and, possibly, the capacity of the Surgeon General’s office.

In his remarks to the audience at the commissioning ceremony, Murthy alluded to the difficult road to his confirmation saying, “By any reasonable measure, I shouldn’t be standing here.” After an active campaign by the NRA to block his confirmation because of objections to Murthy’s stance on gun violence and public health and the inaction of a group of senators leaving the confirmation in limbo for months, here he was, America’s “Top Doc”. But the allusion went beyond poking at the political machinations that govern the appointments of public officials because it also spoke to the grassroots efforts across the country to support him during the process. It became a team of health professionals and advocates united in a common goal, with Murthy representing an ideal of optimism, enthusiasm for change, and hands-on commitment to improving public health. In his words, “We got here by standing on principle.” To extrapolate from his speech a bit, the principle that he referred to is an ideology. It is the grand dream that America is human potential waiting to be realized. But where health is concerned, the American dream is chimeric—the status quo too often presents lethal obstacles to that human potential by hampering open discourse, inadequately investing in basic science and prevention, and espousing a sluggish reluctance to address inequity. To that point, what could very well become the slogan of his term as Surgeon General was his statement, “To put it simply: health equity is a civil rights issue.” Indeed, it is both a civil rights and a human rights issue.

Murthy’s optimism about and passion for improving health equity—not only in the USA but abroad—will be a major asset to the office of the Surgeon General. The US Public Health Service Commissioned Corps, which the Surgeon General oversees, is poised to become an even more prominent player in improving global health. Having trained and highly skilled health professionals who operate within the CDC and other Health and Human Services agencies who can quickly and effectively mobilize is increasingly important to address ongoing global health risks such as Ebola. In hindsight, the process of Murthy’s confirmation has been very timely. It has presented a singular opportunity to assess more closely what the role of the Surgeon General should be, especially during major public health crises, and may have a lasting effect on the remit of the office, by all indications one that is expanding. How public health issues are prioritized to balance the burden of outbreaks with the deep footprint of non-communicable diseases will not come without difficult choices and the need for sustained commitment and engagement. Murthy has made it known that as Surgeon General, he is prepared to take on those challenges.

From The Lancet USA, hearty congratulations to Vice Admiral Vivek Murthy—stand on principle, but hit the ground running.
FRIDAY, MARCH 20, 2015—04:18

Biosimilars breaking ground

Rebecca Cooney

Zarxio is not making history because it is a new drug—it was approved as a Neupogen biosimilar in the European Union in 2009 to treat patients undergoing chemotherapy or with neutropenia. But it is a groundbreaking event because it signifies some key shifts in American pharmaceutical regulations. Zarxio, in essence, is a trial run for a new system that may pose, if not major obstacles, some hurdles for sure. Here are few to consider:

**Drug safety**
For a biological product to be considered as biosimilar, it needs to have the same mechanism or mechanisms of action, to be administered in the same dosage and strength, and intended for the same indication as the reference product. But after meeting those requirements, as laid out by the FDA, the “abbreviated” licensure pathway for biosimilars relies more heavily on safety and effectiveness data from the reference biological product. But is that a sufficient standard for biosimilars to meet? That is where the need for post-marketing safety surveillance becomes especially salient. Groups like the Southern Oncology Network on Adverse Reactions (SONAR) have stressed the need for detecting and disseminating safety signals from serious adverse drug reactions above and beyond what is mandated by the FDA in the post-marketing environment. It is a pragmatic approach that is likely to become a necessary part of pharmacovigilance in the age of biosimilars.

**Market effects**
The primary motivations for producing follow-on drugs, whether biosimilars or generics, have always been to lower costs, to increase access, and to improve health outcomes. By some estimates, the entrance of biosimilars to the American market could save over $44 billion over the next decade. But estimates are simply estimates. It has not been determined whether biosimilars will actually end up costing less than reference biologics in the USA. That is a major concern. Even if biosimilars are cheaper on average, there are other costs that need to be taken into consideration, including those associated with regulation and the very real threat that biosimilar competition could work as an anti-competitive deterrent through lower returns on research and development investments.

Biosimilars may have broken ground, but it is not clear whether they can fix pharmaceutical prices.

Listen to the podcast with Dr Charles Bennett on the FDA approval of the first biosimilar in the USA and the impact of biosimilars on the market.

Read a review published in The Lancet Oncology on “Regulatory and clinical considerations for biosimilar oncology drugs”.

Listen to the Lancet Oncology podcast with Dr Charles Bennett on biosimilar oncology drug regulations and safety.
THURSDAY, MARCH 5, 2015—22:30

Ethics and Ebola

Rebecca Cooney

With the response to the Ebola outbreak still ongoing, there is an opportunity to reflect on the ethical issues present in the current crisis and to draw on the experiences from similar public health emergencies. Tasked with considering the response to date and formulating recommendations to improve responding in the future, the Presidential Commission for the Study of Bioethical Issues, an advisory panel comprising experts from medicine, law, and ethics, released the report, *Ethics and Ebola: Public Health Planning and Response* on February 26, 2015.

It is an unusual document in its scope, tone, and the implications of its recommendations. The report opens with the ethical justification for the USA’s involvement in global health emergencies—that engagement is not only a moral obligation in the service of promoting social justice, but also that it is a matter of self-interest given that the world is more interconnected now than ever. In this context, the Commission gives seven recommendations to guide public health planning and response. Some of the recommendations are straightforward, for example, the call to strengthen domestic and global health emergency response capacity, including national and international public health organizations and WHO, and the need for public health officials to communicate clearly and accessibly during public health crises with special attention on mitigating stigma and discrimination. The report also, however, proposes more novel recommendations, such as appointing a single US health official who would be accountable for coordinating the domestic and international public health emergency response. Infrastructure is not the only domain where changes should be made. The Bioethics Commission devotes considerable attention to improving the research by actively balancing scientific integrity and rigor with innovative clinical trial design.

Although it remains to be seen whether the recommendations are taken up by the Obama Administration, the report is a useful framework for addressing the key ethical issues that come with any acute public health crises. The hope is that when the next global emergency arises, the USA will be better prepared to protect and promote health, wellbeing, and equality at home and beyond its borders.

For more on the background of the report on ethics and Ebola and the Bioethics Commission’s recommendations and listen to the latest United States of Health Blog podcast, with Colonel Nelson Michael, Director of the US Military HIV Research Program and one of the members of the Commission.
Complements to your health

Rebecca Cooney

On February 10, 2015, researchers from the National Center for Complementary and Integrative Health (NCCIH), National Center for Health Statistics (NCHS), and the NIH released the report, *Trends in the Use of Complementary Health Approaches Among Adults: United States, 2002–2012*. Drawing on data from the National Health Interview Survey, health information which is collected continuously by the CDC, the analysis looks at the patterns in the usage of complementary health approaches over three time points—2002, 2007, and 2012. Although the overall number of Americans reporting using a complementary health approach has stayed relatively stable over time, the specific practices shift. For example, nonvitamin, nonmineral dietary supplements were reported as the most common type of complementary health approach used across all the time points, but whereas the use of some individual supplements such as probiotics have increased, others like ginko biloba and ginseng have decreased—patterns which may signify that consumers are taking heed of physician recommendations and evidence from clinical trials.

In a new United States of Health Blog podcast, Dr Josephine Briggs, Director of the NCCIH, and Dr Richard Nahin, NCCIH’s Lead Epidemiologist, discuss the major findings of the report and some of the potential implications for public policy. Listen to the podcast here.

For more on NCCIH see https://nccih.nih.gov/
Planning families, planning futures

Rebecca Cooney

Implementing and supporting voluntary family planning programs in 45 nations is a complex task, but USAID’s mission is straightforward—to advance and promote healthy families by offering reproductive services so that couples can choose “whether, when, and how” often to have children. Family planning and reproductive services can be a seemingly circumscribed facet of global health. From a global vantage point, however, the benefits of facilitating those choices are anything but limited. Supporting voluntary family planning is fundamental to protecting and improving the health of women by reducing abortions and high-risk pregnancies and enabling educational and employment opportunities that might otherwise not be available. The benefits are not limited to women’s health. Children’s health is also protected and improved when couples can choose how to space pregnancies and to provide adequate resources to their children. Healthier mothers, children, and families all contribute to healthier societies.

Taking into account the progress made in the last 50 years of USAID’s commitment to voluntary family planning and reproductive health—for example, increasing modern contraceptive use and reducing the average number of children per family—what will be the priorities for the next epoch? Perhaps the most crucial factor is the continued drive to scale up programs and access. There is great demand by women in their child-bearing years for family planning through modern contraceptive options and a persistent and wide gap in access for those in high-income compared with low-income countries. Even with much left to be done to provide access, greater demand is an encouraging sign. Education and informed choice are central to paving the way for greater health equity around the world. Through their efforts to promote voluntary family planning and reproductive health, USAID and its partners continue to work toward the global vision of educated, healthy people.

To read more on the global demand for family planning and some specific recommendations on how to meet that demand, see this Comment published in The Lancet.

Listen to a discussion of the major milestones and future priorities of the USAID Office of Population and Reproductive Health with Ellen Starbird, its director.

Read the chapter on family planning in 50 Years of Global Health (USAID) and see USAID Family Planning Program Timeline and USAID Family Planning Webpage.
Clinical trial data: share and share alike

Rebecca Cooney

Although there are reporting guidelines for clinical trials and systematic reviews and meta-analyses, there are no set rules, as yet, for the sharing of data for secondary use. In an age in which technological innovation occurs at an accelerating pace, clinical trial data sharing has been slack, hindered by fiefdoms and turf wars.

Notwithstanding the difficulties of overcoming some antediluvian ideas about the biomedical research ecosystem, there is now real momentum in reforming the life cycle of clinical trials and the longevity of data from those trials. After a lengthy process weighing the risks and benefits of different forms of data sharing and considering the various stakeholders’ points of view, the Institute of Medicine (IOM) has delivered a consensus report entitled, Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk. It is a major milestone in the long overdue overhaul of the clinical trial enterprise because it takes into account the perspectives of all the parties involved: the participants, funders and sponsors, regulatory agencies, investigators, research institutions, journals, and professional societies. Further, it makes specific recommendations for the respective stakeholders, some of which are immediately actionable; for example, asking internal review boards to provide guidelines and templates for informed consent that could apply to future data sharing. Other recommendations take the long view, such as making funding for clinical trials conditional on including a data sharing plan. And, in case you are wondering, there are specific recommendations that apply to editors too. For example, the report suggests that authors should provide the data and metadata used in secondary analyses at the same level as the original publication, something journals will have to enforce.

But with the new vision of the clinical trial pipeline, the report is clear in pointing out the many issues that remain to be worked out. The challenges extend across domains. Take the case of protection—which does not only apply to patient privacy. Protection is a serious concern in guarding intellectual property and ensuring that professional mobility and acknowledgment are incentivized through data sharing practices. Technical and infrastructure considerations are substantial and might prove to be the most difficult to optimize. Can we agree on certain endpoints, forms of data collected, and common terminology? Where will these data be housed? Which platforms are necessary? Training a workforce that can maintain data sharing is also a tangle when comparing trials conducted where there are fewer resources. The IOM report can’t resolve all of these issues, but there is a now a much better map of where the discussion and implementation of these recommendations is headed. Responsible data sharing means that everyone involved is responsible. All of this converges on fostering a research culture that values transparency and promotes clinical data sharing—those who share in the burden will also share in its rewards.

For more on the IOM report, listen to the podcast with Dr Bernard Lo, Chair of the Committee on Strategies for Responsible Sharing in Clinical Trial Data.
WEDNESDAY, DECEMBER 31, 2014—16:02

New Year’s resolution: commit to memory

Rebecca Cooney

But not all changes are welcome. If you or someone you know has experienced personality changes, memory loss, or who has a family history of Alzheimer’s disease, consider making the New Year’s resolution to commit to memory by having a memory screen. It is simple, widely available, and free. Memory screening and early detection can have a profound impact in the course of Alzheimer’s disease. As part of a new campaign, the Alzheimer’s Foundation of America is encouraging people and families to take that first step and to talk about memory screening.
Year in review
Lancet USA 2014
Rebecca Cooney

The Ebola epidemic, which is far from reaching any conclusion, has been transformative in many ways. While the focus has rightly shifted back to West Africa, the brief experience this Fall of Ebola on American soil exposed both the good and the reprehensible aspects of how, as a nation, we deal with the threat of infectious diseases. Fear has an incisive way of exposing our limitations. Once the Ebola crisis hit home, as it were, those limitations became painfully clear in the proliferation of misinformation, the political and media tendency toward xenophobia, and the shortcomings in our response preparedness for tactically addressing outbreaks. As negative as that assessment stands, it is also important, however, to once again point out that the health system in the USA is the strongest in the world. The innovation, resolve, and expertise that we have is something that we should be proud of and the reason for continuing our commitment to those parts of the world that need our assistance most.

The confirmation of Vivek Murthy for Surgeon General had all the makings of a Hollywood film—a young, outspoken Harvard and Yale-educated MD/MBA is appointed by the president to be “America’s Next Top Doctor”. But after seizing on an old tweet of his proclaiming that “Guns are a health care issue”, one of the most influential special interest groups, the National Rifle Association (NRA), clamors for his appointment to be blocked. Partisans and politicians in key swing states bend to the pressure and the confirmation appears to grow cold after 13 months. But, after a series of unforeseen political twists, in the feel-good ending of the year, Murthy is confirmed as the youngest Surgeon General of the United States.

Certainly one of the more gruesome stories widely covered this year was the controversy around capital punishment by lethal injection. Nationwide shortages of sodium thiopental, one of the three compounds used in lethal injection cocktails, gave rise to the exploration of alternatives in states that administer lethal injections. The aftermath of such experimentation was several highly publicized “botched” executions in Oklahoma, Ohio, and Arizona. With many Americans still firmly in favor of capital punishment, but a growing and vocal opposition as well, the future of lethal injection in the USA is very much still an open debate.

Prescription opioid abuse has dramatically risen in the last 25 years, and not surprisingly with it, so have the number of opioid poisoning deaths. But much more surprising is who is dying. A report released by the CDC in September 2014, included data showing that the greatest increase in opioid poisoning deaths during the years 1999–2011 was in adults age 55–64. Not exactly the group of individuals most associated with accidental drug overdoses. It is a complex problem without a ready solution. New governance of prescription patterns, reliance on analgesic alternatives, and educating patients about the dangers associated with opioids are some reasonable options, but without much greater public health efforts to curtail opioid abuse, it is a situation that is unlikely to change.

The Lancet United States of Health Blog will return after the New Year.
Getting a move on

Rebecca Cooney

The Lancet has moved: come and visit us in London!

Moving is never much fun. That feeling of fearful instability knowing you are leaving a safe, secure, and perhaps much loved home. The uncertainty of finding a place that can meet your needs and hopes, let alone your dreams. The anxiety for those who travel already long distances and worry those distances will only get longer. And the unanswered questions. Where can I park my bicycle? Can I choose whom I sit next to? What is the policy on offices?

Working at what are effectively ten medical and scientific newspapers, publishing daily, can be intense. Our lives are ruled by deadlines. Stress levels rise and fall according to the rhythms of the publication cycle. So where and how you live, and with whom you live, matters a great deal. Last week we packed our bags in Camden Town—our home for 12 years—and moved into the City of London. This was—this is—a major life event.

For those of us old in tooth and claw, this move proved to be the best in a generation.

I joined The Lancet in 1990. Back then, we lived in the opulent and decadent surroundings of one of London’s most beautiful squares—Bedford Square. Thomas Wakley, our founder, lived at almost the same address, and a blue plaque commemorates his home a stone’s throw from where we once worked. We felt close to our origins. And it was wonderfully convenient. We could walk across the road to the London School of Hygiene and Tropical Medicine for a cup of coffee.

But with the advent of computers we knew we couldn’t last long in a cramped and listed Georgian building. So we moved closer to the British Museum (and Great Ormond Street Hospital). The office in Theobald’s Road was brand new. We shared our floor with other journals, and we loved the shine of it all.

At first, we rebelled when told we were moving to Camden Town, to the north of central London. But we trudged up the road with our boxes and settled in, a little reluctantly.

Time is a great healer and over 12 years we made Camden our happy home. But slowly the building began to fray. Windows leaked. Lights broke. Carpets got stained. And, most importantly of all, we grew. We grew beyond anything we had imagined. It was time to look for a new home once again.

And then someone suggested London Wall. London where?

We were to leave fashionable North London for the historic traditions of the City and, for the first time ever, we were asked what we would like. Teams of editors, production staff, our journal office, and our press, web, and marketing teams all took part in shaping our new home. The style was to be very different from anything that had gone before. More light than we had ever seen. Corners to think and to talk.

In 24 years at The Lancet I haven’t seen people as excited as they have been this week. It’s early days, of course. It’s fresh. It’s original. I hope we all feel the same in a few weeks and months. I think we will. Come visit and see for yourself.

If it’s not us you want to see, come for the great iconic London views (and coffee) at least. This may be my last move at The Lancet. I can truthfully say, I think it will be our best.

Richard Horton
richard.horton@lancet.com
Veterans uncovered

Aaron van Dorn

Many people believe that all veterans are covered by the Veterans Affairs (VA) health-care system, but less than half (8.9 million) of the 22 million veterans in the USA are covered by VA health benefits, according to a Viewpoint published in The Lancet this week. In fact, most veterans are covered by private health insurance, supplied by employers or purchased on the private market. That leaves many veterans—who are disproportionately likely to be young, single, African American and veterans of Iraq and Afghanistan—without access to adequate healthcare.

However, the authors argue that universal health coverage for veterans is within reach, thanks to the Affordable Care Act and its Medicaid expansion and subsidies for private health-care. According to the authors, 87% of currently uninsured veterans could be eligible for health coverage through the Medicaid expansion, via the subsidized private health insurance market, or by enrolling in VA health benefits. Uninsured veterans are more likely to be clustered in states that have rejected the ACA’s Medicaid expansion. Of the top five states with the highest number of uninsured veterans, four are states that have rejected the expansion (the fifth, California, has accepted the expansion, but is also the most populous state in the union and has a population 12 million larger than the next largest state). In fact, nine of the ten most populous states are in the top ten states with the highest number of uninsured veterans, which is unsurprising, since those ten states represent 53% of the total population of the USA.

The way forward for ensuring that all of those who have served have access to healthcare is a challenge, but a crucial step may lie in increasing Medicaid. States that have rejected Medicaid expansion for political reasons are doing their veterans—and every citizen who lacks healthcare—a grave disservice by not working towards ensuring that American, veteran or not, has access.
Windows and Gates: bringing global health home

Rebecca Cooney

When it comes to investment in global health, the message is exactly the right one, at the right time, that Americans should hear. But it is also a message that needs to be amplified in a couple of ways. The USA is by far the largest development assistance donor for health. By the Global Humanitarian Assistance program estimates for 2013, the USA provided $4·7 billion in humanitarian aid, much of which is devoted to medical and health-care resources.

First, we need to challenge the notion that we are throwing money at someone else’s problem. Foreign aid for health is a strategic investment and there are windows of time in which maintenance or increasing of that level of assistance will have the biggest impact. Now is one such window. Second, imagine that the $6·2 billion for the emergency Ebola fund that Congress is considering could have been invested in building health infrastructure where it is most needed and where it could have made the most difference. Our strategy for improving global health doesn’t have to be crisis driven.

As Bill Gates suggested in his address at ASTMH 2014, as an alternative to waiting for the next Ebola outbreak, let’s think about making this the last Ebola outbreak. If we extinguish Ebola in west Africa, we extinguish Ebola in the USA.

It has and will continue to be a hard-fought battle to quell this current outbreak. We have to look at our failures, lapses, and shortcomings, it’s imperative to do so. But we need to recognize our achievements and acknowledge our successes that also once seemed out of reach, such as elimination of polio in almost every country and reducing malaria deaths by nearly half, and to apply that same continued drive to make a difference. The USA, including the federal government, non-governmental organisations, private foundations, and charities, has done so much to improve the collective health of the world and that is an idea to which Americans need to feel attached. It is not a platitude to say help others to help yourself, because global health is American health.
Honoring veterans

Rebecca Cooney

Today we honor all of those who serve and have served and to recognize the extraordinary contributions of service people.

2014 marks 100 years since the beginning of World War I, which in many ways shaped modern medicine. For a unique look back at this remarkable time, The Lancet presents a special Themed Issue: Legacy of the 1914–18 war.
Towards Universal Health Coverage: lessons the GOP can learn from the Latin American experience

Vin Gupta

In their recent Wall Street Journal op-ed, both issued direct intentions to repeal Obamacare in the next Republican-controlled Congress. Before treading this path, both congressmen would be wise to the heed the political lessons of Latin American countries that have successfully implemented Universal Health Coverage (UHC) over the last twenty years. Successful health care reform in our southern hemisphere has hinged on the cooperation and leadership of political elites from opposing parties.

Take, for example, Mexico, a country that had several key political ingredients at play when it adopted broad health reform in 2003 in the form of Seguro Popular. The country had recently elected an opposition party after decades of single-party rule and they were experiencing robust economic growth rates as a result of oil profits. Moreover, Mexico was experiencing an epidemiological transition with the onset of higher rates of non-communicable diseases that, as former Ministry of Health official Dr Octavio Gomez-Dantes notes, necessitated more health resources via reform.

The push for this reform, however, was not demanded by the electorate. Rather, as Gomez-Dantes describes, “Change in health policy was unlike the social mobilization that preceded Brazilian health reform in the 1980s in that it was purely ministerial-driven, taking advantage of a general atmosphere of democratization to push change.” The political livelihood of elected officials did not depend on pushing through or opposing UHC schemes; it was an organic movement led by visionary political leaders to improve the country’s delivery of healthcare.

Colombia similarly saw a movement towards UHC that was driven by a government-led push to inculcate health as a human right in the nation’s constitution in the early 1990s. Dr Ramiro Guerrero, a former government public health official, notes that, “Health care reform gained consensus quite rapidly in political circles without necessarily being pushed by a social movement.” All citizens, including those who did not pay into a public or private health coverage scheme via income taxes, are covered with a package of basic healthcare services. Dr Guerrero further highlights a climate of social harmony on the topic of financing for UHC; there is little protest among opposition parties, the upper-middle class elites, labor groups, or the media regarding the logistics of implementation of universal health coverage. As he notes, “Our political parties may not agree on everything, but they do cooperate on the topic of health care reform and this has paved the way for broad social acceptance, making implementation easier.”

American political leaders need to follow the Latin American approach and promote acceptance of the Affordable Care Act. Implementation and acceptance by stakeholders will inevitably be easier. Continuing to decry health reform in the absence of offering a better alternative has contributed to the toxicity of Washington’s current political climate, drawing excessive media coverage and heightening social malaise in the process. Americans deserve a Congress that views health as a basic human right and, in the absence of a perfect solution, our political leaders should embrace the example of their peers in Mexico and Colombia to ensure the durability and functioning of Obamacare.
The battle for a surgeon general

Rebecca Cooney

Chaffetz’s remarks were in reference to President Obama’s appointment of Ron Klain, an attorney, as the Ebola czar. Whether Klain is the appropriate person for the job is ancillary to what an Ebola czar, as opposed to a surgeon general, can do. It is a pivotal move on the part of the Obama administration to shape the action plan to stem new cases of Ebola, either contracted abroad or domestically. The position is in essence managerial, a point person to coordinate the multiple agencies providing services or support to curtailing the spread of the virus. At the acute stage of this crisis, we need one individual devoted to that task. Moreover, an Ebola czar doesn’t require a Senate hearing or confirmation. That is a critical point and also where certain politicians could do with a stark reminder. The USA would have a confirmed surgeon general if the appointment of Vivek Murthy was not still in limbo. Recommended back in November 2013, the process has stalled owing to backlash from the National Rifle Association over a comment tweeted by Murthy a year before that “Guns are a health care issue.”

Guns are indeed a health care issue. With the continued public health threat that mass shootings and homicides pose in the USA, public health must include open discussion, funding for research, and policy implementation to curtail gun violence. A surgeon general is not just an infectious disease czar, nor an honorary title conferred through a certain number of years of service. A surgeon general is an advisor and advocate for the health of all Americans. Vivek Murthy is an excellent candidate to fill that role. We strongly urge the Obama Administration and the Senate to confirm him as the next Surgeon General of the USA.

Vivek Murthy

To read our previous endorsement of Vivek Murthy in March 2014, see Confirm Vivek Murthy for US Surgeon General
Planning up a storm

Rebecca Cooney

The massive storm rendered the city incapacitated, with precious few ways in or out. Some of you may recall a line drawing of the island of Manhattan, marked “NoPo/SoPo”: North of Power/South of Power. New York City was literally bisected by access to electricity, The Lancet’s office firmly below the 30th Street demarcation. Apart from several consecutive days spent in my apartment in Brooklyn attempting to keep my then 3-year-old entertained against a backdrop of the constant eerie howling gale, I was merely inconvenienced.

And then the reports started coming in—cars floating in the East Village in Manhattan, entire neighborhoods of Staten Island, Brooklyn, and the Jersey Shore devastated and uninhabitable, and even more tragic, bodies being pulled from water-logged rubble in the Rockaways. Suddenly, being housebound was overshadowed with the grim realization that some of the wreckage was but two miles away. On the phone with my family in Northern California, who had weathered droughts, wildfires, and the Loma Prieta earthquake in 1989, I tried to impart—this was unlike anything I had seen before.

By most estimates, Hurricane Sandy doesn’t hold a candle to the devastation wrought by Hurricane Katrina in 2005. Nonetheless, it was catastrophic, taking the lives of over 117 people in coastal states, costing at least $65 billion in damages, and fundamentally changing the orchestration of disaster response. Given the anniversary and impulse to indulge in the journalistic meme, “What have we learned?”, I was curious to see what the academic world had to say. In the two intervening years, there have been scores of papers about the aftermath of Hurricane Sandy, spanning the social sciences, psychiatry, disaster medicine, nursing, and emergency care. Though the disciplines have different approaches to quantifying health outcomes, there are some consistent themes and lessons that emerge. Here are just a few.

• To account for everyone, the most vulnerable individuals need to be identified and they may not always be obvious. The difficulty of evacuating structures like high-rise buildings is great itself. But in some areas Sandy responders faced a further challenge of trying to communicate with elderly people who only spoke Russian. Urgent and distressing pleas went out to locate volunteers who could speak both Russian and English to assist in evacuations. Although it is just one example of the barriers that can present themselves during a crisis, it poignantly demonstrates the essential task of incorporating community-level action plans. In a place like New York, residents can be vastly different, even in a few square miles.

• Natural disasters can compromise infrastructure itself. Therefore, redundancy and alternatives are critical. In New York City, five hospitals had to be closed at some point during the storm and three were forced to move patients to other facilities after flooding or power generator failures. Beyond hospitals, out-patient care, dialysis facilities, and nursing homes were also affected. But out of the chaos of the storm, some important and novel adaptations were made, including using a free-standing emergency department at Bellevue Hospital and collaboration between hospitals to meet the patient surge.

• Disaster planning needs to account for the short term and the longer term. Anthropogenic climate change is creating bigger, stronger, and more potentially devastating storm cycles. There may not be much we can do to stave off “super storms”, but there are ways to reduce our societal vulnerability to the impact of storms. A very large part of disaster planning for New York and other highly populated coastal regions has to account for how it will function under extreme weather.

A natural disaster of the magnitude of Hurricane Sandy could happen at any time. Although we have the hindsight to see where we could have done more to prevent loss of life or to allay suffering, we often don’t have the foresight to make changes before another crisis occurs. But do we have a great opportunity to put all the insight we’ve gained into practice? You can plan on it.
Federal agencies questioned about US Ebola response

Rebecca Cooney

An auspice for hospice care

Rebecca Cooney

Every year, about 1·5 million dying Americans receive hospice care. The IMPACT Act makes important progress in addressing some of the major issues with the way in which the health-care system in the USA treats dying and end-of-life care by providing a means for reform of the oversight and funding mechanisms for post-acute care (PAC) providers. These include skilled nursing facilities, inpatient rehabilitation facilities, long-term care hospitals, and home health agencies. The act manages to provide, as it were, a little something for everyone. With the intention of improving care in a data-driven way, the IMPACT Act requires PAC providers to collect and submit standardized assessment, quality, and resource usage data. That’s an important stipulation. Surveys of Medicare certified-hospice providers are now mandated at least every 3 years instead of every 8 years. But this also provides incentives to PAC providers because these data will be used by the Medicare Payment Advisory Commission to evaluate and recommend payment systems on the basis of characteristics of individual beneficiaries. Effectively, by increasing oversight at the provider level, it lays out a plan for streamlining and tailoring the system to better meet the needs of individuals.

Although the leading voices in the field of hospice and palliative care have long called for wide-scale investment and development of infrastructure to support end-of-life care—at least since the 1970s when the hospice movement came of age in the USA—the timing of the legislation passing is itself auspicious. The Institute of Medicine released a report in mid-September, Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life, that emphasizes the professional duty and commitment to dying patients and the existing gaps in the caliber of care delivered. As is the case in so many other areas of health care, particularly where Medicare use is concerned, entrenched socioeconomic factors pose substantial barriers to access of end-of-life care. The report points out areas where the biggest opportunities lie. Importantly, for example, it notes person-centered, family-oriented care, and improving policies and payment systems to support better quality end-of-life care.

It is an infrequent event that a bill targeting a systematic problem within health care is passed period, let alone legislation that is as uncontroversial and politically supported. But as Steve Jobs said, “Death is the destination we all share.” Perhaps it is the range of potentially negative conditions around the eventuality of dying that can make it so difficult to confront, but which also makes it so valuable to consider how the process is regarded and how we support those in the midst of dealing with it—whether it be the patient him or herself, the patient’s family, or the practitioners providing care. The IMPACT Act and the greater general cognizance of the need to improve end-of-life care is, at the very least, a light at the end of the tunnel.
Graying the dragon

Rebecca Cooney

Drug-poisoning Deaths Involving Opioid Analgesics: USA, 1999–2011, a brief released by the National Center for Health Statistics of the US Centers for Disease Control and Prevention (CDC) in September 2014, revealed some troubling trends. Although it has been generally acknowledged that deaths due to opioid-analgesic poisoning have risen over the past two decades, the statistics are worrying. According to Holly Hedegaard, one of the authors of the report and an epidemiologist at CDC, there are several key findings. From 1999 to 2011, the years included in the study, the age-adjusted rate for deaths due to opioid-analgesic poisoning nearly quadrupled (from 1·4 to 5·4 per 100 000). Most (about 70%) deaths due to opioid-analgesic poisoning recorded in 2011 involved natural and semisynthetic opioid analgesics, such as hydrocodone, morphine, and oxycodone. Interactions with benzodiazepines have increasingly contributed to opioid-analgesic poisoning, present in 13% of deaths in 1999 and rising to 31% of in 2011. Although over the entire period of the study deaths due to opioid-analgesic poisoning were highest in the 45–54 year-old age group, the greatest increase in rates over the past decade was noted for people aged 55–64 years, a six-fold increase, from 1·0 per 100 000 in 1999 to 6·3 per 100 000 in 2011.

It sounds simple. An aging population with more painful chronic disorders translates into more prescriptions and more potential for poisoning deaths. But like most public health issues, reducing the number of opioid-poisoning deaths is complex and will require effort on multiple fronts. The most recent development to engage providers is the discussion about revisiting guidelines of opioid dosing. In a position paper out this week in Neurology, the American Academy of Neurology (AAN) stressed the need to change policy to address pain management approaches by taking a more cautious, more comprehensive, and longer-term view of prescription opioid treatment for pain. On the basis of epidemiological, clinical, and safety data, the AAN outlines the potentially controversial proposal that daily dosing in excess of 80–120 mg should involve a pain management specialist and that the use of opioids for chronic disorders, such as headache, lower back pain, and fibromyalgia, is not recommended. How these proposed guidelines are received and whether they are ultimately adopted remains to be seen, but the AAN position and the epidemiological data make a very strong statement—when it comes to treating pain, there is no gray area in the over-reliance and overabundance of opioid-analgesic prescriptions.
Organ donation: the gift of life

Rebecca Cooney

Today’s issue of The Lancet includes an editorial on the organ donation system in the USA and some potential changes that have been proposed to make the distribution of organs more equitable. Although 98% of adults have heard of organ donation, the process by which people become organ donors and how the organ donation system is organized is still unfamiliar to most Americans. We hope to help change that and to present some basic information on organ donation in the USA.

Organ donation in the USA by the numbers
• 28,953 organ transplants were performed in 2013
• 123,000 Americans are awaiting organ transplants (2000 patients are children)
• 18 people die every day while waiting for a transplant
• 1 donor can benefit 8 lives: 25 organs and types of tissue can transplanted, including the liver, kidneys, heart, bone marrow, heart valves, and eyes

Who manages organ donation in the USA?
The United Network for Organ Sharing (UNOS), which is a private, non-profit organization that is contracted by the Department of Health and Human Services to oversee the national organ transplant system. See here to learn more about the history, functions, and missions of UNOS.

Read more about the national waiting list and access Organ Procurement and Transplantation Network (OPTN) data.

How do you become an organ donor?
Anyone can become an organ donor, regardless of his or her age or medical history. Register with your state Organ and Tissue Donation Registry. Make your status known by indicating that you are an organ donor on your driver’s license, in your will or advance directive, and by letting your family and physicians know.

What about becoming a living donor?
Over 130,000 Americans of all ages have become living donors since 1988. Kidney, lung, liver, and pancreas organ transplants can now come from living donors.
Lean more about living donor programs.
THURSDAY, SEPTEMBER 11, 2014—15:19

In remembrance

Rebecca Cooney

Read The Lancet’s themed issue of the 10th anniversary of 9/11.
Stepping into the breach

Rebecca Cooney

Hackers are striking with greater impunity, and they are doing so more often. Driving the rapid escalation of healthcare breaches are the massive quantities of high-value data that can be gleaned quickly. According to at least one analysis by the IT Security company RedSpin, the number of patient records affected by protected health information breaches rose from 5,434,661 in 2010 to 7,095,145 in 2013.

Not only are hackers more intrepid, but they are getting more sophisticated too. Sophisticated protection systems are needed to prevent malware from penetrating networks, and once inside, perpetrators can use a data breach as a potent form of corporate espionage to ferret out proprietary and sensitive information used for medical devices and pharmaceuticals. With many recent attacks on health data coming from international sources, the situation runs the gamut from consumer privacy to national security.

That point is forcing the federal government to pay closer attention. In July, a test server for the Healthcare.gov site—the health insurance enrolment marketplace—was compromised. Although the Department of Health and Human Services' Centers for Medicare and Medicaid Services was quick to disclose the breach, with the website only in its infancy, it is almost certain to happen again. And next time, patient data could be accessed. From a realistic perspective, it is difficult not to view the transparency of reporting breaches as an acknowledgment that the government is unable to prevent future attacks. The US Department of Health and Human Services even has a webpage devoted to chronicling breaches that affect 500 or more individuals. It is also important to note that a breach is not just a major exfiltration of patient data—it can also be something as mundane as the loss of a laptop computer or unauthorized access of paper medical records. With so many points of access in the chain of storage of health-care information, the onus is on practitioners, corporations, and the government to vigilantly protect personal data. Health care data security is only as strong as its weakest link.
A drop in the bucket
Rebecca Cooney

The campaign has produced a deluge of donations. Compared with US$2·5 million donated in the same period in 2013, in the space of less than a month (July 29–August 25), the challenge has generated nearly $80 million dollars. With donations continuing to pour in, that amount is now double the current National Institutes of Health (NIH) FY 2014 funding of about $40 million for ALS. While that is spectacular news for charitable groups this year, it is the tip of the iceberg when it comes to the gap between current funding levels and the amount of resources necessary to adequately study ALS and other progressive neurodegenerative disorders.

The fact of the matter is that biomedical research in the USA is being iced out by dwindling federal support. In the past decade, budget cuts and inflation have pushed NIH purchasing power down 25%. The sequestration in 2013 brought another deep cut of $1·71 billion. Scaling back funding to NIH, the largest supporter of biomedical research in the world, means widespread repercussions. Fewer grants are being funded, existing grant budgets have been cut on average about 4·7%, and research award stipends are flat. Although these statistics can sound circumscribed, they are indices of a much more diffuse and pernicious state of affairs that threatens and delays biomedical progress. For diseases such as ALS that are poorly understood, that can make the difference between a lack of treatment options and the discovery and development of viable therapeutics.

From an optimistic perspective, the legacy of the ALS Ice Bucket Challenge may end up being much broader than we have yet to appreciate. Not only is it raising awareness about the disease itself, but it underscores the much larger issue of how we fund research and makes salient the enormous commitment that is necessary to produce biomedical advances. But the real metrics for success will actually be what comes next. Will the increase in donations be sustained or will donor fatigue set in? Will the attention on ALS be a catalyst for raising awareness about other neurodegenerative diseases and other orphan diseases? Will we begin to see a public opinion shift in support for increasing federal financial commitments? One thing is certain, when it comes to improving funding for biomedical research, it is time to break the ice.
Bad props

Rebecca Cooney

At the crux of the debate is how the legislation is crafted, a trident of superficially related issues. The first is the increase in the cap on medical malpractice lawsuits, which would raise the existing $250 000 ceiling on pain-and-suffering damages established under the Medical Injury Compensation Reform Act (MICRA) to over $1 million. For many years consumer watch groups and California trial lawyers have argued to increase the cap, suggesting that the current limits leave many victims of medical malpractice unable to secure and pay for top legal representation with enough leftover compensation for their suffering. But the CMA has been quick to charge that the legislation is being pushed by trial lawyers and would contribute to skyrocketing health-care costs. The proposed cap increase could profoundly affect practitioners and community clinics in rural areas that would be unable to meet rising medical malpractice insurance costs. Consumers would also be hit. According to Richard Thorp MD, the president of the CMA, health-care sector costs could swell by an estimated $10 billion annually. To put it in a more material perspective, for a family of four, the increase could be $1000 a year. For many Californians, Dr Thorp says, that could mean the decision between health care and groceries.

Though it comes with a potentially astronomical price tag, the medical malpractice cap is but one prong of the legislation. The second component would require mandatory drug and alcohol testing for physicians that, if passed, would be the first ever law of its kind in the USA. On the surface at least, it is a sentiment that plays well with voting focus groups because it is a fairly tidy argument: if police officers and pilots have to submit to random drug testing, why shouldn’t doctors be subject to the same standards? But plunging deeper, the argument isn’t the problem. The conditions under which doctors would be tested are. Not only would physicians undergo random drug testing in hospital settings, but also after any adverse events. The initiative fails to establish what would constitute a “positive” drug test or how an adverse event is defined, but it does stipulate that any physician who had contact with a patient who has experienced an adverse event must report back for drug testing within 12 hours. Those who failed to show would be presumed guilty and have his or her medical license suspended. It is not surprising that a great many medical and health-care groups in California have balked at such a draconian proposal.

The third point of the initiative is also concerned with monitoring drug use, but of patients. Like many other states, California has a prescription drug-monitoring program in place, a database called the Controlled Substance Utilization Review and Evaluation System (CURES), which tracks prescriptions of class II, III, and IV drugs, such as Vicodin (hydrocodone) and Valium (diazepam). CURES was first established in 1996 as a way to help curb “doctor shopping”—or the practice of obtaining prescriptions from multiple providers. Under the Proposition 46 initiative, physicians would be required to access CURES before writing a prescription for a controlled substance. It sounds like a reasonable plan but for the fact that the technology is woefully out of date, can’t update records in real time, and is reliant on the overstretched auspices of the California Department of Justice. If for any reason the system is down, physicians would be unable to provide care. As it stands, the outmoded database presents a very real security threat to patients’ personal health and prescription histories. What is more, the initiative fails to include any funding mechanisms to help update the system or to ensure patient privacy.

Patients and consumers deserve to be protected. But in the case of Proposition 46, any protection that might be conferred is lost in a sea of poorly thought out contingencies and financial consequences. Come November 4, there is a serious risk that Californians could end up with an overly punitive, costly, and misguided law that puts rhetoric and legal wrangling ahead of common sense.
Keeping a lid on medical marijuana

Rebecca Cooney

There are many voices in the medical marijuana debate, but who is being heard often depends on the proximity to election season. In New York state, the process of legalizing marijuana has been a slow burn, involving decades-long lobbying on the part of groups such as the Marijuana Policy Project and the National Organization for the Reform of Marijuana Laws (NORML). Several other states face similar processes, including Florida, Ohio, and Pennsylvania, all of which have pending medical marijuana legislation.

There is also some noteworthy dissention. One example is the National Institute on Drug Abuse (NIDA), which has cautioned about the effects of loosening marijuana laws resulting in easier access for children and adolescents. It is difficult to challenge the substantial amount of evidence that exposure to marijuana has serious adverse consequences for adolescents, including increased lifetime substance abuse and psychiatric disorders, although the effect of medical marijuana legislation on recreational use is not yet clear. Proponents of medical marijuana legislation are quick to dismiss this by pointing to a recent study by Choo and colleagues that found no correlation between medical marijuana legalization and teen use. But it is not nearly so cut and dry. However, work by Palamar and colleagues and by Bostwick suggests the opposite, that increased prevalence of marijuana is likely to increase use among teens. The fact of the matter is that we simply don’t know enough to say unequivocally whether there are, if any, longer-term public health risks produced by the legalization of medical marijuana. That puts politicians in a bind in crafting legislation that gives physicians the treatment option, but doesn’t usher in an additional set of problems.

The situation surrounding medical marijuana lights up two points in particular. The first is that the majority of Americans support the medical use of marijuana. There is a need, there is a demand, and there is momentum. The second is that there is a serious challenge in how to adequately regulate marijuana. For medical marijuana to occupy the same space as other prescription drugs, there must be realism about the potential side-effects on society. Prescription drug abuse in the USA has dramatically increased in the past few decades, and most prescribed drugs don’t hold a candle to the allure or cultural mystique that marijuana has. By the same token, like any medications that might have substantial positive effects for some patients, there is no reason not to expedite the process for those who could benefit most Medical marijuana legalization, and regulation, needs to be rapid and adaptable. As New York Governor Andrew Cuomo said, “We want to do it as quickly as possible, but we need to do it right.”
FRIDAY, JULY 25, 2014—19:23

Death knell for the death penalty?

Rebecca Cooney

Since the death penalty was reinstated by the US Supreme Court in 1976, 1382 people have been put to death. Executions have, however, become fewer and farther between. Although it varies widely across the states, the number of new death sentences overall has declined about 75% from the peak in 1995. Much of this reduction can be attributed to a confluence of factors, such as a decrease in violent crime, a larger number of incarcerated violent offenders, and the great expense and time that the legal process of executions carries.

It is not only the substantial financial and cumbersome appeal processes that mire the system. The dysfunction is deepened by the prolonged and haphazard nature of its implementation. Nowhere is this clearer than in the state of California, where death row inmates are held on average 25 years—almost a decade longer than the rest of the country—and where only 13 executions have taken place out of the more than 900 people who have received the death sentence. On July 16, 2014, in a landmark decision severely castigating the system, federal judge Cormac J Carney ruled that the death penalty as practiced in California was unconstitutional. He concluded that “arbitrary factors, rather than legitimate ones like the nature of the crime or the date of death sentence, determine whether an individual will actually be executed”, and, consequently, the death penalty “serves no penological purpose”.

Legal reasoning aside, the more gruesome aspects of the death penalty debate have also grabbed headlines. After multiple delays and stays of execution in both federal appeals court and the Supreme Court of Arizona, Joseph R Wood III was put to death on July 23, 2014. Witnesses reported that the execution by lethal injection, which is estimated to take approximately 10–15 min, lasted nearly 2 hours. This lengthy execution comes on the heels of a similar botched execution in Oklahoma, where inmate Clayton Lockett took 45 min to succumb to a mixture of midazolam, vecuronium bromide, and potassium chloride. At issue in both executions is lethal injection using multi-drug cocktails, which are becoming increasingly common because of drug shortages and the lack of consensus or standards for what should and can be administered.

Interestingly, the majority of Americans are still in support of the death penalty. According to one Gallup poll in 2013, 63% of those surveyed said that they were in favor of the death penalty for a person convicted of murder. That support may die down. With the surge of coverage on the procedural failings and the grisly details of mishandled executions, will Americans change their minds about the death penalty? Perhaps it is time to put the death penalty to death.
Hobby Lobby, a nationwide chain of arts and crafts stores with about 21,000 employees and owned by an Evangelical Christian family, filed suit over the federal mandate for contraceptive coverage—not all contraceptive coverage, but four of the 20 forms of birth control protected under the ACA. The four contraceptive methods in question include two “morning after” or emergency contraception pills, copper intrauterine devices (IUDs), and progestin-releasing IUDs. Although Hobby Lobby has objected to these methods for being potential abortifacients, emergency contraception and IUDs are not classified as such by organizations including the American College of Obstetricians and Gynecologists. At the heart of the lawsuit, however, is the notion of whether a closely held for-profit corporation is allowed exemptions similar to those of non-profit organizations on the basis of sincere religious belief—regardless of whether a conviction is in line with medical consensus. In an unexpected turn, the US Supreme Court handed down a 5-4 ruling in favor of Hobby Lobby, suggesting that the HHS contraception provision violates the Religious Freedom Restoration Act.

The decision is fraught with possibilities and what ifs. The most frightening part of setting down this path is that there is no logical endpoint. For the few, selective exemption from provision of contraceptive coverage might be a victory of religious liberty. But for the many, it is a massive infringement on the requirement of basic comprehensive care and a glaring intrusion on the provider-patient relationship.

That being the case, why the relative quiet from the medical community? According to Shoma Datta, a gynecologist in New York City, for individual doctors and nurses “It’s an issue that often doesn’t get much coverage because it is something that a very small portion of medical providers in general deal with on a daily basis in terms of reproductive health and actually dealing with contraception or contraception services. So it’s a small percentage of health-care workers... It’s also a very politically charged and obviously very sensitive issue and it’s difficult to come out publically either with colleagues, in a work environment, or with patients.”

Minority of providers or not, the ruling should have all providers talking. The Hobby Lobby decision sets the stage for potential exemptions reaching into every domain of health care. Protecting the practitioner-patient relationship is protecting the practice of good medicine itself.

Listen to the full podcast with Dr Shoma Datta here.
Reborn on the Fourth of July

Rebecca Cooney

But is it really only the VA that is the problem here? Or does the blame lie deeper?

Americans should have the ability to trust governmental agencies such as the VA to perform the duties and functions that they are intended to. But when things go awry, when a system breaks down or is of a fundamentally flawed design, who is really culpable? We all are. The current state of the VA system is a reflection of how the USA regards veterans in general—revered and celebrated on a few days a year and a budget burden for the balance. Instead of the safety net that it should represent for those who have made incredible sacrifices for our country, in many cases, the VA has provided general neglect. And our complacency has been a dereliction of duty.

If you want a positive spin, consider this: as awful and shameful as the details of misconduct at the VA are, this process is absolutely necessary. This is progress. This is the flashlight that reveals the cockroaches scurrying at our feet. This is a defining opportunity to make changes in the VA system since we now have a much better idea of the scope and magnitude of the problems, where money is being spent, and where resources need to be channeled. And most importantly, it is time to strike while the iron is hot. Because where the federal government’s memory is short, its attention span is even shorter.

By contrast with most issues of the day, there is strong bipartisan support for reform at the VA. But in crafting legislation that will address increasing access to care, the price tag will be the source of contention. Interestingly, this might be one of the iconic situations that we are faced with as a nation where throwing money at the problem is not the answer. The answer is accountability. We can fund the construction of new facilities, but budgets and schedules need to be managed. We can hire more practitioners, but these positions need competitive compensation to attract qualified and committed individuals. We can establish more treatment programs, but outcomes must be monitored and reported. All of this can be achieved by demanding external oversight. By revamping delivery of care to align funding with performance and performance with expectations, there is still the potential to turn the VA around. What started in Phoenix might just end up helping the VA rise from the ashes.

Read this week’s Editorial on the IOM assessment of PTSD treatment at the Department of Defense and the VA.
Cheesed off at the FDA

Rebecca Cooney

Cheesemaking suppliers recommend cleaning wood boards between uses or as needed by scrubbing them with hot water and mild soap and then leaving them to dry in sunlight, just as European cheesemakers have done for thousands of years. According to a recent communication from the FDA Center for Food Safety and Applied Nutrition’s Dairy and Egg Branch (CFSAN), that may not be enough to sanitize wood shelving. Though wood shelving is permitted by the state of New York, several artisanal cheesemakers were investigated and cited earlier in 2014 for contamination. In an exchange that became public, the FDA indicated to state regulators that wood shelving did not meet the criteria for current Good Manufacturing Practice. Widespread concern over the possible crackdown on wood boards prompted cheesemakers and cheese lovers across the country to decry the FDA’s position as “draconian” and “unpalatable”.

At issue is the FDA’s interpretation of the “adequately cleanable” and “properly maintained” clauses of the Code of Federal Regulations that outlines the care of equipment and utensils used to manufacture food. In some ways, this could be the first real public challenge to the FDA’s remit, which changed substantially under the Food Safety Modernization Act signed into law in 2011. Whereas the FDA had previously focused on identification of contamination, its redefined role shifts efforts toward prevention of contamination.

Considered from a purely public health perspective, it is a bit of a quandary. Cheese and the boards on which it is ripened have the potential to be contaminated by Listeria monocytogenes, which can be deadly for pregnant women, newborn babies, and people who are immunocompromised. With yearly listeriosis outbreaks to the tune of an estimated 1600 illnesses and 260 deaths, and the most recent multistate outbreak linked to a cheese manufacturer, it is not surprising that federal agencies such as the FDA might put cheesemaking practices under close scrutiny. Further, irrespective of whether the FDA elects to strictly apply the existing standards to cheese boards, the statute has in fact been on the books since 1986, and this is not the first time that concerns surrounding wood shelving and listeria have been raised.

This time, however, artisanal cheesemakers across the country, the American Cheese Society, and politicians from “big cheese” states such as Vermont and Wisconsin, swiftly mounted campaigns to urge FDA officials to reconsider their stance. Apart from the major costs of replacing shelving, these groups have stressed the potential market share lost by replacing cheese produced in the USA with imported cheese that is not subject to the same standards.

In an unforeseen move, the FDA recanted its hardline approach. In an open letter on June 11, the FDA addressed the current flap, saying, “To be clear, we have not and are not prohibiting or banning the long-standing practice of using wood shelving in artisanal cheese.” While this statement should ameliorate some of the cheesemaking community’s fears, they aren’t entirely out of the woods yet. The FDA continues to be “concerned” and there is not enough scientific evidence at this time to determine what substantive risks, if any, wood boards pose.

Slicing this exchange down, the word “risk” might be the most important. For any policy intended to improve prevention, the calculation of risk is fundamental. When it comes to enforcing very strict food industry prevention guidelines with large associated economic burden, that calculation of risk becomes that much more difficult. Although the FDA might have made a misstep in its earlier assessment, public discourse is a very positive development that could help to improve future decisions on food safety. Let’s hope the cheese doesn’t stand alone.

For the statement issued by the FDA see http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm
For more about the FDA Food Safety Modernization Act (FSMA) see http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm
All sound, no fury

Rebecca Cooney

Although the killers and victims might have not known each other and the shootings might have occurred in three different states, these are not isolated incidents. This is not a trend or an uptick—the USA is in the midst of a relentless public health crisis. It is rapid, it is contagious, it gives no regard for sex or age, and above all, it is deadly. Once you have been struck by it, you do not recover. The crisis is gun violence, and it is becoming so interwoven with our daily lives and our self-perception as a nation, that we seem to have a lethal inability to tackle it objectively.

Medical and health journals, The Lancet included, publish pages upon pages of peer-reviewed articles, reviews, and correspondence about gun violence. Authors and editors extol the importance of communication between doctors and patients, we chide those who impede the scholarly work investigating its epidemiology, and we hope that progress can be made in understanding the range of factors that contribute to it. But it is becoming increasingly clear that much of what medical and health researchers have to say is not being heard. We huff, and we puff, but the House does not blow in. Nor the Senate. The cacophony of special interest groups in Washington continues to politicize and drown out the real conversation that needs to take place, which is: how do we bring all the information and expertise that we have together in the service of curtailing gun violence?

In the midst of the tense political and funding environment in the USA and with so many other pressing threats to health that deserve our attention, it will always be a challenge to garner the resources needed to continue to collect up-to-date data. But how we have approached this horrific public health crisis to date is simply inadequate. Despite the political hurdles, there must be a stronger commitment from the medical and research communities to openly and clearly address gun violence as a public health issue and to influence policy. We have to be louder. When it comes to protecting public health, our ferocity should be in our facts.
Welcome to The Lancet USA

Rebecca Cooney

The designation of a special relationship between us holds true today, and one of the clearest examples is our continued joint influence in medicine and health. As the closest of allies, the USA and the UK continue a mutual path of leadership, endeavoring to produce the highest level of medical research and to guide the discourse on medicine and global health. At The Lancet, we feel that the importance of the role that the USA plays in that discussion is indisputable.

Thus, here we continue the special relationship by highlighting the noteworthy and momentous contributions, the changes unfolding, and the uniquely American happenings that affect the practice of medicine and our health and well-being.

The United States of America is a country unlike any other. It fascinates the rest of the world and it fascinates those of us who live here—sometimes for our follies and sometimes for our great achievements. Medicine and healthcare in the USA have become one of those areas most prone to being identified with both—a two-sided emblem that prompts controversy, fuels political tensions, and often shapes how we interact with the rest of the world. It is an unprecedented time in the history of medicine and the history of the USA. This blog will consider those most salient issues and strive to promote the debates that matter most to American health.

As the North American Editor of The Lancet, I look forward to opening these conversations. As Roosevelt wrote to Churchill, "It is fun to be in the same decade with you." I think it is fun to be in the same decade with you too. I look forward to what we have to say.