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6 EXAMINING THE REAUTHORIZATION OF THE
7 PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT

8 WEDNESDAY, JUNE 6, 2018

9 House of Representatives

10 Subcommittee on Health

11 Committee on Energy and Commerce

12 Washington, D.C.

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16 The subcommittee met, pursuant to call, at 10:00 a.m., in
17 Room 2123 Rayburn House Office Building, Hon. Michael Burgess
18 [chairman of the subcommittee] presiding.

19 Members present: Representatives Burgess, Guthrie, Barton,
20 Shimkus, Blackburn, Latta, Lance, Griffith, Long, Brooks, Mullin,
21 Hudson, Collins, Carter, Walden (ex officio), Green, Engel,
22 Schakowsky, Matsui, Castor, Eshoo, DeGette, and Pallone (ex
23 officio).

24 Staff present: Karen Christian, General Counsel; Paul
25 Eddatel, Chief Counsel, Health; Margaret Tucker Fogarty, Staff

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26 Assistant; Ali Fulling, Legislative Clerk, Oversight &
27 Investigations, Digital Commerce and Consumer Protection; Ed Kim,
28 Policy Coordinator, Health; Ryan Long, Deputy Staff Director;
29 Kristen Shatynski, Professional Staff Member, Health; Alan
30 Slobodin, Chief Investigative Counsel, Oversight &
31 Investigations; Danielle Steele, Counsel, Health; John Stone,
32 Senior Counsel, Health; Austin Stonebraker, Press Assistant; Josh
33 Trent, Deputy Chief Health Counsel, Health; Hamlin Wade, Special
34 Advisor, External Affairs; Jessica Wilkerson, Professional
35 Staff, Oversight & Investigations; Jeff Carroll, Minority Staff
36 Director; Tiffany Guarascio, Minority Deputy Staff Director and
37 Chief Health Advisor; Samantha Satchell, Minority Policy Analyst;
38 Andrew Souvall, Minority Director of Communications, Outreach
39 and Member Services; Kimberlee Trzeciak, Minority Senior Health
40 Policy Advisor; and C.J. Young, Minority Press Secretary.

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41 Mr. Burgess. Let me just ask all of our guests to please
42 take their seats. The Subcommittee on Health will now come to
43 order. The chair recognizes himself for five minutes for an
44 opening statement.

45 But first, you know, as auspicious as we gather today it
46 is a day that is so steeped in history. Last night was the
47 California primary election. We all remember 50 years ago after
48 the California elections when the country lost Senator Robert
49 Kennedy.

50 This is also the 74th anniversary of the landing in Normandy
51 and D-Day. This is the 100-year anniversary of the battle of
52 Belleau Woods when the Marines basically initiated World War I
53 for the United States of America, and it is 100 years since the
54 Spanish Flu ravaged not just our country but the world.

55 So it's appropriate that we convene today to authorize the
56 Pandemic All-Hazardous Preparedness Act. Again, a century ago,
57 our country was in the worst pandemic in its history, claiming
58 the lives of almost 700,000 Americans and killing more than 50
59 million people worldwide.

60 We have elicited testimony and we will discuss this critical
61 legislation. It is paramount that we remember the significance
62 of this centennial anniversary.

63 Sporadic flu activity has been spreading through the United
64 States, Europe, and Asia in the months following in the country
65 and our soldiers faced an illness that we were not prepared to

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66 handle.

67 In that October over a hundred years ago, more than 100,000
68 Americans died as a result of the Spanish flu. It goes without
69 saying that we have indeed come a long way. A century later we
70 were substantially more prepared. As we consider this
71 legislation we must remember that there is more to be done to
72 support America's public health security.

73 The creation of the assistant secretary of preparedness and
74 response under the original legislation in 2006 has helped us
75 to make monumental strides in preparedness, coordination, and
76 response.

77 Close collaboration and efforts between the Centers for
78 Disease Control, the Food and Drug Administration, our local,
79 state, and tribal and territorial health partners has been vital
80 in making progress in this regard.

81 Much like politics, public health is local and it is executed
82 on the ground by our hospitals, by our health departments, and
83 our emergency responders who are our front lines addressing
84 infectious diseases, disasters and threats.

85 I do want to thank my fellow Texan on our second panel, Dr.
86 Umair Shah, for being here today and to share his testimony and
87 for his leadership in protecting the health of Harris County,
88 Texas.

89 Recently, Dr. Shah and his team responded on the front lines
90 for Hurricane Harvey, which caused such catastrophic damage in

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91 the Houston metropolitan area and did require a large
92 coordinated response from all of the organizations that we had
93 before us today.

94 You'll hear more about critical issues that must be addressed
95 to continue and strengthen the nation's preparedness and response
96 capabilities. We will talk about proposals to strengthen the
97 Strategic National Stockpile, our cache of live saving
98 medications and supplies for public health emergencies.

99 We also must address the policies that affect our regional
100 disaster response system. It is essential the program continues
101 to integrate and coordinate at the local level.

102 Additionally, we must provide assurances to protect those
103 who respond to our health emergencies. We will also discuss
104 sustaining the robust and reliable security capabilities such
105 as disease surveillance, containment, risk, and countermeasure
106 distribution.

107 We must evaluate the domestic biologic surveillance systems
108 such as BioWatch, taking a closer look at what can be done to
109 bring these programs up to date so that they are operating with
110 the most efficient technologies and capabilities.

111 I believe we must look for innovative ways to continue to
112 advance medical countermeasures, ensuring that Americans can
113 access medications that will provide critical protection in the
114 future.

115 As we consider the problem of antimicrobial resistance in

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116 this country, we must address new methods to curb this growing
117 problem.

118 Front line facilities and responders in Dallas, Texas
119 experienced this first hand in 2014 when a patient presented with
120 Ebola in a D/FW emergency department. We must remember that
121 infectious diseases are a mere plane ride away and we must continue
122 to ensure that we are prepared and ready to respond.

123 This pandemic all-hazards preparedness reauthorization is
124 critical in protecting the lives of all Americans and providing
125 the necessary tools and infrastructure to ensure that they are
126 in place when disaster strikes.

127 I want to thank both Representative Susan Brooks and Anna
128 Eshoo for working on this draft legislation which is being
129 considered today.

130 Lastly, I want to thank all of our witnesses for testifying
131 before us this morning. I do look forward to a productive
132 discussion on a broad array of issues that will be the focus of
133 this authorization.

134 And will yield the balance of my time to the gentlelady from
135 Tennessee, who I believe is celebrating a birthday on this day
136 rich in history.

137 Mrs. Blackburn. I am, indeed, celebrating a birthday and
138 I thank you for yielding.

139 Thank you all for being with us to discuss this. We have
140 focused so on how the response ought to be to address our national

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141 disasters and our natural disasters, and this has been a process.

142

143 We have worked with our friends in the Senate, our friends
144 here. As you know, this is something we have done in a bipartisan
145 manner so we thank you for your time, and I yield back to the
146 gentleman.

147 Mr. Burgess. Chair thanks the gentlelady. The gentlelady
148 yields back.

149 The chair recognizes the gentleman from Texas, the ranking
150 member of the subcommittee, Mr. Green, five minutes for an opening
151 statement, please.

152 Mr. Green. Thank you, Mr. Chairman, and again I'd like to
153 welcome the panels -- both the first panel and I particularly
154 want to thank Umair Shah, the executive director of Harris County
155 Public Health, for joining us this morning on the second panel.
156 They help keep my constituents healthy.

157 Events in recent years including natural disasters, cyber
158 terrorism, influenza epidemic has posed a threat to our public
159 health systems and our national security.

160 PAHPA provides a framework that allows us to address in a
161 coordinated way various threats both natural and manmade. As
162 a founding member of the Congressional Public Health Caucus and
163 a long-time advocate for public health, I hope our committee will
164 look at the very real threat that antimicrobial resistance poses.

165

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166 Antibiotics and antimicrobial agents have been used for the
167 last 70 years to treat patients who have infectious diseases.

168 These drugs greatly reduce illnesses, death, and infectious --
169 from infectious diseases.

170 However, these drugs are being used so widely and for so
171 long that the infectious organisms that the antibiotics are
172 designed to kill have adapted to them and make the drugs less
173 effective.

174 Each year in our country at least 2 million people become
175 infected with bacterial that are resistant to antibiotics and
176 at least 23,000 people die annually as a result of these
177 infections.

178 In the past years, the Generating Antibiotic Incentives Act
179 -- GAIN -- and the Antibiotic Development of Advanced Patient
180 treatment -- ADAPT -- have sought to address both the economic
181 hurdles and the regulatory barriers to the development of new
182 antibiotics.

183 Through the reauthorization of PAHPA we need to ensure that
184 the proper incentives are in place that will lead to investment
185 in the development of new antibiotics and antimicrobial agents.

186 I believe the creation of a market entry reward program that
187 incentivize the manufacturers to develop novel antibiotics would
188 provide the best bang for our buck in this space.

189 I'd like to work with my colleagues and I have over the years
190 with Congressman Phil Gingrey recently on our committee and also

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191 currently with Congressman Shimkus. I'd like -- it's such a
192 critical issue.

193 In addition to addressing antimicrobial resistance, we also
194 need to further consider the proposal to move the Strategic
195 National Stockpile -- SNS -- from CDC to the office of Assistant
196 Secretary for Preparedness and Response.

197 My home state and our district has -- was heavily impacted
198 by Hurricane Harvey last year in response to the flooding. The
199 SNS was deployed to Houston and provided needed material to help
200 local and state health departments respond to the overwhelming
201 needs of the community.

202 SNS had been deployed countless times since its inception.
203 It was placed in CDC over the years. CDC has worked closely
204 with state and local health departments to respond to public
205 health emergencies.

206 Before our committee codifies any change in the SNS, we must
207 learn whether it's the best policy to advance human health.
208 Additionally, as we have discussed the move of the stockpile from
209 CDC to ASPR we have to ensure that the systems and networks which
210 have been in place are not disrupted in order that the stockpile
211 may be deployed successfully when needed.

212 Mr. Chairman, I yield the remainder of my time to my colleague
213 from California and co-sponsor of the bill, Congresswoman Eshoo.

214 Ms. Eshoo. I thank the gentleman for yielding, and welcome
215 to the witnesses. And Mr. Chairman, thank you for your opening

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216 remarks, especially about the 50th anniversary of Senator Robert
217 Kennedy.

218 In 2001, our nation endured the attacks of September 11th
219 and the anthrax attacks shortly after that. It was one of the
220 most grueling times, I think, in the modern history of our country.

221 Congress realized that our country was not prepared to
222 coordinate responses to mass casualty events or chemical attacks.

223 I authored legislation with then Representative Richard Burr,
224 who was a member of the committee, that established the Office
225 of the Assistant Secretary for Preparedness and Response -- we
226 refer to it as ASPR -- to be responsible for coordinating federal
227 responses and the Biomedical Advanced Research and Development
228 Authority we call BARDA to be responsible for developing the
229 needed medical countermeasures for chemical, biologic,
230 radiological, and nuclear threats.

231 That important bipartisan legislation, the Pandemic
232 All-Hazards Preparedness Act -- or PAHPA -- was signed into law
233 in 2006.

234 The threats we faced in 2001 have not gone away. They have
235 evolved and new threats have emerged and that's why it's important
236 that this committee work to reauthorize PAHPA in a timely manner
237 before it expires at the end of this fiscal year.

238 We need to give the agency the tools that they need and the
239 resources they need to respond to the threats that confront us.

240 This is a discussion today and I think all members need to

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241 keep that in mind because stakeholders and others have not seen
242 their suggestions come into a draft yet.

243 So I think all members need to keep that in mind and I'd
244 like to compliment Congresswoman Brooks. I couldn't have a
245 better partner in this.

246 So thank you, Mr. Chairman. I yield back.

247 Mr. Burgess. The chair thanks the gentlelady. The
248 gentlelady yields back.

249 The chair recognizes the gentleman from Oregon, the chairman
250 of the full committee, Mr. Walden, five minutes for an opening
251 statement, please.

252 The Chairman. Well, thank you, Mr. Chairman. Thanks for
253 your leadership on this issue and that of Ms. Eshoo and Mrs. Brooks
254 as well. I know we will be hearing from both of them even more
255 during this process.

256 I appreciate their work together on this. They've been the
257 team leaders for this for our committee.

258 Since the terrorist attacks of September 11th, 2001, our
259 country has taken important steps to fortify our health
260 preparedness and response infrastructure.

261 The federal government has recognized that we must foster
262 development of important medical countermeasures in the event
263 of a potential chemical, biological, radioactive, or nuclear
264 attack.

265 Preparing for and responding to these kinds of incidents

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266 and mass casualty events requires the collaboration of all levels
267 of government with hospitals, biotech firms, community leaders,
268 members, and other partners both public and private all across
269 the country.

270 Recent diverse threats illustrate the importance of our
271 country having an effective and an efficient emergency
272 preparedness system in place.

273 In the last few years alone, we have seen the arrival of
274 the Zika virus, last year's devastating hurricane season, the
275 WannaCry malware outbreak, and looking ahead, I can think about
276 other prospects including the projected devastating earthquake
277 of Cascade event that they predict could hit the Oregon coast
278 as it has hundreds and hundreds of years ago.

279 In 2004, Congress authorized Project BioShield. I was here
280 when that happened, and later in 2006 enacted the Pandemic and
281 All-Hazards Preparedness Act.

282 In addition to establishing a strategic plan to direct
283 research, development, and procurement of medical
284 countermeasures, PAHPA also created the Assistant Secretary for
285 Preparedness and Response -- ASPR -- and the Biodefense Advanced
286 Research and Development Authority -- BARDA -- within the
287 Department of Health and Human Services.

288 So today's hearing really will take a closer look at this
289 bipartisan discussion draft led by our colleagues, Susan Brooks
290 and Anna Eshoo. Thank you both for your leadership on this bill.

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291 This bipartisan bill builds upon our previous work to
292 modernize our health preparedness and response systems, ensuring
293 that we are well equipped across all levels and government
294 agencies to handle current emergency -- emergent bio threats,
295 chemical attacks, radiological emergencies, cybersecurity
296 instances, and mass casualty events.

297 This is an important conversation. It's an important issue.
298 We will move forward. We will move forward expeditiously.

299 We realize there is a deadline ahead for reauthorization
300 and so we look forward to getting your feedback as we -- as we
301 put this legislation into final form and move it through this
302 committee.

303 With that, I'd yield the balance of my time to the gentlelady
304 from Indiana, Mrs. Brooks.

305 Mrs. Brooks. Thank you, Mr. Chairman, and thank you for
306 holding this hearing today to examine the issues surrounding the
307 reauthorization of PAHPA.

308 I am proud to be working on this important bill with my good
309 friend, Representative Eshoo, who was one of the authors of the
310 first PAHPA bill in 2006 as well as the lead author of the last
311 reauthorization in 2013.

312 As everyone here knows, this is not a question of if we will
313 face a threat. It is more of a question of when we will face
314 the threat. The threat of chemical, biological, radiological,
315 or nuclear incidents continues to grow.

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316 Every day our adversaries are looking for more effective
317 and faster ways to produce a threat. We have already faced
318 threats from naturally occurring outbreaks such as Ebola and Zika
319 as well as from hurricanes.

320 In addition, cyber-attacks like the WannaCry incident
321 illustrate the vulnerability of our public health system.
322 Reauthorizing PAHPA is an important public health and national
323 security issue and I look forward to working with all members
324 of the committee on this bipartisan effort.

325 The discussion draft bill that we have written creates a
326 PAHPA -- a public health emergency respond fund for the HHS
327 secretary to use as a funding bridge when we face an outbreak
328 like Ebola so that immediate funding is available so that we can
329 supplement them with an emergency appropriation bill.

330 The bill strengthens the hospital preparedness program to
331 improve surge capacity by allowing grantees to use federal funding
332 for health care surge capacity response activities in addition
333 to the preparedness activities.

334 It establishes a pandemic influenza program as well as an
335 emerging infectious disease program at BARDA. Our bill includes
336 and this draft includes requests from CDC, ASPR, HHS, and FDA,
337 and we look forward to working with everyone to improve the bill
338 and ensure that it's ready for introduction later this month.

339 Thanks the PAHPA, already we have seen 14 products placed
340 in the Strategic National Stockpile to be used in an emergency.

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341 Our bill increases funding for the Strategic National Stockpile
342 to \$610 million per year in order to keep the authorized level
343 consistent with what we have currently appropriated.

344 In addition, the bill codifies moving the SNS from the CDC
345 to ASPR but, really, it's more an appropriate realignment of the
346 responsibilities and it's a move that the administration is
347 already making. And so it seems as members of Congress it's
348 important that we provide that oversight and the guardrails for
349 any move or any changes.

350 PAHPA reauthorization is a unique opportunity to examine
351 our response to all threats and ensure we look forward to the
352 future, that we have the procedures, the resources, and the
353 support in place to protect ourselves and our citizens, and I
354 look forward to hearing from our witnesses this morning.

355 I yield back.

356 Mr. Burgess. And the chair thanks the gentlelady. The
357 gentlelady yields back.

358 The chair now would like to recognize the ranking member
359 of the subcommittee -- ranking member of the full committee, Mr.
360 Pallone of New Jersey, five minutes for an opening statement,
361 please.

362 Mr. Pallone. Thank you, Mr. Chairman.

363 Today, we will examine the reauthorization of a critical
364 law known as the Pandemic All-Hazards Preparedness
365 Reauthorization Act, or PAHPA.

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366 It's designed to prepare for and respond to health security
367 events and emergencies that unfortunately are all too common,
368 and these include bioterrorism acts, the spread of emerging
369 infectious diseases, and natural disasters.

370 In order to effectively prepare for and respond to these
371 types of events, we must have extensive coordination between
372 federal, state, local, and tribal governments and the private
373 sector organizations, and the critical programs included in this
374 law help to accomplish that goal.

375 That's why I am disappointed that on a bill of such magnitude
376 my staff and our witnesses including the administration did not
377 receive the draft legislation until late last week.

378 This has been a very broken legislative process to date,
379 and now the administration is limited in the feedback it can
380 provide on the specific provisions of the bill.

381 And I hope, moving forward, we will work together to ensure
382 that these policies are fully understood. Federal funding and
383 support for local, state, and tribal public health activities
384 is critical to saving lives.

385 This existing public health infrastructure is how we respond
386 to all types of hazards. Unfortunately, our public health
387 capacity and infrastructure is not as strong as it could be.

388 Public dollars have been depleted and the workforce has
389 shrunk. Public funding is also not stable or reliable from year
390 to year, making planning across all levels of government

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391 difficult.

392 I am worried that there is a lack of public health funding
393 at a time when communities are facing increased need. For
394 example, climate change is creating conditions for increased
395 extreme weather events.

396 Last year, hurricanes in Texas, Florida, Puerto Rico, and
397 the U.S. Virgin Islands placed significant stress on our public
398 health system and we need to increase public health funding
399 including to programs authorized by this bill to bolster both
400 our ability to prepare for and respond to these threats.

401 While I am generally supportive of the draft bill, I'd like
402 to outline some specific concerns and questions. First, the
403 public health emergency response fund is funded under transfer
404 authority, and this is short-sighted.

405 We witnessed the downside of this approach firsthand during
406 the Zika outbreak when the Republican Congress forced the
407 administration to fund our initial Zika efforts through transfers
408 of existing appropriations.

409 As a result, a state like Michigan, which was confronting
410 its own public health emergency -- the Flint water crisis -- had
411 some of its public health funding sent to states at high risk
412 of local Zika transmission.

413 Michigan lost funding that it could have used to address
414 its own crisis in Flint and we shouldn't have to pick one crisis
415 over another. New real funding should be put in this fund.

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416 Second, I have yet to hear a strong argument for moving the
417 Strategic National Stockpile -- or SNS -- from the Centers for
418 Disease Control and Prevention to the Assistant Secretary of
419 Preparedness and Response -- or ASPR -- in statute.

420 The secretary of HHS has already started the process of
421 moving the SNS under existing law and I see no reason to codify
422 this move before we know the consequences.

423 We must make certain that placing the SNS in ASPR instead
424 of CDC does not weaken our current preparedness and response
425 capabilities before making such a move permanent. From what I
426 can tell, we are trading some debatable improvements and
427 procurement efficiency on the front end for the ability to more
428 effectively reach communities and individuals with the materials
429 they need in case of a public health emergency, and I would argue
430 that ensuring that we can reach people with potentially lifesaving
431 drugs and medical supplies in the event of a public health
432 emergency must be our top priority.

433 CDC has the relationships and expertise that make the most
434 sense managing and operationalizing the stockpile as well as the
435 record of successful stewardship of the SNS.

436 And third, I have numerous questions regarding the intent
437 of the cybersecurity language in this draft. As many are aware,
438 the Oversight and Investigations Subcommittee has been working
439 on this issue and has discovered challenges regarding internal
440 and external cybersecurity preparedness within HHS.

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441 I agree we need to do more to protect our health system from
442 cyber-attacks and the potential interruptions of care because
443 of these attacks.

444 However, we need to make certain that placing increased
445 cybersecurity authorities within ASPR as part of other emergency
446 preparedness and response programs is the optimal solution, and
447 if it is, that we authorize the resources to support any new
448 authorities.

449 Simply adding the word cybersecurity to certain programs
450 within the Public Health Service Act and FDA's emergency use
451 authorities will do little to boost our preparedness and response
452 for cybersecurity threats unless it is done thoughtfully and with
453 consideration for the problems we are trying to solve.

454 So I look forward to learning what exactly the role of the
455 assistant secretary for preparedness and response would play
456 under this legislation in the event of a cybersecurity attack
457 on the health care system.

458 I believe we should evaluate this legislation, Mr. Chairman,
459 based on whether Americans in all corners of the country will
460 be safer or not, and I look forward to continuing our work on
461 this bill.

462 So thank you, Mr. Chairman.

463 Mr. Burgess. The chair thanks the gentleman. The
464 gentleman yields back.

465 This concludes member opening statements and the chair would

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466 remind members that pursuant to committee rules all members'
467 opening statements will be made part of the record.

468 And we do want to thank our witnesses for being here this
469 morning and taking the time to testify before the subcommittee.

470 Each witness will have the opportunity to give an opening
471 statement followed by questions from members.

472 Our first panel this morning we will hear from Dr. Robert
473 Kadlec, assistant secretary for preparedness and response from
474 the United States Department of Health and Human Services.

475 We will also hear from Rear Admiral Stephen Redd, director
476 of the Office of Public Health Preparedness and Response, Center
477 for Disease Control and Prevention, and Ms. Anna Abram, deputy
478 commissioner for policy planning, legislation, and analysis at
479 the United States Food and Drug Administration.

480 We appreciate each of you being here today and, Dr. Kadlec,
481 you're now recognized for five minutes to summarize your opening
482 statement, please.

483 STATEMENTS OF DR. ROBERT KADLEC, ASSISTANT SECRETARY FOR
484 PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN
485 SERVICES; REAR ADMIRAL UPPER HALF STEPHEN REDD, DIRECTOR, CENTERS
486 FOR DISEASE CONTROL AND PREVENTION; ANNA ABRAM, DEPUTY
487 COMMISSIONER FOR POLICY, PLANNING, LEGISLATION, AND ANALYSIS,
488 U.S. FOOD AND DRUG ADMINISTRATION

489

490 STATEMENT OF DR. KADLEC

491 Dr. Kadlec. Thank you. Good morning, Chairman Burgess,
492 Ranking Member Green, and distinguished members of the committee.

493

494 I am Dr. Bob Kadlec, the Assistant Secretary for Preparedness
495 and Response -- ASPR. Thank you for this opportunity to appear
496 before you today as you consider the second reauthorization of
497 the Pandemic All-Hazards Preparedness Act.

498

499 This committee championed the drafting and passage of PAHPA
500 more than a decade ago and I want to acknowledge the original
501 vision and leadership of Representative Mike Rogers and Anna
502 Eshoo, now under the stewardship of Representative Brooks and
503 Representative Eshoo as well. Thank you again for your hard
504 efforts in this work.

504

505 One of our Constitution's sacred obligations to our citizens
506 is to provide for the common defense, to protect the American
507 people, our homeland, and our way of life.

507

The ability of our nation's public health and medical

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508 infrastructure to quickly mobilize a coordinated national
509 response to 21st century threats like pandemics, deliberate
510 attacks, and natural disasters is a national security imperative
511 and is at the heart of my efforts at the ASPR.

512 When ASPR was originally established by PAHPA, the objective
513 was to answer a very simple question -- who's in charge of federal
514 public health and medical preparedness and response functions.

515

516 The approach adopted was modeled on the Goldwater-Nichols
517 Act that created the unity of effort at the Department of Defense.

518 My goal is to ensure that we can mobilize the capabilities of
519 the federal government to support state, local, tribal, and
520 territorial health authorities to save lives and protect
521 Americans.

522 I have four key priorities: provide strong leadership,
523 develop a regional disaster health response system, advocate for
524 CDC sustainment of robust responsive public health security
525 capabilities and advance an innovative medical countermeasure
526 enterprise.

527 I will elaborate on two of these. The importance of national
528 health care readiness and medical surge capacity was highlighted
529 during the last hurricane season when ASPR led federal medical
530 and public health response and recovery activities under the
531 national response framework.

532 We worked closely with FEMA and state and territorial health

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533 officials to augment health care with HHS disaster medical
534 assistant teams, many of whom are your constituents who are health
535 care providers, and public health commission core officers as
536 well as physicians and health care providers from the VA,
537 Department of Homeland Security, and the Department of Defense.

538 As we speak, we are implementing many lessons learned from
539 the hurricanes and from the 2014 Ebola outbreak two work with
540 our colleagues across HHS and the federal interagency to better
541 coordinate our national preparedness and response to the current
542 Ebola outbreak in the Democratic Republic of Congo as well as
543 actively monitoring the dynamic global national security
544 landscape as well as the weather landscape.

545 As we look forward we are actively engaging our public and
546 private partners in health care delivery to understand how we
547 can most effectively improve their readiness for potential
548 catastrophic threats.

549 I believe we need to modernize our existing programs to build
550 a tiered regional system utilizing local health care coalitions
551 and trauma center systems that integrates all medical response
552 capabilities, expands specialty care expertise in trauma and
553 other related disciplines such as burn and radiation treatment,
554 and incentivize the health care system to integrate measures of
555 preparedness into daily standards of care. I call this the
556 foundation of a regional disaster health response system.

557 The second area to highlight is our medical countermeasure

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558 enterprise. PAHPA established the Biomedical Advanced Research
559 and Development Authority -- or BARDA -- which is the component
560 of ASPR to bridge the so-called valley of death in the late stage
561 of development of vaccines, drugs, and diagnostics where many
562 products historically languished or failed.

563 By using flexible nimble authorities, multi-year advance
564 funding, strong public-private partnerships, and cutting-edge
565 expertise, BARDA has achieved a remarkable 35 FDA approvals.

566 Just yesterday, we announced an exciting new public-private
567 engagement model called DRIVE -- the Division for Research,
568 Innovation, and Ventures -- which is designed to accelerate
569 innovation, address some of the nation's most pressing health
570 security challenges and potentially affect major health care
571 markets.

572 It is the brain child of this committee in the 21st Century
573 Cures Act. At a time when synthetic biology and personalized
574 medicine are not just conceivable but attainable, the time is
575 right to apply an innovative approach to some of the most daunting
576 far-reaching health security problems such as sepsis and early
577 diagnosis of infectious disease.

578 We are opening our doors to more innovators and, most
579 importantly, investors to better leverage advances in science
580 and technology.

581 Thank you again for your bipartisan commitment to this
582 national security imperative. I am happy to answer any questions

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583 you may have.

584 Thank you.

585 [The prepared statement of Dr. Kadlec follows:]

586

587 *****INSERT 1*****

588 Mr. Burgess. The chair thanks the gentleman.

589 The chair now recognizes Rear Admiral Redd. Dr. Redd,
590 you're recognized for five minutes, please.

591 STATEMENT OF ADMIRAL REDD

592

593 Admiral Redd. Chairman Burgess, Ranking Member Green, and
594 members of the subcommittee, I am Rear Admiral Stephen Redd,
595 director of CDC's Office of Public Health Preparedness and
596 Response.

597 Thank you for the opportunity to testify before you today
598 to describe the role that CDC plays in public health preparedness
599 and response including those responsibilities under the Pandemic
600 and All-Hazards Preparedness Reauthorization Act.

601 Today, I will highlight CDC's role in protecting the nation
602 against health threats and I will describe that in three areas
603 -- preparedness, protection, and response.

604 Within that discussion, there are three themes that I would
605 like you to appreciate -- first, the work that CDC does every
606 day in public health lays the foundation for responding to
607 emergencies; second, CDC's world-class scientific and medical
608 expertise ensures we are ready to respond to any threat; and third,
609 our longstanding connection to state and local health departments
610 ensures that public health systems function effectively both day
611 to day and during emergency responses.

612 Let me first address the issue of preparing for emergencies.

613 CDC works every day with state and local health departments.

614 IN fact, we have 590 staff assigned to state and local health
615 departments. We fund the public health emergency preparedness

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616 cooperative agreement program and the Cities Readiness
617 Initiative.

618 Our public health emergency preparedness grants go to every
619 state, eight territories, and four cities. These funds support
620 staff, enable exercises to test and validate capabilities and
621 pay for laboratory and communications equipment.

622 Cities Readiness Initiative funds the nation's 72 largest
623 cities to develop and test plans to receive and dispense medical
624 countermeasures from the Strategic National Stockpile.

625 Turning now to detecting threats, CDC's laboratories and
626 surveillance systems are able to detect and identify agents
627 causing illness, whether that cause is microbial or from chemical
628 or radiation exposure.

629 Every year, laboratories from all over the world send several
630 hundred thousands of specimens to CDC because they know that we
631 will be able to identify pathogens other laboratories cannot.

632 Rapid identification of disease permits intervention before
633 a health threat becomes a crisis. CDC's laboratory response
634 network maintains an integrated, scalable, and flexible system
635 of 153 federal, state, and local laboratories.

636 The development of this network over the past 15 years has
637 provided a larger capacity to test and report more quickly than
638 was possible before. For example, during the Zika outbreak, CDC
639 and other laboratory response network laboratories processed over
640 207,000 specimens.

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641 Now, turning to response, when there's a crisis, CDC
642 responds. We are able to deploy scientific and medical experts
643 anywhere in the world.

644 For example, by the end of the 21-month Ebola response, 3,700
645 CDC staff, more than a quarter of our workforce, shifted from
646 their day-to-day duties to assist in the response.

647 Fifteen hundred staff deployed to West Africa, accounting
648 for over 2,000 trips. Today, we are responding to the much
649 smaller outbreak in the Democratic Republic of Congo.

650 During health emergencies, CDC communicates. For example,
651 during the 2009 H1N1 response, CDC held 39 press conferences and
652 21 telebriefings. During the Zika response, CDC published 51
653 morbidity and mortality weekly report articles ensuring that the
654 public and health professionals had the latest and best
655 information.

656 Being able to prepare for, detect, and respond to public
657 health threats is a top priority for CDC. Our preparedness and
658 response capabilities are built on a broad and deep scientific
659 medical and program expertise.

660 Our longstanding partnerships with state, local, and public
661 health authorities assured an integrated approach wherever that
662 approach is needed, resulting in better responses and better
663 public health outcomes.

664 Thank you for the opportunity to testify here today. I look
665 forward to answering your questions.

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666

[The prepared statement of Admiral Redd follows:]

667

668

*****INSERT 2*****

669

Mr. Burgess. Thank you, Dr. Redd.

670

Ms. Abram, you're recognized for five minutes, please.

671 STATEMENT OF MS. ABRAM

672

673 Ms. Abram. Thank you.

674 Chairman Burgess, Ranking Member Green, and the other
675 members of the committee, thank you for the opportunity to appear
676 today and discuss reauthorization of the Pandemic and All-Hazards
677 Act, or PAHPA.

678 Medical and public health preparedness and response is of
679 critical importance to the health and security of our nation and
680 I am pleased to be here today to share how FDA is working toward
681 the shared goal of making sure we have the medical products we
682 need to protect Americans from a range of public health threats,
683 whether naturally occurring, like a pandemic, or the result of
684 a deliberate attack.

685 We are reminded of the urgency and need to remain ever
686 vigilant against identified and emerging public health threats
687 as we carefully monitor the current outbreak of Ebola virus
688 disease, this time in the Democratic Republic of Congo.

689 I can assure you that FDA is dedicated to helping end this
690 outbreak as quickly as possible and we are actively engaged with
691 our federal colleagues testifying here with me today, as well
692 as with medical product developers, international organizations
693 including the World Health Organization, to support international
694 response efforts.

695 This most recent Ebola outbreak accentuates the continuing

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696 threat posed by emerging infectious diseases, which can and often
697 do emerge with little to no warning and the need for us to continue
698 to optimize our preparedness and response capabilities.

699 PAHPA, which was passed in 2006 and reauthorized in 2013,
700 in addition to other key pieces of legislation that has served
701 to significantly strengthen our nation's preparedness and
702 response capabilities to respond to public health emergencies
703 involving chemical, biological, radiological and nuclear -- or
704 CBRN -- threats as well as emerging infectious disease threats
705 such as the Zika virus, Ebola virus, and pandemic influenza.

706 Prior to joining FDA, I worked for more than a decade on
707 health care policy with your colleagues in the United States
708 Senate, serving as a health policy director to U.S. Senator
709 Richard Burr from North Carolina on the Health, Education, Labor,
710 and Pensions Committee for many years.

711 In that capacity, I collaborated with colleagues serving
712 in the United States House of Representatives, including this
713 committee, and it's nice to see some of those colleagues here
714 today.

715 I was actively involved in working on a range of health care
716 issues and my tenure was very much highlighted by my work on
717 medical and public health preparedness and response issues
718 including the bipartisan 2013 PAHPA Reauthorization ACT, or
719 PAHPA, and more recently the 21st Century Cures Act.

720 PAHPA recognized the key role FDA plays in emergency

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721 preparedness and response and codified and built on FDA's ongoing
722 efforts to augment our review processes and advance regulatory
723 science to enable better response to public health emergencies
724 and emerging health threats.

725 The provisions in PAHPRA have been critical to FDA's efforts
726 to drive innovation in the medical countermeasure space and have
727 provided FDA with essential tools that continue to support our
728 mission to protect and promote public health.

729 At FDA we've made it a priority to utilize these authorities
730 to proactively work with our private sector and government
731 partners to help facilitate the translation of discoveries in
732 science and technology into safe and effective medical
733 countermeasures as part of advancing public health and
734 strengthening our national security.

735 We share Congress' goal to have safe and effective medical
736 countermeasures available in the event they are needed and we
737 have made key progress towards this important goal.

738 As of the end of fiscal year 2017, FDA has approved, licensed,
739 or cleared 121 medical countermeasures including supplementals
740 to approvals, licensures, and cleared medical products.

741 We have issued more than 60 emergency-use authorizations
742 since 2005 including about 40 since 2013, including for Ebola
743 and Zika. Medical countermeasures can face unique development
744 challenges that require medical product sponsors to rely on animal
745 models because even efficacy trials would not be ethical.

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746 PAHPRA required FDA to issue final guidance regarding the
747 development of animal models to support the approval and clearance
748 of medical countermeasures.

749 FDA finalized this guidance in October 2015 and to date,
750 13 medical countermeasures have been approved under the animal
751 rule including the approval of a new indication for a medical
752 countermeasure to increase survival of adult and pediatric
753 patients acutely exposed to myeloid suppressive doses of
754 radiation as could occur after a radiological or a nuclear event.

755 This is the third FDA-approved medical countermeasure that
756 is indicated to increase survival in patients exposed to myeloid
757 suppressive doses of radiation.

758 Other approvals under the animal rule include inhalational
759 anthrax therapeutics of botulism anti-toxin, antibiotics for the
760 treatment and prophylaxis of plague, prophylaxis against the
761 lethal effects of some nerve agent poisoning and treatment of
762 known or suspected cyanide poisoning.

763 We have been actively implementing the new authorities
764 within our medical countermeasures initiative, specific to our
765 engagements with the Department of Defense as well.

766 In January of 2018, the agency launched enhanced engagements
767 with the Department of Defense under a joint program to prioritize
768 the efficient development of safe and effective medical projects
769 intended for our U.S. military personnel.

770 We are fully committed to working with our colleagues at

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771 the Department of Defense to support the needs of our U.S. military
772 personnel and look forward to continue to enhance collaborations
773 in these endeavors.

774 Finally, I am pleased to share that today we are releasing
775 our medical countermeasures initiative program update which
776 highlights the many notable achievements the agency has made to
777 advance the development and availability of safe and effective
778 medical countermeasures in fiscal year 2017.

779 This report provides an in-depth insight into the breadth
780 of activities and the progress FDA has contributed to our nation's
781 medical countermeasure assets.

782 FDA remains deeply committed to working closely with its
783 partners and fully using the authorities and resources Congress
784 provides us to advance this mission.

785 We look forward to partnering with this committee and the
786 Senate in the reauthorization of PAHPA. Thank you again for the
787 opportunity to testify today and I would be happy to answer any
788 questions.

789 [The prepared statement of Ms. Abram follows:]

790

791 *****INSERT 3*****

792 Mr. Burgess. Well, I thank you for your testimony. I thank
793 all of our witnesses for their testimony. We will proceed to
794 the question and answer portion of the hearing.

795 Let me recognize myself for five minutes for questions and,
796 as always, I will run out of time before I finish questions.
797 So we will be submitting some for the record.

798 Ms. Abram, let me just ask you, several years ago in the
799 middle of a flu epidemic in Fort Worth, Texas, I came home one
800 Thursday night to the Channel 8 news and they said the FDA was
801 making available expired Tamiflu to the area hospitals.

802 So, as you can imagine, Dr. Hamburg and I had a call the
803 next morning, and she assured me that expired Tamiflu would in
804 fact be just as efficacious. But as far as the Strategic National
805 Stockpile goes, do you try to rotate stock in and out so we don't
806 end up with an expired national stockpile?

807 Ms. Abram. So FDA supports the Strategic National Stockpile
808 very much from a technical and regulatory perspective. Congress
809 has given us the authorities to help to extend the shelf life
810 of products.

811 So we will look at products to see if -- even if they have
812 a certain expiration date that they've been assigned whether or
813 not it would be appropriate and they could still convey a
814 therapeutic benefit if they were used.

815 And I don't know if my colleague would like to add anything
816 further to that.

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817 Admiral Redd. That's exactly right. The products are
818 maybe labelled expired but they're tested to assure that they
819 haven't expired.

820 Mr. Burgess. So, Dr. Kadlec, let me just ask you -- of
821 course, we had Ebola in Dallas, Texas, a few years ago and
822 recognized the unified response was certainly necessary in that
823 public health emergency and all systems need to be able to
824 coordinate their efforts at the federal, state, and local level.

825 So can you perhaps enlighten us further how ASPR would
826 identify partners who would be involved in this collaboration
827 and enhance our medical surge capacity?

828 Dr. Kadlec. Yes, sir. In fact, during this Ebola outbreak
829 we've -- basically, the secretary asked me to basically lead the
830 coordination across the department. So we've been holding
831 regular conversations with HHS partners as well as other federal
832 interagency partners to do two things.

833 One is establish whatever is needed to support the response
834 overseas, keep the disease over there rather than over here, and
835 the second one is making sure that our capabilities domestically
836 are prepared.

837 We do have the National Ebola Treatment Network that was
838 created with supplemental funding that runs out in fiscal year
839 2019 that created three centers -- national centers for the
840 treatment of Ebola patients as well as 10 regional centers in
841 addition to the NIH clinical facility here in Bethesda. So it

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842 was basically assuring that the training, the equipping, and the
843 requirements were all up to date in terms of if their case should
844 show up on our soil how would we respond.

845 Second is mobilizing the assets that were -- that were funded
846 largely by BARDA, though NIH had some significant capabilities
847 to include diagnostics that were basically made available and
848 donated by the company to DRC as well as vaccines that BARDA
849 supported with Merck that was deployed and has immunized and the
850 folks down there, the responders, have immunized 1,100 folks so
851 far in vaccination.

852 So there have been a number of activities that we've kind
853 of monitored, coordinated on, and just ensured that we had
854 everything kind of ready to go should this outbreak kind of take
855 a different turn than it has so far shown.

856 Mr. Burgess. What we discovered two and a half years ago,
857 whenever the previous outbreak occurred, is a state like Texas,
858 where you have got some big distances between communities,
859 hospitals were -- did form networks and were agreeable to helping
860 each other at the same time. If you had a car show up with a
861 group of folks where high index of suspicion for a problem, all
862 of the assets in a local area could be consumed very quickly.

863 Are you looking at how to -- how to deal with that?

864 Dr. Kadlec. Yes, sir. And beyond those 10 regional
865 treatment centers we've also had 60 designated state Ebola
866 treatment centers and 178 Ebola assessment hospitals. So we've

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867 really focused on the concentration of those skills and supplies
868 necessary for those front -- you know, if you will, leading edge
869 hospitals or clinics to basically initially evaluate patients,
870 safely do so for themselves and for their patients and then make
871 the referrals up the chain to higher levels of care and treatment.

872 Mr. Burgess. Let me -- let me ask you this. You stressed
873 strong leadership several times in your testimony. I am grateful
874 that you are where you are. I want you to be there.

875 But just in general, as far as your position is concerned,
876 I mean, there are some -- there are some jurisdictional issues.

877

878 There are some Interagency issues. There has been some
879 discussion about designating the office of the vice president
880 as part of that central command. What are your thoughts about
881 that?

882 Dr. Kadlec. Sir, in an operational sense, I think the ASPR
883 performs a function as part of the national response plan. In
884 terms of orchestrating probably beyond the operational levels
885 of the strategic levels, particularly for resourcing, having a
886 friend or an ally at senior levels in the White House is a good
887 thing.

888 Having served as a special assistant to the president during
889 the Bush administration -- the second tour -- I can only say that
890 having support by the vice president or someone of stature like
891 his would be exceptional and very force multiplying in terms of

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892 having the support to get the resources to support what we need
893 to do at the operational or at the tactical level.

894 Mr. Burgess. Thank you, and my time expired. I will
895 recognize the gentleman from Texas, Mr. Green, five minutes for
896 questions, please.

897 Mr. Green. Thank you, Mr. Chairman.

898 Dr. Kadlec, antibiotic resistance is a real and growing
899 problem. I think we all agree to that, that in occurring
900 pandemics, chemical, biological, radiological, and nuclear
901 attack medical counter measures need to be able to treat the
902 initial injury from these attacks.

903 But, as you know, these patients may be suffering from burns
904 and wounds, for example, that are susceptible to secondary
905 bacterial infections. Antibiotics are an integral part of that
906 with the growing threat of antibiotic resistance in public health
907 as well as preparedness and response efforts.

908 Can you tell us what role you see BARDA playing in shoring
909 up this pipeline of new antibiotics?

910 Dr. Kadlec. Well, thank you for the question, sir, and BARDA
911 has been very active in this area. They set up a program called
912 CARB-X which is an active program which is interesting because
913 it really forms as a model for what we believe the DRIVE program
914 will look like.

915 It's the idea of creating private -- public-private
916 partnerships and in this case CARB-X and BARDA has basically

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917 interactions with 28 different companies who make novel
918 anti-bacterial drugs, vaccines, or diagnostics, and as a result
919 of that, there have been identified eight new classes of
920 antibiotics.

921 So that's important. But, significantly, for the taxpayer,
922 \$70 million of federal investment by CARB-X has resulted in about
923 \$485 million in private equity following that investment.

924 So not only are we trying to create new avenues and interest
925 in this area which, quite frankly doesn't have a large commercial
926 market for the drug companies, but we've worked effectively with
927 the private sector to kind of build, I think, the requisite
928 investment to identify promising candidates that we can move
929 through the developmental cycle and pathway to ultimate
930 licensure.

931 Mr. Green. There are not enough new antibiotics in the
932 pipeline. Almost 75 percent of those products in clinical
933 development are based on previously-approved classes of
934 antibiotics. Novel structures and approaches are needed to state
935 ahead of the resistance -- innovative preclinical antibiotic
936 approaches.

937 CARB-X is a global public-private partnership with BARDA
938 and NIAID and other global partners ensure that a robust pipeline
939 of preclinical innovation candidates that a product protect human
940 health from the most serious bacterial infection.

941 Can you describe how BARDA, CARB-X, and NIAID are working

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942 to ensure that there are enough preclinical products moving on
943 the -- on to clinical trials?

944 Dr. Kadlec. Well, sir, they do so by a variety of methods.
945 Part of it is active -- I want to say query which is part of
946 it. And again, I will just use the example that we hope to do
947 -- to build on is using innovation accelerators around the country
948 to basically identify promising candidates that could be
949 antibiotics or antimicrobials that would be part of this CARB-X
950 program or part of the larger innovation program.

951 So the thing is is that we work closely with NIAID on this.
952 We do work with the Wellcome Trust as other organizations as
953 well as with companies to basically identify these.

954 Obviously, it's going to take long-term constant vigilance
955 and, again creating new drugs is just part of the challenge, as
956 Dr. Burgess would identify. Part of it is basically monitoring
957 the environment and I think Dr. Redd can highlight on those pieces
958 as well as practices by physicians in prescribing antibiotics.

959

960 Dr. Redd.

961 Admiral Redd. Yes. First of all, I want to acknowledge
962 the significance of the problem, that if we run out of antibiotics,
963 not just treatment of infects but things like cancer therapy and
964 surgery are going to be much more difficult than they are today.

965 In addition to developing new products, there are steps that
966 need to be undertaken and are being undertaken in the public health

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967 domain. First is just preventing infections in hospitals -- that
968 bacteria in hospitals are -- it's where real resistance is bred.

969 Secondly is tracking and identifying infections when they
970 occur with resistant organisms so that intensive infection
971 control measures can be undertaken to prevent the spread of those
972 organisms to other individuals.

973 And then thirdly, improving the prescribing of antimicrobial
974 -- that if these drugs can be limited to the people who really
975 need them, that will also slow the development of resistance.

976 Mr. Green. Is there any overlap between the CDC's
977 investment in antibiotic resistance laboratory network and what
978 ASPR does?

979 Admiral Redd. There's not. We are funding laboratory
980 testing as part of the surveillance system to identify resistant
981 organisms so that those interventions can be undertaken to prevent
982 their spread.

983 Mr. Green. Well, and I want to thank the CDC because in
984 2005, after Hurricane Katrina in Louisiana, Houston, Texas got
985 about a quarter of a million people from south Louisiana, and
986 CDC was there bringing in the medications and also the public
987 health officers to help our local medical schools and our hospital
988 system.

989 So CDC is very valuable, and I yield back my time, Mr.
990 Chairman.

991 Mr. Burgess. The chair thanks the gentleman. The

992 gentleman yields back.

993 The chair recognizes the gentlelady from Tennessee, Mrs.
994 Blackburn, five minutes for questions, please.

995 Mrs. Blackburn. Thank you, Mr. Chairman.

996 Ms. Abram, I want to come to you for just a minute and talk
997 a little bit about the stockpile and the definition that is there.

998 It is in statute, defined to include drugs, biological products,
999 or devices.

1000 And until 2016, when we passed 21st Century Cures and
1001 included in that the software act, which deals with medical
1002 technology, medical software had been included in that definition
1003 of medical devices.

1004 And what happened or what we did in that was to remove some
1005 classifications of medical software from FDA oversight, and I
1006 know that you're familiar with the legislation and familiar that
1007 FDA is still in the process of implementing that law and making
1008 those determinations which products are going to go where.

1009 And we recently -- I think it was the end of December --
1010 received more guidance documents to that fact. Would -- so what
1011 I wanted to know from you is are there any types of medical software
1012 or applications currently in the stockpile that no longer fall
1013 under the device definition?

1014 Ms. Abram. Thank you so much for the question. You alluded
1015 to this and mentioned it in your remarks. Yes, we are actively
1016 implementing a number of the provisions that were enacted as part

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1017 of Cures including delineating in a risk-based manner the
1018 regulation of various devices and the software kind of components
1019 that get into that.

1020 You know, traditionally, much of what has been procured into
1021 the stockpile has focused more on vaccines, therapeutics,
1022 diagnostics, and some of the other materiel -- for example, I
1023 believe, like, personal protective equipment would be something
1024 purchased there.

1025 And I would like to acknowledge that one of the additions
1026 to the draft that was released over the past week includes the
1027 concept of cyber security, which is, of course, a very important
1028 matter.

1029 Mrs. Blackburn. Okay. Let me ask you this. Would you
1030 recommend that we amend the definition of security
1031 countermeasures to include medical software in applications when
1032 there is a clear need that some of these products may need to
1033 be procured?

1034 Ms. Abram. So the addition of the cybersecurity references
1035 and the context of where that may interface here with the software
1036 considerations and device considerations has raised some novel
1037 questions and considerations.

1038 And having just recently received the text we are having
1039 our subject matter experts look at it quickly because we
1040 understand this is an area of interest for the committee and we
1041 want to make sure we are providing very thorough and thoughtful

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1042 input on these points because, as I mentioned, cybersecurity is,
1043 obviously, a very serious concern and we want to be responsive
1044 to it.

1045 We have looked at it in the context of devices form a total
1046 produce life cycle approach. At the same time, much of the
1047 framework that you're referencing has traditionally been looked
1048 at in a CBRN context.

1049 So this does raise some new questions for us. But we look
1050 forward to working with the committee and providing technical
1051 assistance.

1052 Mrs. Blackburn. Well, I think that -- and probably Ms. Eshoo
1053 and Mrs. Brooks would agree with me -- when you all conduct that
1054 oversight and look at this and formulate an opinion, I think we
1055 would like to have that --

1056 Ms. Abram. Absolutely.

1057 Mrs. Blackburn. -- and include it in the information from
1058 this hearing.

1059 Ms. Abram. Absolutely. We'd be happy to follow up.

1060 Mrs. Blackburn. Okay. That would be -- that would be
1061 great.

1062 Kadlec, let me ask you a little bit about -- we've had a
1063 bill here, the Good Samaritan Act, and of course, there is part
1064 of the language included in the Senate HELP's version of PAHPA,
1065 and I have worked on this for several years and I am appreciate
1066 that it is included. Part of that language is included here.

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1067 But I am interested to hear your thoughts on how we can truly
1068 harness the services of health care professionals who are willing
1069 to volunteer their skills during emergencies.

1070 And, you know, after Katrina we saw the need to get people
1071 into the area. After the Boston Marathon bombing, we saw the
1072 need to get people in.

1073 So I would love a quick response on that.

1074 Dr. Kadlec. Well, thank you, ma'am, for the question. And,
1075 clearly, there's a real significant role for volunteers in this
1076 situation. I think the best case scenario is when they identify
1077 before the crisis or the disaster happens and there are two
1078 programs that allow that -- Medical Reserve Corps and ESAR-VHP,
1079 which is a volunteer program to allow people to enroll so they
1080 can be identified.

1081 I think the key thing is is, as many know, that sometimes
1082 even though volunteers come forward, their ability to help is
1083 going to be based on their knowledge and training. And so we
1084 would prefer that those people would be identified before an event
1085 and then we have confidence, you know, what to do and the right
1086 things to do so they do not cause any further injury or harm.

1087 We are very supportive of volunteers. They're a critical
1088 part of the response as we've seen historically and we know in
1089 the future they'll be there as we witnessed in the cases of several
1090 events recently. So very supportive of this notion.

1091 Mrs. Blackburn. I yield back.

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1092 Mr. Burgess. The gentlelady's time has expired.

1093 The chair now needs to recognize the gentleman from New York,
1094 Mr. Engel, five minutes for questions, please.

1095 Mr. Engel. Thank you, Chairman Burgess and Ranking Member
1096 Green, for holding this very important hearing.

1097 I don't think we'll have properly considered pandemic
1098 preparedness without discussing the threat of antimicrobial
1099 resistance, a serious international drug crisis wherein diseases
1100 are able to resist the very drugs meant to destroy them.

1101 To underscore the seriousness of antimicrobial resistance,
1102 I want to talk about tuberculosis, or TB, not only because Ranking
1103 Member Green and I are two of the co-chairs of the House TB
1104 Elimination Caucus, because TB and airborne infection kills more
1105 people worldwide than any other infectious disease, and drug
1106 resistant TB is the most common and deadly airborne antimicrobial
1107 resistant disease.

1108 Cases of anti-resistant TB cost much more to treat than
1109 drug-sensitive TB in cases of multi-drug resistant TB, and
1110 extensively drug-resistant TB unfortunately becoming much more
1111 frequent.

1112 While we may typically think drug resistance is caused by
1113 inappropriate treatment, most drug resistant TB cases are now
1114 caused by transmission from person to person, making it much
1115 easier for drug resistant TB to spread to new parts of the world.

1116 History has shown us that we cannot stop infectious threats

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1117 with isolationist policies. We need to invest in new tools to
1118 keep Americans safe and the growing threat of antimicrobial
1119 resistance and the very real possibility that one day,
1120 unfortunately, there might be a drug-resistant outbreak in the
1121 United States.

1122 So Dr. Kadlec, let me ask you what more can BARDA do to spur
1123 the development of novel antimicrobials and ensure that we have
1124 the tools we need to address antimicrobial resistance and improve
1125 health security in this country?

1126 Dr. Kadlec. Thank you, sir, for the question and, again,
1127 I would just, again, like to reemphasize the role that BARDA does
1128 have in this area, working closely with NIAID and with foreign
1129 activities Wellcome Trust to basically create CARB-X, which is
1130 really the opportunity to pool resources to promote research into
1131 a variety of different potential candidates.

1132 I mentioned the possibility of eight new classes of
1133 antibiotics. Do this date, 30 potential high-quality
1134 antibacterial products have been identified and are being
1135 evaluated for this.

1136 So I think part of this is is realizing that there is a --
1137 there is an ongoing activity that BARDA is working with NIAID
1138 on.

1139 It's informed by CDC in terms of its role subject to
1140 monitoring the environment and identifying those cases and
1141 evaluating the sensitivities of those organisms, whether it be

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1142 TB or anything else, quite frankly, and the ability to evaluate
1143 what we can do to promote renewed interest and research and
1144 commitment not only by the government but also by the private
1145 sector into these areas.

1146 Mr. Engel. Thank you very much.

1147 Let me also say, to truly protect Americans from health
1148 threats I believe we, obviously, cannot limit our focus to threats
1149 within the United States itself.

1150 So Dr. Redd, you know from your years of service, including
1151 during the 2009 H1N1 pandemic and the 2014 West Africa Ebola
1152 outbreak, the disease that knows no borders, do you think it's
1153 important for the U.S. to evaluate the global threats to health
1154 security to ensure that we are prepared to face these threats?

1155 Admiral Redd. Yes, sir. The work that has been done to
1156 strengthen global health security since 2014 is very important
1157 and needs to continue.

1158 I think our work in the Democratic Republic of Congo is
1159 emblematic of the kinds of threats that we need to be able to
1160 detect and, working with host countries, contain at the source.

1161 Mr. Engel. Thank you.

1162 Ms. Abram, would you like to comment on any of the things
1163 that I've mentioned?

1164 Ms. Abram. I would just further add to some of the comments
1165 that my colleagues have made is that FDA is also actively involved
1166 in helping to foster and bring forward next-generation of

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1167 antibiotic products.

1168 We've been implementing the GAIN Act provisions and we've
1169 also been actively implementing the break points provisions that
1170 were included as part of the Cures Act, which are very helpful
1171 in helping to inform providers of proper utilization of the
1172 antibiotics that are available to treat.

1173 Mr. Engel. Thank you.

1174 Thank you, Mr. Chairman. I yield back.

1175 Mr. Burgess. Gentleman yields back. The chair thanks the
1176 gentleman.

1177 The chair recognizes the gentleman from Illinois, Mr.
1178 Shimkus, five minutes for your questions, please.

1179 Mr. Shimkus. Thank you, Mr. Chairman. It's great to have
1180 you all. Thanks for your work.

1181 Anyone who's followed this committee knows that I've been
1182 working on the antimicrobial resistance front for many, many
1183 years. Good to see folks who have been in this battle.

1184 You probably heard me say that we need to develop products
1185 we hope we never has to use. The fact is we are in a race, you
1186 all know, against antibiotic resistance by bacterial and fungal
1187 pathogens and we are losing because these diseases are developing
1188 resistance faster than our efforts can develop new agents.

1189 And BARDA is very valuable to these efforts, but it's clear
1190 that BARDA's work, even combined with commercial potential, isn't
1191 enough.

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1192 FDA Janet Woodcock, CDC's Tom Frieden, and the National
1193 Institute of Allergy and Infectious Diseases -- I hate these
1194 acronyms so I use -- and NIAID's director, Tony Fauci, have joined
1195 every major country's assessment, acknowledging that there is
1196 simply very little incentive for biopharma companies to do the
1197 necessary R&D.

1198 I want to first go to Dr. Kadlec but others can chime in
1199 if they'd like. Can you comment on why antibiotics are a focal
1200 point of BARDA's work?

1201 Dr. Kadlec. For two reasons. As you defined, it is a public
1202 health challenge but, quite frankly, it's inextricably linked
1203 to the issues that relate to the more -- to other threats that
1204 may happen -- emerging infectious disease as well as deliberate
1205 threats.

1206 So it would be a circumstance that you could anticipate I
1207 think as highlighted before either in cases of radiation exposure
1208 where the immune system is depressed or burns where the immune
1209 system is compromised. Infection becomes a significant
1210 consideration as well as if you had the intentional use of
1211 infectious diseases.

1212 Mr. Shimkus. Would you -- would you agree that the situation
1213 is dire?

1214 Dr. Kadlec. Sir, it's difficult and, depending on the agent
1215 or organism you're talking about, it can be dire, and for the
1216 individual who's afflicted by it, it is dire, quite honestly.

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1217 Mr. Shimkus. Can you commit or will you work with my office
1218 and this committee on solutions that spur the proper level of
1219 critically-needed antimicrobial development?

1220 Dr. Kadlec. Yes, sir.

1221 Mr. Shimkus. Mr. Green and I have been trying to deal with
1222 this over the past couple years. He did touch on this issue and
1223 you mentioned the ongoing activities.

1224 But it's my understanding that these efforts may fall short
1225 when it comes to incentivizing development. Anyone want to
1226 comment on that observation? Admiral.

1227 Admiral Redd. I think the point I was going to make is that
1228 these products are used in a system and the detection and infection
1229 control procedures and assessment of effectiveness are all part
1230 of to ensure that these products are used to obtain the greatest
1231 effect.

1232 More products are, clearly, needed but we also need to do
1233 better in who is prescribed antimicrobials, making sure that there
1234 is -- have as narrow a spectrum as is possible and, hopefully,
1235 that race we can kind of slow down the spread and evolution of
1236 resistance so that as new products develop there will be a --
1237 they'll be effective for longer periods of time.

1238 Mr. Shimkus. Go ahead.

1239 Ms. Abram. Yes, I was just going to add, there's another
1240 facet to this that I think is important and you actually touched
1241 upon this in the opening of your question, which is around the

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1242 development of products that you hope to never have to use but
1243 you may need to use.

1244 And so one of the aspects of actually being able to capture
1245 some of this data and real-world experience with the utilization
1246 of antibiotics and these other naturally occurring circumstances
1247 helps to add to our data set for understanding how these products
1248 might be used in the event of a bioterrorism event.

1249 Mr. Shimkus. And I've always been concerned. We haven't
1250 worked -- there are some ongoing activities -- my observation
1251 is that they're too small. When you're doing the -- you need
1252 to -- the companies need -- I mean, I always talk about raising
1253 capital, assuming risk and a return. Now you want to raise
1254 capital, assume risk, hoping never to get a return.

1255 How do -- and even though there's attempts being made to
1256 encourage that we just -- I still think it's too small, based
1257 upon the risk out there.

1258 So go ahead.

1259 Dr. Kadlec. Sir, I think you're kind of highlighting the
1260 issue of kind of two kind of categories of incentives. One is
1261 the push -- what can we do to help companies be successful in
1262 their endeavor to bring new antibiotics or class of antibiotics
1263 to the table, and then what's the pull -- what's the incentive
1264 on the other side that would kind of somehow offset the cost,
1265 either opportunity or real, to execute that.

1266 We are actively looking at that. I think in the past

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1267 Congress has responded in terms of, like, the priority review
1268 vouchers, obviously, the incentives in terms of investments into
1269 this are.

1270 But we are trying to evaluate what is -- what is the road
1271 to success and what's a sustainable road to success, which is
1272 another story here in terms of looking at incentives over time
1273 that make sense as well as are affordable.

1274 Mr. Shimkus. Excellent. Thank you very much.

1275 Yield back.

1276 Mr. Burgess. The chair thanks the gentleman. The
1277 gentleman yields back.

1278 The chair recognizes the gentlelady from Illinois, Ms.
1279 Schakowsky, five minutes.

1280 Ms. Schakowsky. Thank you, Mr. Chairman, and I want to thank
1281 our panellists all for being here.

1282 One absolutely essentially part of disaster preparedness
1283 is having the workforce in place to respond to public health
1284 emergencies and the workforce is, of course, the backbone of
1285 disaster preparedness, in my view, and that's why I am proud I've
1286 introduced H.R. 5998, which is the Securing Experts to Control,
1287 Understand, and Respond to Emergencies -- or the SECURE Act --
1288 to support and build a robust disaster preparedness workforce
1289 and the bill would actually simply reauthorize the education loan
1290 repayment program for the Epidemic Intelligence Service -- EIS
1291 -- at the Centers for Disease Control.

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1292 So I am hopefully that this program can be reauthorized and
1293 make it a part of the underlying bill. EIS officers are health
1294 professionals who serve on the front lines of public health
1295 emergencies as boots on the ground, disaster detectives who
1296 investigate outbreaks and assist during natural disasters.

1297 And since its creation in 1951, the EIS program has trained
1298 more than 3,600 officers and based in state and local public health
1299 departments across the country.

1300 EIS officers deploy more than 200 times -- are deployed more
1301 than 200 times every year, responding to public health emergencies
1302 at home and abroad.

1303 So Dr. Redd, I wanted to ask you how important in our ability
1304 to recruit this workforce is this program, the loan repayment
1305 program?

1306 Admiral Redd. So I agree with you that the Epidemic
1307 Intelligence Service, or the EIS, is a major asset for CDC and
1308 the country. It's a major vehicle to recruit health
1309 professionals and, in particular, physicians to public service.

1310 I was actually an EIS officer quite a few years ago. The
1311 proportion of physicians that have been included has decreased
1312 over the years and I think that probably -- that is a part of
1313 that.

1314 I am not going to specifically address your bill but I can
1315 say that for myself when I came to the EIS program I did have
1316 student loans and it would have been -- it would have been an

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1317 incentive to have some method to have those loans repaid.

1318 I think it is really critical that we continue and strengthen
1319 the EIS program.

1320 Ms. Schakowsky. So why don't you tell us all what EIS
1321 officers -- how they protect the public's health, what kind of
1322 events do they respond to, and what role do they play in responding
1323 to those events?

1324 Admiral Redd. Sure. So Epidemic Intelligence Service
1325 officers are either -- have doctorate degrees in public health
1326 sciences or in medicine, generally finish their training, come
1327 to CDC for post-graduate training. So the EIS program is a
1328 two-year experiential training program.

1329 Officers are assigned either within CDC or with state and
1330 local health departments and the experience part is investigating
1331 outbreaks. So when -- for example, I investigated a
1332 Legionnaire's disease outbreak in California as part of my EIS
1333 experience, working with state health departments and local
1334 health departments to identify risk factors and implement control
1335 measures.

1336 It's really -- it's a great lead-in to public service and
1337 to public health --

1338 Ms. Schakowsky. That's really what I wanted to get at.
1339 After the EIS two-year training period, 85 percent of EIS
1340 graduates enter the public health workforce.

1341 So I think what I am hearing you say and I would agree that

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1342 EIS acts as a pipeline for the next generation of health care
1343 leaders and contributes to a strong workforce. Would you agree?

1344 Admiral Redd. Absolutely. I am just -- as a personal
1345 matter, I am pretty sure I wouldn't be here today if I hadn't
1346 done the EIS program a number of years ago.

1347 Ms. Schakowsky. Well, thank you. I know you can't comment
1348 on the legislation but I am going to really try and make sure
1349 that this incentive to get more people into this program is part
1350 of the legislation.

1351 Thank you so much for your service.

1352 Mr. Burgess. The gentlelady yields back. The chair thanks
1353 the gentlelady.

1354 The chair recognizes the gentleman from New Jersey, Mr.
1355 Lance, for five minutes.

1356 Mr. Lance. Thank you, Mr. Chairman.

1357 Good morning to the distinguished panel. Dr. Kadlec,
1358 scientists and drug companies are looking to discover and develop
1359 approaches other than traditional antibiotics to combat bacterial
1360 infections and these can range from using viruses to attack the
1361 bacteria, creating vaccines to prevent hospital-acquired
1362 infections, applying known successful interventions in treating
1363 cancer by changing the way the human immune system responds to
1364 infections.

1365 Scientists harness cutting-edge science that will combat
1366 bacteria in new ways and potentially reduce risk of resistance.

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1367 Would you please talk about BARDA's role in fostering the
1368 discovery and development of non-traditional approaches?

1369 Dr. Kadlec. Sir, BARDA is very interested in those kinds
1370 of approaches and, quite frankly, I think it's part of the
1371 innovation side that was required through 21st Century Cures Act
1372 is now building a program to actually look for those kind of
1373 innovative ideas.

1374 To your point about viruses to beat bacteria that's phage
1375 technology, which BARDA is actively investigating and actually
1376 looking at different programs that exist that could be relevant
1377 in terms of addressing -- again, a novel way of addressing
1378 antimicrobial resistance.

1379 Every bacteria has a counter virus that effectively can
1380 either disarm it, kill it, or potentially change its antibiotic
1381 resistance patterns.

1382 And so those are things that are actively being investigated
1383 right now. It is, I think, one of the areas that probably deserves
1384 more consideration. We welcome the opportunity through the 21st
1385 Century Cures Act to kind of open these new doors to innovative
1386 approaches and to maybe non-traditional approaches and we look
1387 forward to Congress' continued support to do more of that, going
1388 forward.

1389 Mr. Lance. Thank you very much, Doctor.

1390 To the panel in general, the Presidential Advisory Council
1391 on combatting antibiotic-resistant bacteria was created under

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1392 an executive order in 2014 and has twice been continued, most
1393 recently in 2017.

1394 The Advisory Council is set to expire on September 20th,
1395 2019, unless there is another continuation by executive order.

1396 Considering the danger posed by antibiotic-resistant bacterial
1397 infections, the fact that this remains quite high, is there any
1398 reason why the Advisory Council should not be extended to continue
1399 its mission to produce reports and recommendations that influence
1400 federal combatting antibiotic-resistant bacteria activities both
1401 here and abroad?

1402 Admiral Redd. Well, I think this problem is going to be
1403 with us for the foreseeable future. So I think that, regardless
1404 of the exact structure used to organize our response to that,
1405 this will be a problem that we'll be -- we'll be facing for years
1406 and years to come.

1407 Mr. Lance. So that means, I assume, that looking in the
1408 future we probably should extend this beyond the current deadline?

1409 Admiral Redd. I think that's a -- that's a decision that
1410 won't be mind to make. I think we'll have to look at what progress
1411 we've made and how that panel had encouraged that -- encouraged
1412 that progress.

1413 Mr. Lance. Thank you.

1414 Would anyone else on the panel like to comment?

1415 Yes. Go ahead.

1416 Ms. Abram. I was just going to add, there's,

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1417 understandably, a considerable amount of interest in the
1418 antimicrobial-resistant issues and one point I haven't made be
1419 remiss if I didn't is also the importance of regulatory certainty
1420 when it comes to bringing forward the next generation of
1421 antibiotics products and they, like other medical
1422 countermeasures, can face unique development challenges.

1423 And so one thing that FDA has also been very focused on is
1424 putting out product-specific guidance. For example, we've
1425 issued guidance on the clinical trial design for specific diseases
1426 including prophylaxis of inhalational anthrax.

1427 And so we are trying to do our part, what we can to help
1428 make the pathway as clear as possible, recognizing that there
1429 are some inherent challenges that have been discussed at length
1430 at the hearing.

1431 Mr. Lance. Thank you very much, and please keep up the good
1432 work -- a very distinguished panel.

1433 I yield back 37 seconds, Mr. Chairman.

1434 Mr. Burgess. The chair is overjoyed and thanks the
1435 gentleman for yielding back.

1436 The chair now recognizes the ranking member of the full
1437 committee, Mr. Pallone, five minutes for questions, please.

1438 Mr. Pallone. Thank you, Mr. Chairman. I am trying to get
1439 in some questions about the Strategic National Stockpile and also
1440 the priority review vouchers. So I am going to ask -- try to
1441 be quick in answering the questions.

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1442 Dr. Redd, I am interested in learning more about CDC's past
1443 work in leading the Strategic National Stockpile. Can you
1444 describe the range and type of deployments as well as the types
1445 of products CDC has delivered through the SNS program?

1446 Admiral Redd. Thank you for that question.

1447 There have been in the neighborhood of a hundred deployments
1448 since the formation of the Strategic National Stockpile. Many
1449 of these are very small deployments, for example, for treatment
1450 of adverse reaction to smallpox vaccine -- vaccinia immune
1451 globulin -- also for containing or for treating people who've
1452 been involved in a botulism outbreak with the antitoxin.

1453 The largest deployment of the stockpile was during the H1N1
1454 pandemic. A quarter of the stockpile of antiviral drugs -- about
1455 12 million treatment courses -- were distributed to states.
1456 Also, personal protective equipment was distributed.

1457 Another product that is frequently distributed -- it's
1458 called federal medical stations. These are basically hospitals
1459 but without the building. They are -- they've been deployed for
1460 the hurricanes.

1461 About every other year there's a significant deployment of
1462 federal medical stations.

1463 Mr. Pallone. Okay. How does CDC help ensure that state
1464 and local health departments are ready for the last-mile
1465 deployment of the SNS in which items are dispensed to the public
1466 in the event of a public health emergency?

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1467 Admiral Redd. Well, the state and locals have a very
1468 important responsibility to assure that products are dispensed
1469 quickly and in accordance with guidelines.

1470 So we've been working through really two different parts
1471 of our state and local program. The Cities Readiness Initiative
1472 funds states to develop those systems.

1473 We also have an assessment process called the medical
1474 countermeasure operational readiness review where we have worked
1475 with each of the grantees and, in fact, the grantees have worked
1476 with their subgrantees and local departments -- around 500
1477 assessments of state and local capability. The things that we
1478 found in that are that there are some areas where we need to
1479 improve.

1480 The capability to dispense from a manpower standpoint, the
1481 staffing and then also staffing for security areas that are not
1482 universally but pretty general challenges that state and local
1483 health departments face.

1484 Mr. Pallone. All right. Thanks.

1485 I understand that some of these training activities are
1486 funded through the SNS program appropriations. So, Dr. Kadlec,
1487 will SNS funding continue to be used to pay for these important
1488 training activities?

1489 Dr. Kadlec. Yes, sir. I think the key thing is
1490 understanding in this transition of oversight that nothing, and
1491 nobody's moving, if you want to call it that, and we are leveraging

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1492 all the resources and expertise that CDC has offered in the past.

1493 And, again, to highlight one thing that Dr. Redd talked about
1494 is in a recent preparedness summit that was held in Atlanta, we
1495 did an informal survey of state and local authorities about what
1496 kind of help they need.

1497 And so what we found out is true to his characterization
1498 they need more people to help deploy and dispense these kinds
1499 of things, particularly if they were interested in the opportunity
1500 for residential delivery or potentially capitalizing on retail
1501 distributors that could be used to distribute some of these
1502 products in the event of an emergency and that's maybe the one,
1503 if you will, new area that we are hoping to work with CDC, going
1504 forward, is using our state representatives from ASPR to basically
1505 work together to help more on the sense of what can we do nationally
1506 to help state and local authorities do that. Part of it may be
1507 mobilizing the federal workforce, which has been considered
1508 before. Part of it may be looking at alternative means to help
1509 with residential delivery. People have suggested even Amazon.

1510
1511 And then the third area is really about what can we do with
1512 retail outlets that could basically facilitate for this. And
1513 so in the end, I think what we hope to build is a stronger
1514 partnership with our state and local authorities, realizing if
1515 they're not successful, no one is successful, and that is our
1516 intent is to basically build on the past success of the programs

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1517 and basically further extend them to support state and local
1518 authorities.

1519 Mr. Pallone. All right. Thank you. I wanted to ask about
1520 priority review voucher but I think I've run out of time. So
1521 I will have to get back to you on that. Thank you.

1522 Mr. Burgess. Gentleman yields back. The chair thanks the
1523 gentleman.

1524 The chair recognizes the gentleman from Ohio, Mr. Latta,
1525 five minutes for your questions, please.

1526 Will the gentleman suspend? I didn't realize Mr. Barton
1527 had come on the end of the dais. The gentleman --

1528 Mr. Barton. I will only take two or three minutes.

1529 Mr. Burgess. The gentleman is recognized for five minutes.

1530 Mr. Barton. Normally, I would yield to Mr. Latta but I've
1531 got to leave and go to another meeting. So I am just going to
1532 be real quick.

1533 First, thank our panel, especially Dr. Kadlec. It says that
1534 you used to work for Senator Burr and Senator Kennedy. The
1535 senator doesn't talk about it but he used to be a congressman
1536 on this committee and he and I worked on what's now Medicare Part
1537 D, the prescription drug benefit, way back when and, of course,
1538 Senator Kennedy helped me tremendously on what was the
1539 reauthorization of the National Institute of Health.

1540 So they were both good -- you know, Senator Kennedy has passed
1541 away but, you know, Senator Burr is still over there and they're

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1542 both good men.

1543 So you were trained right, or maybe you trained them right.

1544 I don't know.

1545 Dr. Kadlec. Well, sir, Anna Abram was also trained by him
1546 so you got a pair of us here, bookends.

1547 Mr. Barton. Oh, well, that's good. Well, apparently, the
1548 big controversy in the pending reauthorization is the transfer
1549 of the stockpile from CDC to APR whatever.

1550 I am going to start with you, Admiral. You're the one who
1551 controls it now. Why should we keep it with you?

1552 Admiral Redd. Well, we are implementing the transfer and
1553 so that is a process that's underway. We've worked -- been
1554 working closely with ASPR. We've actually formed a number of
1555 committees to make sure that the transition doesn't result in
1556 any degradation --

1557 Mr. Barton. So you don't oppose the transfer?

1558 Admiral Redd. Well, I will say that we are -- we are working
1559 to make sure that we -- that when we make the transfer it doesn't
1560 result in any loss of capability.

1561 Mr. Barton. It's obvious your Navy training is kicking in.
1562 You have been giving a directive and you're -- I thought I would
1563 get a little different answer.

1564 Well, I will go to you, Dr. --

1565 Admiral Redd. Let me mention a couple of areas that are
1566 -- that we are working closely with -- that in these five

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1567 committees the two areas that I think are really essential to
1568 sustain are the linkage with subject matter expertise at CDC in
1569 the stockpile and in the decision making process, and the other
1570 was the question earlier about the state and local capabilities
1571 in our work to strengthen or assure that the state health
1572 departments are able to dispense.

1573 That's something that we are working very closely on, I would
1574 say, on a more than weekly basis.

1575 Mr. Barton. Okay. Well, that's a great answer.

1576 Dr. Kadlec, why should we transfer it to your agency?

1577 Dr. Kadlec. Well, sir, we are in the business -- all in
1578 the business about preparedness and response. I think the
1579 secretary, when he made his decisions, thought about three things
1580 in particular -- integrating with the operation -- other
1581 operational assets that exist within the national medical system.

1582

1583 There's another logistics system within HHS that supports
1584 disaster response. The second thing is is how do we streamline
1585 the medical countermeasure enterprise to make sure what we have
1586 in it can be sustained and replenished over time efficiently as
1587 well.

1588 And then the last thing is, is to this point is how can we
1589 better support state and local authorities in the last mile.

1590 Mr. Barton. It sounds like your two groups are working well
1591 together. Would you both agree with that?

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1592 Dr. Kadlec. Yes, sir.

1593 Mr. Barton. Okay. And Ms. Abram, since you don't have a
1594 dog in this hunt, does the FDA have a position on where it should
1595 go and if so, what is it?

1596 Ms. Abram. The FDA stands ready to support the Strategic
1597 National Stockpile wherever it ends up being housed.

1598 Mr. Barton. It's a very political correct answer.

1599 With that, Mr. Chairman. I yield back.

1600 Mr. Burgess. The gentleman yields back. The chair thanks
1601 the gentleman.

1602 The chair recognizes the gentlelady from California, Ms.
1603 Matsui, five minutes for questions, please.

1604 Ms. Matsui. Thank you, Mr. Chairman. I want to thank the
1605 witnesses for being with us today.

1606 Some of the scariest potential attacks that the world is
1607 vulnerable to today are now posed by chemical and biological
1608 weapons as well as cyber-attacks.

1609 We made so much progress with the innovation of new drugs
1610 and treatments as well as technology. But those new advancements
1611 come with new vulnerabilities.

1612 We also continue to see damage from ever-increasing natural
1613 disasters. We want our health system to be prepared to respond
1614 to hurricanes, fires, and earthquakes as well as things like Ebola
1615 and anthrax.

1616 PAHPA is critical to our success in both responding to public

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1617 health emergencies including minimizing harm of any attacks and
1618 this field is constantly changing. So we need to keep up. I
1619 am pleased that we are working on the reauthorization in a
1620 bipartisan manner on this committee. I look forward to working
1621 with my colleagues, Representatives Eshoo and Brooks, to advance
1622 their legislation.

1623 One of the main issues that we are discussing today is the
1624 Strategic National Stockpile supplies that can be deployed in
1625 case of a variety of types of emergencies under discussions which
1626 you have all been talking about with your last -- in the last
1627 witness here is the -- whether it's appropriate and necessary
1628 to transfer some SNS functions from CDC to assistant secretary.

1629
1630 I am interested in hearing more of your thoughts on this.
1631 But I want to ask a specific question related to safety of
1632 products stored in a stockpile.

1633 I understand that vaccines and other injectable drugs can
1634 be contaminated by glass because the glass containers may break,
1635 crack, delaminate, or contain glass particles.

1636 In some cases, glass failure is a result of recalls because
1637 they pose a potential threat to patient safety. Dr. Redd, do
1638 you have any concerns about the impact of glass failures on the
1639 safety, security, or sterility of counter measures in the
1640 stockpile?

1641 Admiral Redd. So I think the issue of assuring the safety

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1642 of the material that is stored in the stockpile is a very important
1643 issue. The products are stored at undisclosed locations.

1644 There is a standard monitoring of those materials. As Ms.
1645 Abram noted earlier, there's a process for products for which
1646 the shelf life extension program is appropriate to test them and
1647 make sure that they retain their capability. For products that
1648 need to be stored at certain temperatures there is quite a system
1649 --

1650 Ms. Matsui. Right. How about glass in particular? Dr.
1651 Kadlec or Ms. Abram, would you like to comment on the issue of
1652 glass contamination?

1653 Ms. Abram. Yes. I would be -- I would be happy to take
1654 that one and thank you for the question.

1655 We recently put out -- the agency, FDA, did put out
1656 information specific to some of the analysis we have been looking
1657 at in recent years. You're touching upon the phenomenon that
1658 can occur with glass vials.

1659 Glass affords many advantages as a packaging. However,
1660 there can be this phenomenon where you have these thin flexible
1661 fragments that break off.

1662 Ms. Matsui. Right.

1663 Ms. Abram. -- and that's something that we've been
1664 studying to look at.

1665 We issued an advisory in 2011 and went back and did some
1666 pretty extensive surveillance of products on market that had these

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1667 type of vials, going back to fiscal year 2008 through fiscal year
1668 2017.

1669 We've actually seen a decrease in the number of recalls
1670 associated with particulates and so we recently shared. Based
1671 on that analysis, we didn't see a new or emerging safety signal
1672 or trend. We chose not to update the analysis at that time.

1673 There's been particular interest around kind of new glass
1674 design and how that compares to the more traditional borosilicate
1675 glass vials, and in that regard our studies demonstrated that
1676 the novel glass vials exhibited improved performance in terms
1677 of withstanding mechanical stress and scratching relative to type
1678 one borosilicate glass vials in the study.

1679 But we also looked at this from the standpoint of chemical
1680 durability because, under certain stress conditions such as a
1681 more basic environment, the novel glass vials exhibited an
1682 improvement over one of the borosilicate glass vials. But there
1683 was no definitive difference in performance relative to the other
1684 borosilicate vials.

1685 Ms. Matsui. So are you continuing to follow up on this to
1686 ensure that, you know, you look at the glass, ensure --

1687 Ms. Abram. Yes.

1688 Ms. Matsui. Okay.

1689 Ms. Abram. Absolutely.

1690 Ms. Matsui. Okay. Thank you, and I am running out of time
1691 already. I have further questions and I will submit them.

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1692 Thank you. I yield back.

1693 Mr. Burgess. The gentlelady yields back. The chair thanks
1694 the gentlelady.

1695 The chair now recognizes the gentleman from Ohio five minutes
1696 for questions, please.

1697 Mr. Latta. I thank the chairman very much and I also want
1698 to thank our witnesses for being with us today on this very
1699 important topic.

1700 And Dr. Kadlec, if I could pose my questions to you right
1701 off the bat, first of all, I want to thank you very much for your
1702 service to our country in the Air Force for your 20 years of
1703 service.

1704 And as we talk about cybersecurity, I think it's really
1705 important because this committee has been involved in very --
1706 not only involved but concerned about what's going on out there,
1707 and I've served on a cybersecurity task force in the past and
1708 in the hearings that we've had so it's a very -- it's huge issue.

1709 I represent a very unique district -- that I have more
1710 community hospitals than anybody else in the state of Ohio, and
1711 when I am out one of the things I hear from my community hospitals
1712 is to -- on the cybersecurity and cybersecurity threats that
1713 they're under.

1714 In the last Congress, Mr. Welch from this committee -- from
1715 Vermont -- and I did the Internet of Things Working Group and
1716 we heard from folks, especially when we are dealing with

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1717 telehealth and when you look at electronic medical records and
1718 the Internet of Things what's happening on the great things there.

1719 But then, again, on the cyber side it's always a concern.

1720 So the question I have is as I've seen in your testimony
1721 that the healthcare sector very nearly suffered a severe
1722 cyber-attack last year due to the -- because of WannaCry.

1723 In fact, while the United States was spared the worst of
1724 the damage, the U.K. had 34 percent of its hospitals affected
1725 and there are numerous other examples of recent and growing
1726 cybersecurity threats to the healthcare sector.

1727 All that being said, I notice that cybersecurity isn't listed
1728 in one of the key -- of your key priorities. Does this mean that
1729 cybersecurity isn't a key priority at ASPR and, if not, is there
1730 a part of HHS that does consider healthcare cybersecurity be a
1731 priority?

1732 Dr. Kadlec. Thank you for your question, sir, and I just
1733 want to reiterate the importance of this issue as it relates to
1734 our health care systems because they can range from hospitals
1735 to actually individual devices that may be at risk and I think
1736 it's important to note that in the Department of HHS that the
1737 deputy secretary basically manages the overall cybersecurity of
1738 the department.

1739 And so from that standpoint, each operation and staff
1740 division has its own cybersecurity piece of this but it's managed
1741 and if you will -- overseen at that level to ensure that there

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1742 is uniformity of policy as well as oversight and capabilities.

1743 Mr. Latta. Well, let me follow up then because you say the
1744 deputy secretary is there, because in their report from -- to
1745 this committee last spring the previous HHS secretary had
1746 designated your office as the health care sector specific agency
1747 to lead the health care cybersecurity.

1748 Did you agree with that designation?

1749 Dr. Kadlec. Sir, I don't disagree with it. I think one
1750 of the things that happened as a result of the WannaCry event
1751 is that because the potential impacts are much greater than just
1752 simply ASPR that they can affect CMS, FDA, CDC, all of OpDivs
1753 and StaffDivs that I think it was the decision at that point in
1754 time.

1755 But to be fair to your question, sir, I will be very happy
1756 to provide an answer for the record, if you'd like.

1757 Mr. Latta. Okay. Let me just follow up, though.

1758 So the -- with the deputy secretary then because would you
1759 -- are you saying then that you think that that -- the specific
1760 and the proper position would be having that cybersecurity control
1761 for the -- for the agency -- for the HHS, then?

1762 Dr. Kadlec. Sir, I think the fact is is that the only person
1763 higher than the deputy secretary is the secretary to manage the
1764 issue and I think the issue here is is that the deputy secretary
1765 I think performs a vital function to ensure that it remains on
1766 the forefront of everyone's consideration for the different staff

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1767 and operational divisions of HHS.

1768 Mr. Latta. Well, if you could follow up again on that with
1769 me I would greatly appreciate it.

1770 Dr. Kadlec. I would be happy to, sir.

1771 Mr. Latta. And we look forward to that.

1772 Mr. Chairman, I am going to yield back the balance of my
1773 time.

1774 Mr. Guthrie. [Presiding.] The gentleman yields back his
1775 time.

1776 The chair recognizes the gentlelady from California, Ms.
1777 Eshoo, five minutes for questions.

1778 Ms. Eshoo. Thank you, Mr. Chairman, and thank you to the
1779 witnesses for your testimony.

1780 Just a couple of comments before I get to my questions.
1781 I wish Dr. Bright were here today, who heads up BARDA. He
1782 couldn't. I think there was a conflict relative to his schedule.

1783

1784 But I want the members to have a deep appreciation of what
1785 BARDA has accomplished -- 35 approved measures in 10 years. I
1786 don't know of a pharmaceutical company that has produced 10 major
1787 drugs in a decade.

1788 And so that really is a -- it's an outstanding record. Many
1789 members have raised the issue of anti -- the whole issue of
1790 antimicrobial infections. Now, God forbid there's an anthrax
1791 attack and we have something for that but you're in the hospital

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1792 and you have -- you know, you contract a terrible infection and
1793 I think that we are all worried about that. I mean, I don't know
1794 of conversation with friends of mine where someone doesn't mention
1795 someone having been in the hospital and contracted an infection.

1796 So I want members to know that Dr. Bright is all over this.
1797 I mean, he truly is, even in the meeting that Congresswoman Brooks
1798 and I had just recently over at BARDA.

1799 Questions -- Admiral, you described in detail how the CDC
1800 is responding today, and I know that we just heard Congressman
1801 Barton raise the issue of CDC, the stockpile.

1802 I think it's important for all members to know that the
1803 stockpile isn't moving anywhere. It's going to remain with the
1804 CDC.

1805 There is an administrative change here. With the shift from
1806 -- in that -- what's in the legislation from CDC to ASPR, what
1807 actually changes for you? Do you have to get permission from
1808 ASPR to do something?

1809 Is it that you and ASPR are going to coordinate? In a very
1810 clear way, can you just set down in a sentence or two what is
1811 going to change?

1812 Admiral Redd. So thanks for that question, and you're
1813 correct. The people --

1814 Ms. Eshoo. Well, I know that. But just tell us what it
1815 is.

1816 Admiral Redd. The -- sure.

1817 [Laughter.]

1818 Ms. Eshoo. You don't have to thank me.

1819 Admiral Redd. The stockpile provides funding within CDC
1820 and that's one of the things that we are talking about with ASPR
1821 is what things in that mission --

1822 Ms. Eshoo. So it's not decided yet, you're saying?

1823 Admiral Redd. Well, some areas are, some aren't. But we
1824 are still working on the details.

1825 Ms. Eshoo. Well, that's interesting. All right. Thank
1826 you.

1827 To Dr. Kadlec, always good to see you. In your opening
1828 statement, you used the term in terms of responsibilities, one
1829 of them territorial responsibility. It's very important.

1830 The official government death count for Hurricane Maria,
1831 relative to Puerto Rico, was 64. Now the New England Journal
1832 of Medicine last week, one of the most prestigious publications
1833 in our country, they concluded that the death toll was 70 -- seven
1834 oh times higher than the official estimate.

1835 What is ASPR doing in Puerto Rico? I think that even in
1836 the meeting that we had we came over to the agency, I think you
1837 sensed my lack of confidence in what ASPR is doing.

1838 Dr. Kadlec. Yes, ma'am.

1839 Let me first just comment on the New England Journal article
1840 because I think it's important to realize --

1841 Ms. Eshoo. Well, do you accept that?

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1842 Dr. Kadlec. I accept it that it's an estimate. I accept
1843 it that --

1844 Ms. Eshoo. Well, there's -- look, there are two and there's
1845 a chasm between the two. So tell the committee what you're doing
1846 on the --

1847 Dr. Kadlec. Sure, ma'am.

1848 On the issue of the mortality rates, I've been working this
1849 --

1850 Ms. Eshoo. Tell us what you're doing in Puerto Rico right
1851 now. Who's on the ground, what's being used, are people being
1852 inoculated?

1853 Dr. Kadlec. I just wanted to differentiate between
1854 mortality for sure. We have 40 personnel down in Puerto Rico
1855 right now working with the Puerto Rican Department of Health
1856 looking how to basically make their system more resilient and
1857 that goes to the issue of not only the hospitals, which are both
1858 private and public, as well as federally qualified health --

1859 Ms. Eshoo. So you're having discussions with their public
1860 health people, with their -- do you have people that are
1861 administering anything to the Puerto Rican people?

1862 Dr. Kadlec. Based on the requests from the Puerto Rican
1863 Department of Health, no, ma'am, at this point in time. We
1864 basically extended our emergency prescription assistance program
1865 that was basically providing 30 days of prescriptions free to
1866 people.

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1867 We've left 13 DMAT caches there, which is a host of medical
1868 supplies that we --

1869 Ms. Eshoo. Well, my time is -- my time has --

1870 Dr. Kadlec. Sure, ma'am.

1871 Ms. Eshoo. -- run out. But I --

1872 Dr. Kadlec. And we also --

1873 Ms. Eshoo. -- I really would like a full report from you
1874 on it.

1875 Dr. Kadlec. Sure. Be happy to. We can do that, ma'am.

1876 Ms. Eshoo. Yes.

1877 Dr. Kadlec. I would just also add we are also maintaining
1878 or taking care of about a hundred or so people who were evacuated
1879 from the Virgin Islands and Puerto Rico who are dialysis dependent
1880 until they can go home and receive their care at home. But we'll
1881 be happy to provide a more fulsome picture for you and for the
1882 record.

1883 Ms. Eshoo. Thank you. Yield back.

1884 Mr. Burgess. [Presiding.] The gentlelady's time has
1885 expired.

1886 The chair is pleased to recognize the gentleman from
1887 Virginia, Mr. Griffith, five minutes for your questions, please.

1888 Mr. Griffith. Thank you very much.

1889 Let's continue with Puerto Rico for a minute, and I
1890 appreciate what you all are doing down there. But Dr. Kadlec,
1891 did -- or Dr. Redd -- Admiral Redd -- were any of the stockpiles

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1892 that we've talked about today used in Puerto Rico?

1893 Dr. Kadlec. Yes, sir. We deployed both our DMAT, or
1894 disaster medical assistant team caches, actually 13 of them, as
1895 well as field medical stations, which are these kind of like
1896 hospitals in a box kind of thing.

1897 Mr. Griffith. Right. So here's my question. Back to you,
1898 Ms. Abram.

1899 When we start talking about the vials and the delamination
1900 and whether or not there's a better product, you indicated that
1901 the new novel product does better under stress but it was -- one
1902 product was better than the other in chemical situations or more
1903 normal situations it was pretty much the same.

1904 My question is, though, isn't the stockpile for emergency
1905 situations and wouldn't the stress be greater if you're sending
1906 something in either before or immediately after a hurricane or
1907 other natural disaster and so wouldn't we want to have the better
1908 product in those situations?

1909 Ms. Abram. We want to make sure that we have high quality
1910 safe and effective medical countermeasures in the event they need
1911 to be used and there's a number of steps that go into making sure
1912 that the products that we have are what we are expecting them
1913 to do in terms of safety efficacy and being effective.

1914 Mr. Griffith. And my concern is just this.

1915 Ms. Abram. Yes.

1916 Mr. Griffith. If they're just sitting on the shelf and we

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1917 go in one day into the back storage room and say we need these,
1918 I get it. The current glass works.

1919 But if there's a risk of delamination, which we've see in
1920 the past, and there's a product that takes care of that, with
1921 the stockpile wouldn't -- at least with the stockpile wouldn't
1922 we better off using the glass that's less likely to have glass
1923 fragments floating around in what we are trying to then use in
1924 an emergency situation?

1925 Because when people are trying to get something in there
1926 in a hurry, whether before or after the storm, they're not
1927 necessarily handling it with kid gloves. Wouldn't you agree
1928 they're not handling it with kid gloves under those circumstances?

1929 Ms. Abram. The handling is a matter like -- of importance
1930 to the product, depending upon if it's something that has to be
1931 temperature controlled. That's one of the issues that is at play
1932 with the Ebola response efforts right now.

1933 So depending upon the counter measure, depending upon how
1934 it's going to be used, it could bring unique handling and care
1935 instructions.

1936 Mr. Griffith. I appreciate that. Thank you.

1937 I do want to ask about and I've heard a lot and I am stepping
1938 a little bit outside of my comfort zone. I've heard a lot about
1939 the antimicrobials and the antibiotics and the concerns there.

1940 I am just wondering is BARDA looking at some interesting and
1941 new novel approaches?

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1942 I recently toured a facility in my district -- a very small
1943 start-up group, Techulon, and they have a platform technology
1944 for gene targeting. So I asked my team to find out what that
1945 is and here's what I got back, so I don't get it wrong.

1946 It is an anti-sense approach. It knocks down gene
1947 expressions. That kills the pathogen -- basically, disrupts gene
1948 functions, which means there's no way for the pathogen to adapt
1949 because basically you're going in and knocking out part of their
1950 genes and they die. Are we looking at some of that kind of new
1951 novel approach?

1952 Dr. Kadlec. Sir, I would like to hear more about it, quite
1953 frankly. I haven't heard of that particular approach but I would
1954 be welcome to the idea that we would hear about it and
1955 understanding how we could learn more and potentially see it in
1956 the future of our efforts.

1957 Mr. Griffith. But it's fair to say for both you and the
1958 rear admiral that there's a -- there's a lot of interesting things
1959 going on out there and it's hard to keep track of it. I will
1960 make sure you get some of the info on this.

1961 Dr. Kadlec. Sir, and again, you know, compliments to the
1962 committee with the creation of the Medical Countermeasure
1963 Innovation Partnership because that's one of the things we hope
1964 to do with this program called DRIVE is to basically set up the
1965 opportunity for great ideas to come in.

1966 We've identified so far as of yesterday eight accelerators

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1967 around the country in your states -- different states around the
1968 country to basically be these receptive points for these great
1969 ideas so that we can make sure kind of sweep them up and don't
1970 miss them.

1971 Mr. Griffith. Thank you. I appreciate that.

1972 I would be remiss -- and I appreciate the chairman bringing
1973 this up in his opening remarks -- if I didn't mention the historic
1974 nature of today's date.

1975 Being the representative on this committee from Virginia,
1976 we have a national D-Day memorial in Bedford because, per capita,
1977 they lost more boys on D-Day than any other part of the country,
1978 and I had the opportunity to know the sister -- meet the sister
1979 of one of the boys who was part of the D-Day boys of Bedford and
1980 knew Bob Slaughter, who pushed for the memorial and had the great
1981 thrill about 12 years ago before he passed away to introduce my
1982 daughter to him at a -- in a local cafeteria.

1983 He was just there, as humble as he could be, but these were
1984 true heroes and they really did save the possibility of a vibrant
1985 world with democratic principles in place and it all came down
1986 to that one morning on this day 74 years ago.

1987 So I yield back.

1988 Mr. Burgess. Gentleman yields back. The chair thanks the
1989 gentleman.

1990 The chair recognizes the gentlelady from Colorado, Ms.
1991 DeGette, five minutes for questions, please.

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1992 Ms. DeGette. Thank you, Mr, Chairman.

1993 I want to thank Representatives Eshoo and Brooks for their
1994 leadership on this important draft that we are discussing today.

1995 Medical countermeasures are really an important element of
1996 preparing for pandemics.

1997 Several of our witnesses have mentioned the 21st Century
1998 Cures Act, which Fred Upton and I authored but which everybody
1999 on this committee had input into, and Representatives Eshoo and
2000 Brooks were really instrumental in helping us put some of the
2001 medical countermeasures into that bill.

2002 They included encouragement of complex, adaptive, and other
2003 novel trial and medical advice designs, fostering potential use
2004 of real-world evidence for the development of drugs, and
2005 harmonizing FDA human subject protections with the common rule,
2006 otherwise known as the federal policy for protection of human
2007 subjects.

2008 And in addition, Cures including provisions that would waive
2009 certain paperwork requirements during a public health emergency
2010 along with streamlining BARDA procurement process and allowing
2011 BARDA to enter into agreements with independent non-profit
2012 entities to support medical countermeasure development.

2013 Now, Commissioner Abram, you spoke a little bit earlier about
2014 the recent Ebola outbreak in the Democratic Republic of the Congo.

2015 I am wondering if you can talk for a minute about exactly how
2016 the lessons learned in the 2014 Ebola outbreak are being used

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2017 to help contain the recent outbreak.

2018 Ms. Abram. Absolutely, and I will likely ask my colleague
2019 from CDC to join as well.

2020 Ms. DeGette. Great.

2021 Ms. Abram. We've been very much supporting the efforts and
2022 helping to facilitate the export of vaccine that's being used
2023 overseas as part of the outbreak control measures.

2024 We've also continued to engage with our international
2025 collaborators and conversations with developers around
2026 diagnostics and therapeutics.

2027 And so I think one of the continual lessons learned and
2028 actually that PAHPRA was very effective in doing is helping to
2029 make some accommodations and adjustments in our authorities so
2030 that we can be even better prepared in prepositioning which helps
2031 us then when we do have these emergent situations to be even more
2032 timely in the response effort.

2033 Ms. DeGette. That's good to hear. Yes?

2034 Admiral Redd. So I think one of the lessons of 2014 is that
2035 when an outbreak like what is happening in the Democratic Republic
2036 of Congo occurs you really have to pursue it until there are no
2037 more cases.

2038 Ms. DeGette. That's right.

2039 Admiral Redd. There was an opportunity to do that in West
2040 Africa in the spring and that opportunity was lost, resulting
2041 in the outbreak over the summer and fall.

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2042 In the Democratic Republic of Congo, CDC has had a
2043 long-standing presence. There are actually 33 staff there --

2044 Ms. DeGette. Excuse me. I don't have a lot of time and
2045 so my question really was what did -- what, from the 2014 outbreak,
2046 helped us now. If you can address that.

2047 Admiral Redd. Sure. I think there is a much more intense
2048 focus on contact tracing, making sure that our partnership with
2049 WHO and the country ministry of health is solid and that things
2050 are slipping through the cracks.

2051 So there's much more intense follow-up, identification of
2052 cases. Laboratory testing is in place now. We are working on
2053 measures of exit screening with the ministry. So all the things
2054 that we should have done in 2014 are happening now.

2055 Ms. DeGette. Mr. Kadlec, do you want to add on?

2056 Dr. Kadlec. Yes, ma'am. May I just insert that we have
2057 two candidate vaccines, one that's actually being used for ring
2058 vaccination.

2059 We have a point of care diagnostic that has been deployed,
2060 donated by the companies, as well as those vaccines as well as
2061 three different monoclonal antibody therapies that could be used.

2062 The one from NIH is actually deployed down there right now.

2063 Ms. DeGette. Right. Okay. Thank you.

2064 While I've got you on the hot seat, you talked about -- you
2065 indicate that increasing BARDA's authorization levels would
2066 increase BARDA to implement new innovation authorities that the

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2067 21st Century Cures Act provided.

2068 Can you talk about those new authorities and how additional
2069 funding would actually help increase the goals of BARDA?

2070 Dr. Kadlec. Yes, ma'am. We announced yesterday, with the
2071 creation of DRIVE -- the Division for Research, Innovation, and
2072 Ventures -- with the intent that right now \$25 million will be
2073 spent on two areas, which will be one is on the treatment of sepsis.

2074

2075 Sepsis basically afflicts 1.5 million Americans a year,
2076 kills 250,000, costs the health care system \$24 billion, and so
2077 we think that's an area ripe for an opportunity to find things
2078 that could either prevent or mitigate that.

2079 The second area is actually identifying or finding
2080 diagnostics that would identify people who are -- who have been
2081 exposed who are not yet sick so that you can institute treatment
2082 or therapies to actually prevent them becoming ill or potentially
2083 dying.

2084 Ms. DeGette. Thank you.

2085 Thank you very much, Mr. Chairman.

2086 Mr. Burgess. Gentlelady yields back. The chair thanks the
2087 gentlelady.

2088 The chair recognizes the gentlelady from Indiana, Mrs.
2089 Brooks, five minutes for your questions, please.

2090 Mrs. Brooks. Thank you, Mr. Chairman, and thank you all
2091 so very much for your testimony and for your important work.

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2092 I think there continues to be a little bit of confusion that
2093 has come up with the various members regarding what I think the
2094 word that might be causing confusion is the word moving the
2095 Strategic National Stockpile, which is in our draft text of the
2096 bill from CDC to ASPR.

2097 But as I understand it, discussions and things are still
2098 taking place relative to what the roles will be and I think we
2099 all have the same goal and that is to ensure that all medical
2100 countermeasures get to our citizens in the appropriate time and
2101 as fast and as efficient as possible.

2102 And so for our sake, maybe starting with Dr. Kadlec and then
2103 going to Admiral Redd, if we could please talk about what -- where
2104 that stands right now and are there tools or resources you need
2105 to effectively carry out the execution of the Strategic National
2106 Stockpile for our citizens who expect it to work.

2107 Dr. Kadlec and then Admiral Redd.

2108 Dr. Kadlec. Yes, ma'am. Thank you, ma'am. I need --

2109 Mrs. Brooks. We just need to clarify and make sure we
2110 understand.

2111 Dr. Kadlec. Sure. Sure. As Dr. Redd identified earlier,
2112 there are a number of working groups. I think the key thing is
2113 some of them dealt with contracts and particularly how would the
2114 contracts that have been previously administered by CDC be
2115 administered by ASPR.

2116 And so part of that is kind of -- I think the word is novate

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2117 -- contracts to ASPR so that in terms of replenishing the stockpile
2118 in the future so you'd have single oversight of how you would
2119 basically procure -- develop, procure, and resupply this -- the
2120 Strategic National Stockpile.

2121 There are issues around personnel, how many people would
2122 be, basically, transferred to the ASPR and would be the
2123 responsibility of ASPR to basically pay for or provide services
2124 to.

2125 And then, lastly, one of the areas that's still under
2126 negotiation is what percentage, if any, of those people who are
2127 working with the state and locals would be transferred to ASPR
2128 as well.

2129 And so that is an area that is further under discussion.

2130 The intent is to meet with senior CDC officials later this month
2131 to basically hopefully finalize that.

2132 But as to this date, there has been no requirement for any
2133 legislative language -- the facility to transfer is within the
2134 secretary's purview and authorities to do so.

2135 Mrs. Brooks. And I think that's what the greatest concern
2136 is is that local and state authorities -- and one of our next
2137 witnesses in the next panel expresses that as well and so we need
2138 to make sure that that relationship with whomever is responsible.

2139 And I think what I am hearing you say, though, and I would
2140 like, Admiral Redd, you to talk about what you believe the role
2141 is -- and is going to be because we want to make sure that there

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2142 is no problem working with state and local officials that actually
2143 do the work on the ground.

2144 Admiral Redd. Yes, ma'am. I think actually Dr. Kadlec
2145 summarized the current situation quite well. The areas that I
2146 think are critical to just make sure we've got really clear --
2147 good clarity on are the role that subject matter experts at CDC
2148 will have both whether or not they're funded by the stockpile
2149 now or not -- that that linkage with the stockpile and with
2150 planning, for example, in clinical guidance, how the product
2151 should be used, under what circumstances to control or to respond
2152 to emerging events, that we've got that part nailed down and then
2153 similarly work that we have been doing partly funded by the
2154 stockpile, partly by the state and local program that we've got
2155 very good agreement on the work that we are going to continue
2156 in that domain to make sure that state and locals are able to
2157 dispense products.

2158 I think the overall medical countermeasure structure is now
2159 more completely under the ASPR but that state and local role --
2160 we think we have a role to support both state and locals and the
2161 mission of the ASPR.

2162 Mrs. Brooks. And would you agree with that, Dr. Kadlec?

2163 Dr. Kadlec. Yes, ma'am, and we also have a role at the state
2164 and local level and we look to figure out how we can best integrate
2165 that to provide the best support in state and locals.

2166 Mrs. Brooks. Well, and I think integration is the key here

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2167 and it is trying to ensure that everyone is clear as to what CDC's
2168 role is with state and local partnership and what ASPR's role
2169 is. But it sounds as if the contracting piece and the management
2170 of the product, so to speak, and mostly the vaccines, the
2171 diagnostic testing, is what would move to ASPR but yet there will
2172 be -- both agencies will be or both parts of -- will be working
2173 with state and local health officials. Is that correct? Fair
2174 to say?

2175 Dr. Kadlec. That's -- I think that's the overall intent.

2176 Mrs. Brooks. And very briefly, Ms. Abram, a very quick
2177 question relative to diagnostic tests and so forth, and can you
2178 speak to the role of diagnostic tests including point of care
2179 tests and influence in infectious disease detection and
2180 management and how FDA ensures that we have what we need for
2181 diagnostic testing because it's not just about vaccines. It's
2182 also about the diagnostic.

2183 Ms. Abram. Right. When we think about medical
2184 countermeasures it runs the full gamut of medical products from
2185 vaccines, therapeutics, and, of course, diagnostics, and rapid
2186 point of care of diagnostics is something that also colleagues
2187 at BARDA and ASPR are working on.

2188 It's absolutely critical and it's not just critical in the
2189 context of emergency response as a public health emergency. It's
2190 critical as part of good routine care. The sooner you can
2191 pinpoint what a patient is dealing with the faster you can provide

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2192 optimal care.

2193 Mrs. Brooks. Thank you. My time is up. I yield back.

2194 Mr. Burgess. The gentlelady yields back. The chair thanks
2195 the gentlelady.

2196 The chair recognizes the gentlelady from Florida five
2197 minutes for questions, please.

2198 Ms. Castor. Thank you, and thank you to the witnesses for
2199 everything you do to strengthen America's public health
2200 infrastructure, especially when we are talking about medical
2201 emergencies and preparedness and response.

2202 And I want to thank the authors for their bipartisan work
2203 on PAHPA. I am very pleased that we are going to codify what
2204 CDC is doing relating to the children's preparedness unit into
2205 this bill because when we are talking about public health
2206 emergencies, children have very special needs and we have to
2207 ensure that they're not overlooked, and for many years CDC has
2208 had a group of experts working through their children's
2209 preparedness unit.

2210 I mean, just think about the Zika emergency. Child
2211 development was the issue. Think about Flint and the water crisis
2212 -- lead in the water. That had a direct impact on babies and
2213 children. So it's very important that we do.

2214 So, Dr. Redd, does this codification language -- does it
2215 do what we need to do? Is there anything that's left out here?

2216 Admiral Redd. I think we recognize the importance of

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2217 children in emergencies and we'll work on that. Whether or not
2218 --

2219 Ms. Castor. Yes. So this is actually Senate language that
2220 we need to bring into this version because this version just has
2221 kind of the national advisory committee.

2222 Admiral Redd. Well, I think -- I think that both in
2223 preparing for and then responding to almost any emergency,
2224 children are going to be an important part of that and there are
2225 particular considerations that need to be taken into account.

2226 And as you noted, we have, within CDC, a children's
2227 preparedness unit. That unit mobilizes when we -- when we have
2228 a response. For example, in the Ebola response there was work
2229 on reopening schools that unit played an important -- in West
2230 Africa -- that that unit played an important role in.

2231 Ms. Castor. So I hope the authors can look at what the Senate
2232 language is and make sure that we are carrying over this very
2233 important initiative where they bring in the pediatricians, the
2234 psychologists, everyone, at the table to make sure that it's
2235 properly recognized, funded, and structured.

2236 Dr. Redd, the draft legislation also would allow the
2237 secretary to transfer 1 percent of any appropriation to the public
2238 health emergency response fund. The emergency response fund
2239 would supplement the response of local and state authorities
2240 during any number of public health emergencies.

2241 Previously, this has been an issue and it's been a problem

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2242 because transfers during emergency situations resulted in
2243 automatic cuts elsewhere in funding in critical areas for state
2244 and local governments. They were kind of left in the lurch --
2245 created a lot of uncertainty for communities back home.

2246 For example, during the height of the Zika crisis in 2016
2247 funds were pulled from emergency preparedness and public health
2248 grants across the country, despite the fact that those communities
2249 needed to prepare, they needed to respond, and they were hamstrung
2250 at that time.

2251 Probably the most troubling example -- and I am glad Mrs.
2252 Dingell is here because she worked so hard on this -- was the
2253 fact that during that Zika crisis we had a terrible crisis in
2254 Flint, Michigan, and when we -- when they had to go take funds
2255 to address Zika, they swept some of the grants back in Flint and
2256 in Michigan that they needed for their public health emergency.

2257 In a Washington Post article, the president of the
2258 Association of State and Territorial Health Officials said it
2259 is short-sighted to fund the Zika response by weakening all
2260 states' ability to respond to future public health crises.

2261 So based on your experience with the Zika response, could
2262 you describe how state and local public health departments were
2263 impacted when the funds were taken and drained from the public
2264 health emergency prepared cooperative agreement?

2265 Admiral Redd. Yes, ma'am.

2266 Ms. Castor. Go into a little detail for us on that.

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2267 Admiral Redd. So, first of all, this is a real problem.
2268 In the H1N1 response there was a 54-day interval between the
2269 request for funding and the appropriation. For Ebola there was
2270 a four-month interval and for Zika 190 days. So this is -- this
2271 is a significant problem that is inhibiting the best response.

2272 I am not going to speak directly to the bill but I will say
2273 that during the -- during the Zika response the PHEP award overall
2274 was cut by about 8 percent and we heard from states that that
2275 was causing problems with staffing.

2276 That money was -- there was sort of a payback about six months
2277 later but there was a period of uncertainty and I think that
2278 uncertainty really is not helpful to the preparedness interval.

2279 Ms. Castor. And I think congressional members have a lot
2280 of responsibility for those. When you get into government
2281 shutdowns and you can't work together when we are talking about
2282 emergency situations in Flint, Michigan, or Zika or flu we simply
2283 cannot be caught up in these partisan fights. There has to be
2284 a fund -- a pot of money where we can adequately respond to public
2285 health emergencies without getting into the partisan food fights,
2286 not in times of emergency.

2287 So I would hope that the authors would work on that with
2288 all of us as we move forward. Thank you, and I yield back.

2289 Mr. Burgess. The gentlelady's time has expired.

2290 The chair recognizes the gentleman from North Carolina, Mr.
2291 Hudson, five minutes for questions, please.

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2292 Mr. Hudson. Thank you, Mr. Chairman, and thank you to each
2293 members of the panel for what you do on behalf of our country.

2294 Thank you for being here with us today.

2295 Every time there is a disaster or an infectious disease
2296 outbreak I hear from my constituents back home. Hurricane
2297 Matthew, Zika, and Ebola outbreaks are all recent events that
2298 have quickened the pulses of my constituents.

2299 Understandably, they're concerned and want to know what we
2300 are doing to ensure their communities have the resources they
2301 need and these outbreaks are contained.

2302 One thing I've heard from physicians, medical -- emergency
2303 medical responders, and hospitals is that there are continuing
2304 drug shortages, particularly essential emergency medications.

2305 These providers are concerned that they're not prepared to
2306 respond to a massive public health emergency.

2307 Dr. Kadlec, you mentioned in your testimony that the strength
2308 of our nation's public health and medical infrastructure and the
2309 capabilities necessary to respond to emergencies and disasters
2310 are foundational to the quality of life of our citizens and I
2311 completely agree with you.

2312 But I believe these drug shortages hamstring our ability
2313 to properly respond. So I want to see how we can work tighter
2314 to best fix these problems.

2315 So, Dr. Kadlec and Ms. Abram, can you share your thoughts
2316 from both the FDA and ASPR's perspective on assuring the

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2317 availability of emergency medications in a public health
2318 emergency and are there options Congress should be considering
2319 as part of PAHPA and beyond?

2320 Ms. Abram. I will go head and jump in and take it first
2321 and then turn it over to my colleague. Drug shortages is a serious
2322 concern.

2323 It's a serious concern not just in routine everyday clinical
2324 care but also in the context of what a particularly lifesaving
2325 product -- the shortage of a lifesaving product at a time of a
2326 public health emergency might mean. We've got medical
2327 countermeasures and we've also got other products that would
2328 certainly go towards patients and be part of care, perhaps
2329 supportive care.

2330 And we've also recognized that even though we have a very
2331 dedicated team that is focussed on this at the agency amongst
2332 our CDER colleagues, we continue to see some challenges persist.

2333 The agency is doing everything that we can to mitigate and
2334 prevent. Particularly, we've been very forthcoming about some
2335 of our work in the IV saline solution shortages and our work to
2336 work with developers.

2337 We encourage manufacturers to try to build in capacity.
2338 It's not something that we can require. But we do encourage that
2339 they try to do that to help to mitigate.

2340 We've also worked in a discreet manner to help to import
2341 product to supplement where there have been shortages. But it's

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2342 a continual challenge and it's something we continue to look at
2343 and would welcome the opportunity to have dialogue with the
2344 committee around what other solutions might be brought to bear
2345 as part of this.

2346 Mr. Hudson. Thank you.

2347 Dr. Kadlec. Sir, for the purposes of time, I would probably
2348 want to get back to you on the record on this. But I just want
2349 to highlight as -- I think it was alluded to by Ms. Abram and
2350 that is the subject to the events in Puerto Rico and how that
2351 impacted on several critical supplies of critical medicines --
2352 not only saline solution but also pediatric oncology drugs and
2353 the like.

2354 And we have an interest in that in terms of how do you
2355 basically make sure that that critical infrastructure is more
2356 resilient. I will just highlight that there is some interesting
2357 legislation in the House subject to the Disaster Recovery Reform
2358 Act of 2017. I think it's being considered with the FAA Act as
2359 well, and that is subject to how we can use some of our disaster
2360 relief funding in advance of an event to basically make things
2361 more resilient.

2362 So there -- I think there's a couple of pieces here as how
2363 can you make your production supply chain more resilient before
2364 a disaster and then what to do with the events, as Ms. Abram had
2365 mentioned about what can we do to make sure that there is an
2366 uninterrupted supply of these critical supplies.

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2367 But we'll be happy to get back to you with further details.
2368 Mr. Hudson. Great. Well, I appreciate that and appreciate
2369 the commitment to work with us on it.

2370 Just changing topics, Dr. Kadlec, I have become aware of
2371 the time-intensive process involved in producing a vaccine
2372 through egg-based production. Oftentimes, this manufacturing
2373 can take up to six months, which is a lifetime in the ever-changing
2374 world of infectious disease.

2375 I've recently become aware of the new flexible platform
2376 techniques -- technologies that have the potential to reduce
2377 production time for vaccines from months to weeks.

2378 I understand BARDA's primary mission is to support products
2379 that are being tested in clinical trials of which I know of one
2380 product in phase three. But there are also products in
2381 preclinical testing. I understand ASPR and BARDA are examining
2382 these innovative platform technologies. But I want to get some
2383 clarification from you.

2384 How would these rapid response platform technologies benefit
2385 BARDA and its mission and can BARDA play a more proactive role
2386 in fostering the plug-and-play platforms that are beyond basic
2387 research but not yet at the clinical trial stage?

2388 Dr. Kadlec. Sir, I think just two things to echo what your
2389 comments are, our dependence on egg production, which provides
2390 more than 70 percent of our vaccine for flu, and eggs are not
2391 very flexible and they're not very fast. The only other vaccine

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2392 you can produce from an egg is yellow fever. So the idea of having
2393 flexible and fast capabilities which are platform technologies
2394 is either cell or recombinant production that is going to be
2395 critical, going forward.

2396 So we see that as an essence and there's also been the
2397 situation we experienced this past seasonal flu season where some
2398 of the vaccine strains drifted a little bit from the -- from egg
2399 production and so that's another liability.

2400 So there's several reasons why we are relooking what we are
2401 doing. But we really owe you and this committee probably a
2402 detailed brief on not only the situation we experienced in the
2403 past but what may be a strategy to address how to avoid those
2404 limitations and get us the most flexibility and speed in the
2405 future. I will turn to Anna.

2406 Ms. Abram. Yes. I was just going to quickly add we'd be
2407 happy to follow up with some of the work that we've been doing
2408 to advance continuing manufacturing and innovations. We think
2409 that this could be responsive in terms of helping to foster a
2410 more nimble flexible responsive framework.

2411 Mr. Hudson. I agree. Thank you, Chair.

2412 Mr. Burgess. And the gentleman's time has expired.

2413 The chair recognizes the gentleman from Kentucky, Mr.
2414 Guthrie, five minutes for questions.

2415 Mr. Guthrie. Thank you, Mr. Chairman. I thank the panel
2416 for being here today.

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2417 And so this kind of follows on what he's saying about new
2418 platforms. There's a company in my district, Kentucky
2419 BioProcessing, in Owensboro that actually uses a plant-based
2420 platform to more efficiently produce recombinant protein
2421 products.

2422 In fact, applying their platform technology they rapidly
2423 developed an experimental antibody and use it to successfully
2424 treat an American doctor who contracted Ebola while treating
2425 patients in Africa.

2426 I understand a major goal of BARDA is to identify new
2427 approaches and capabilities that allow for better preparedness
2428 and response to multiple public threats by serving as platform
2429 technologies.

2430 So, Dr. Kadlec, how can BARDA interact with and support
2431 companies which have developed such technologies but do not have
2432 a specific medical countermeasure in clinical development?

2433 Dr. Kadlec. Well, I think -- I think that's an issue that
2434 we probably need to follow up with on the notion of this flexible
2435 and agile kind of production capacity and how do we basically
2436 nurture that and promote that in a way that to this date hasn't
2437 been fully actualized.

2438 So I think it's an area that I think we'd be very welcome
2439 to work with you and our colleagues at FDA who are also evaluating
2440 these kinds of innovative ideas and how do we do that.

2441 We think that the DRIVe program that was -- we just announced

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2442 yesterday could be one of those venues to basically evaluate that
2443 as well as promote those kinds of concepts.

2444 Mr. Guthrie. Thank you. I would encourage BARDA to use
2445 its current authorities to support preclinical platform
2446 technologies -- planned technology which has demonstrated its
2447 ability to deliver BARDA's needs in one-third of the time of
2448 traditional platforms.

2449 So that follows up what he just said so I appreciate that.
2450 Matter of fact, the plant they used for Ebola was tobacco. So
2451 it's nice that we have a use for our plant -- for our -- one of
2452 our plants that's positive in that direction. So we appreciate
2453 that very much.

2454 And also, Dr. Kadlec, kind of switching gears a little bit,
2455 could you speak to the how the discussion draft can further empower
2456 ASPR to be the vital coordinating agency for both planning and
2457 responding to a biological threat?

2458 Dr. Kadlec. Well, sir, I think just reauthorizing the
2459 language that already exists is critical. I think there's some
2460 areas in there in terms of effectively improving our ability to
2461 respond in terms of direct hiring for national disaster medical
2462 personnel will be very important. That was one of the critical
2463 shortfalls during the last hurricane season. We only had less
2464 than half of the number of intermittent federal employees who
2465 basically service our disaster medical assistant teams.

2466 We also believe that what you have in your discussion draft

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2467 is so important in terms of providing, if you will, life benefits
2468 to those people who would lose their lives in an event of a response
2469 to make sure that they get the equal consideration as to public
2470 safety officers.

2471 So there's several areas. There's also mention about in
2472 your draft about the PHEMCE, or the Public Health Emergency
2473 Medical Countermeasure Enterprise.

2474 We think the idea of basically having that role to ensure
2475 that, as Dr. Redd said, that we use the expertise within the
2476 department and CDC, FDA, NIH to basically ensure that whatever
2477 we are trying to develop and produce is not only useable but safe
2478 and efficacious to use in our population, both children and adults
2479 and elderly.

2480 So those are all positive things that I think just off --
2481 in the little time that I have. I would be happy to follow up
2482 on the record if you'd like.

2483 Mr. Guthrie. Thank you very much. We appreciate that and
2484 look forward to, hopefully, a briefing as you talked about and
2485 schedule that sometime in the future.

2486 That concludes my questions and I yield back.

2487 Mr. Burgess. The chair thanks the gentleman. The
2488 gentleman yields back.

2489 The chair recognizes the gentleman from Missouri, Mr. Long,
2490 five minutes for questions, please.

2491 Mr. Long. Thank you, Mr. Chairman, and Dr. Kadlec, as you

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2492 may be aware, I've introduced legislation along with Ms. Matsui
2493 to allow the HHS secretary to reorganize HHS cybersecurity offices
2494 as the secretary thinks best.

2495 One of the motivations for this legislation is the
2496 recognition that many organizations including HHS are using the
2497 cybersecurity organizational strategies that were originally
2498 designed in the early 2000s and may not be suited for modern-day
2499 threats.

2500 I think you would agree with me -- I will ask you if you
2501 do -- that the nature and severity of cybersecurity threats to
2502 healthcare have significantly changed over the last 20 years.

2503 I don't think your mic is on.

2504 Dr. Kadlec. Yes, sir. They have.

2505 Mr. Long. Do you think the evolution of cybersecurity
2506 threats may require organizations like HHS to evolve their
2507 cybersecurity strategies including the way they organize their
2508 cybersecurity offices and channels -- or offices and officials
2509 to manage?

2510 Dr. Kadlec. Sir, I believe giving the secretary that
2511 flexibility and the authority would be appropriate.

2512 Mr. Long. And how has HHS addressed its cybersecurity
2513 strategies to confront the changing cyber threats and what more
2514 needs to be done, in your recommendations?

2515 Dr. Kadlec. Sir, thank you for that question. As I
2516 outlined earlier, there is -- the center of gravity for the

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2517 department is in the deputy secretary's office at the present
2518 time.

2519 I think we probably owe you a full and fulsome response to
2520 that question. If you don't mind I will take it for the record
2521 and provide you a complete outline of what is ongoing and
2522 anticipated for the department in these areas that could help
2523 guide your future actions.

2524 Mr. Long. Okay. Thank you.

2525 And Mr. Chairman, I yield back.

2526 Mr. Burgess. The chair thanks the gentleman. The
2527 gentleman yields back and the chair is aware that Dr. Kadlec has
2528 another engagement at HHS. But we'll now recognize the
2529 gentlelady from Michigan, who's not on the subcommittee, five
2530 minutes for questions, please.

2531 Mrs. Dingell. I will be brief. Thank you, Mr. Chairman
2532 and Mr. Green, for holding this hearing.

2533 I do have a concern, like everybody else has. We've asked
2534 a lot of questions but not gotten as much into the long-term care
2535 and hospital preparation when we have these hurricane
2536 emergencies.

2537 So, Dr. Kadlec, I am going to go right to you and ask you.

2538 You have said that a regional disaster health response system
2539 would incentivize the health care system to integrate measures
2540 of preparedness into daily standards of care.

2541 Would this include an important sector of the health care

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2542 system, the long-term care facilities, which in these most recent
2543 hurricanes have really suffered some tragedies?

2544 Dr. Kadlec. Yes, ma'am, and I just want to annotate two
2545 things really quickly. In Puerto Rico, we evaluated in an acute
2546 situation about 1,900 adult senior living facilities of varying
2547 different types in terms of their resilience and their functioning
2548 during that terrible period of time there, and certainly we know
2549 the events in Florida and I just acknowledge that Florida has
2550 established new guidelines for its hospitals and skilled nursing
2551 facilities. So I think we have to have greater sensitivity to
2552 these areas as they take care of some of the most vulnerable
2553 populations in our society.

2554 Mrs. Dingell. Thank you.

2555 In an effort to improve our understanding involved with
2556 threats hospitals and long-term care facilities face I have a
2557 bipartisan bill that directs HHS to engage with the National
2558 Academy of Medicine to conduct a comprehensive study into the
2559 assessment of future threats impacting emergency preparedness
2560 policies and procedures across the health care system.

2561 In your opinion, would a study of this kind be helpful as
2562 you establish a regional disaster health response system?

2563 Dr. Kadlec. I am always having very bright and experienced
2564 people consider these efforts and to do a deep study would always
2565 be beneficial and, obviously, the National Academy of Sciences
2566 is the place to do it.

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2567 Mrs. Dingell. Thank you.

2568 So we talked briefly a minute ago about the tragedies in
2569 Florida where one home lost 12 residents who eventually died.
2570 Following the disaster of this kind, how do we best ensure that
2571 long-term care facilities that lose power are prioritized as
2572 hospitals are and back up and running fast? Because that was
2573 part of the problem.

2574 Dr. Kadlec. Part of the practical situation is is that in
2575 terms of our approach to these events, a pre-event to identify
2576 those facilities -- I don't know if you're familiar with the
2577 Empower program that we have in the department, but I think it's
2578 the idea of identifying those places where people of particular
2579 vulnerability are housed and how quickly you can make sure that
2580 they have the capacity and capabilities and are identified early
2581 so that you can connect with them and that was an issue that,
2582 quite frankly, in Puerto Rico we did on foot, place by place,
2583 because their -- the nature of their facilities was very different
2584 than what you'd find in places like Florida.

2585 Mrs. Dingell. We do need to worry about it.

2586 My colleagues, Debbie Wasserman Shultz, Ms. Eshoo, and I
2587 have a bill that would, among other things, require states to
2588 prioritize nursing homes in the same manner as hospitals are
2589 prioritized in all-hazards public health emergency preparedness
2590 and response plans and would include in those plans information
2591 on how utilities plan to ensure that nursing homes return to

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2592 operating as soon as practical following a disaster.

2593 I would urge all of my colleagues to support that. We are
2594 down to one minute so, Deputy Commissioner Abram, some have
2595 advocated that as a part of the reauthorization of PAHPA that
2596 we should make the MCM PRV program permanent.

2597 Can you comment on FDA's viewpoint regarding whether or not
2598 this program should be permanent at this time?

2599 Ms. Abram. We think it's premature to determine how
2600 effective the program has been. I think Congress had good
2601 foresight when enacting the MCM PRV program and reauthorizing
2602 the pediatric PRV program to charge GAO with looking at this.

2603 One of the dynamics with the priority review voucher programs
2604 -- and we now have three programs: one for neglected tropical
2605 diseases, one focused on peds, one focused on security medical
2606 countermeasures, which I would point out are those which are
2607 linked to material threat determinations.

2608 So these are pretty serious -- is the more vouchers you have,
2609 it diminishes then the incentive and the value of the voucher.

2610 And so I think Congress had good foresight to consider that this
2611 would need to be looked at as how many vouchers are out there
2612 -- is the program having the intended effect.

2613 There has always, throughout the journey of these issues,
2614 been a consistent threshold question, which is have we optimized
2615 the incentives for bringing forward the medical countermeasures
2616 we need to protect the American people and I think if you look

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2617 at the bipartisan history of these issues from BioShield to the
2618 creation of BARDA to the innovation collaboration that Dr. Kadlec
2619 has talked about today to the MCM PRV, this continues to be a
2620 threshold question.

2621 Mrs. Dingell. Thank you.

2622 Mr. Burgess. The gentlelady's time has expired.

2623 Dr. Kadlec, we know you're needing to depart and I think
2624 all the members now asked questions. I do want to just note for
2625 the record that you were part of a bipartisan Energy and Commerce
2626 delegation to the island of Puerto Rico last -- late last year
2627 and were very much a part of our work in assessing the damage
2628 there.

2629 Also, you mentioned in your prepared testimony about the
2630 BioWatch program and I will note that the Shattuck Lecture that
2631 was published in this week's New England Journal of Medicine given
2632 by Bill Gates, the subject innovation for pandemics also talks
2633 about an early detection system. I will probably be submitting
2634 a question for the record for you on that because I believe that
2635 should be part of our work here.

2636 Dr. Kadlec. Thank you, sir. I look forward to it.

2637 Mr. Burgess. And seeing no other -- Mr. Green, any parting
2638 comments?

2639 Mr. Green. No.

2640 Mr. Burgess. Bye. All right. We will excuse this panel
2641 and Dr. Kadlec, again, thank you for your forbearance and we

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2642 appreciate all of you being here today.

2643 And we will transition immediately to our second panel.

2644 [Pause.]

2645 I will ask all of our participants to take their seats and
2646 the subcommittee will continue. We are pleased to have our second
2647 panel here today.

2648 Just as a housekeeping detail there is likely to be a series
2649 of votes on the floor. If that does occur we will adjourn briefly
2650 to -- I mean recess briefly to attend to those votes and then
2651 immediately resume activities here.

2652 But I do want to thank our second panel of witnesses for
2653 being here today. You each have a chance to give an opening
2654 statement followed by questions from members.

2655 We are pleased today to welcome Dr. Umair Shah, executive
2656 director of Harris County Public Health; Dr. Michelle Berrey,
2657 president and CEO, Chimerix, Incorporated; and Mr. Erik Decker,
2658 chief security and privacy officer, University of Chicago School
2659 of Medicine.

2660 We appreciate each of you being here today and we appreciate
2661 you sticking with us through the first panel.

2662 Dr. Shah, you are now recognized five minutes for an opening
2663 statement.

2664 STATEMENTS OF DR. UMAIR SHAH, EXECUTIVE DIRECTOR, HARRIS COUNTY
2665 PUBLIC HEALTH; DR. MICHELLE BERREY, PRESIDENT AND CEO, CHIMERIX,
2666 INC.; ERIK DECKER, CHIEF SECURITY AND PRIVACY OFFICER, UNIVERSITY
2667 OF CHICAGO MEDICINE

2668

2669 STATEMENT OF DR. SHAH

2670 Dr. Shah. Thank you, Chairman Burgess and Ranking Member
2671 Green. A pleasure to see you, Representative Barton. As fellow
2672 Texans, it's always great to have a conversation with you as well.

2673

2674 To members of the House Energy and Commerce Health
2675 Subcommittee, thank you for inviting me to testify this morning
2676 on this very important topic.

2677 My name is Dr. Umair Shah. I am the executive director of
2678 Harris County Public Health, the county health department in
2679 Houston, Texas, the third largest county in the U.S. with 4.7
2680 million people.

2681 I am also the local health authority of Harris County, Texas.

2682 I am also here as the president of NACCHO, the National
2683 Association of County and City Health Officials, representing
2684 the nation's nearly 3,000 local health departments.

2685 I refer you to my full written testimony today. In the
2686 interest of time, I will touch on three main points -- one, that
2687 public health truly matters, especially at the local level and
2688 in emergencies. The PAHPA reauthorization, number two, is

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2689 extremely important to support our work. Number three, CDC and
2690 ASPR must appropriately be funded and getting dollars to local
2691 communities.

2692 So public health is vital to the health of our communities.
2693 This is especially true in emergencies. Public health does all
2694 the behind-the-scenes work and is truly boots on the ground,
2695 performing disease surveillance, ensuring the safety of our
2696 environment, spraying for mosquitoes, providing immunizations,
2697 picking up dangerous animals, supporting chronic disease and
2698 mental health efforts. These are just some of what public health
2699 departments do to keep our communities healthy, protected, and
2700 safe.

2701 I can tell you firsthand how important these roles are
2702 because I am from an impacted community. Dating back to Tropical
2703 Storm Allison in 2001, the nation's first BioWatch had Hurricanes
2704 Katrina, Rita, and Ike, H1N1 pandemic, Ebola, and Zika and, most
2705 recently, 300-plus year floods in three years including Hurricane
2706 Harvey with its 1 trillion gallons of water that were dumped on
2707 Harris County.

2708 Emergencies abound. But our story is one of a community
2709 of resilience, one that has invested in our health and response
2710 systems and understands the importance of working together to
2711 prepare, respond, and recover and that's what Texans do.

2712 Truly, our strong response to Harvey was built on the
2713 responses to Tropical Storm Allison on forward. Indeed, you can

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2714 learn from previous emergencies and investments can and do pay
2715 off. Harvey was just one storm, though.

2716 In the last year, our nation has seen severe weather events,
2717 ice storms, floods, hurricanes, wildfires, acts of violence, a
2718 severe flu season. This doesn't even include the issue of opioids
2719 or global health challenges that impact domestic health.

2720 Truly, two things are certain. Emergencies can and will
2721 be lurking around the next corner and public health agencies will
2722 be there to respond in kind.

2723 But we cannot do our job without the adequate resourcing
2724 and support that both public health emergency preparedness and
2725 the hospital preparedness program funding streams -- PHEP and
2726 HPP -- provide.

2727 That's why, number two, the PAHPA reauthorization bill is
2728 so critically important for our work. Let me now speak briefly
2729 to some of the proposed provisions.

2730 First, we strongly support the reauthorization of the PHEP
2731 and HPP programs through 2023. These are complementary programs
2732 that work hand in hand to enable health departments and health
2733 care systems alike to prepare and respond to emergencies.

2734 Secondly, the Medical Reserve Corps program strengthens our
2735 ability to respond by deploying an army of volunteers. We urge
2736 you to maintain the authorization level under the current law.

2737

2738 Thirdly, with respect to the public health emergency fund,

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2739 we are concerned about the 1 percent transfer authority to infuse
2740 the fund when a public health emergency is declared. The transfer
2741 authority would take vital dollars away from other public health
2742 programs in the midst of a funding cycle and we recognize that
2743 multiple emergencies can be happening at one time.

2744 Finally, the SNS plays a critical role in preparedness
2745 regardless of its structure or location. With the proposed of
2746 authority from CDC to ASPR legislative language must assure
2747 maintenance of appropriate coordination and support of state and
2748 local health departments.

2749 Public health response capabilities cannot get lost in the
2750 sea of other health care system capability needs.

2751 Number three, we feel strongly that CDC and ASPR are agencies
2752 that are critical to support what we do on the ground. They provide
2753 not just funding and resources, technical expertise, and advice,
2754 but they often are the response agencies that deploy at a moment's
2755 notice when necessary.

2756 We must ensure that the authorization levels of both agencies
2757 are maintained.

2758 Truly, as we do our work in public health we remain hidden
2759 from the public's eye. We have a visibility crisis in public
2760 health and it impacts our ability to be appropriately resourced.

2761 I think of public health as the offensive line of a football
2762 team. Of course, it is Texas so I must say football. Whether
2763 it is Tom Brady or Aaron Rodgers, everyone knows the quarterback

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2764 but very few know members of the offensive line, yet they are
2765 critical to the success of that line.

2766 Just that -- just like that we are that -- the
2767 behind-the-scenes offensive line absolutely critical to the
2768 wellbeing of our communities. Since we don't invest
2769 appropriately in public health capacity, we find ourselves
2770 reactively scrambling to act when the next emergency is upon us.

2771 Decreased investment in public health leaves us more
2772 vulnerable and forces us to rob Peter to pay Paul by taking from
2773 elsewhere, and funding fluctuations also take a toll.

2774 If funding for public health is cut by 10 percent, for
2775 example, the expectations of our communities do not decrease by
2776 10 percent in kind. We must have adequate resources to do our
2777 job appropriately.

2778 Let me close by saying I am honored to represent the strong
2779 dedicated public health workforce that give it their all as first
2780 responders in emergencies just like fire, EMS, law enforcement,
2781 et cetera, even when themselves personally impacted.

2782 This proposed bill helps support our work. More is needed,
2783 of course, especially to support the values of innovation,
2784 engagement, equity of collaborative multi-disciplinary linking
2785 of one health, global domestic health, and all-hazards
2786 preparedness with ongoing public health capacity building,
2787 ensuring funds get equitably to jurisdictions based on both need
2788 and risk. This reauthorization is an important step in that

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2789 direction.

2790 Thank you, and I look forward to taking your questions.

2791 [The prepared statement of Dr. Shah follows:]

2792

2793 *****INSERT 4*****

2794

Mr. Burgess. Thank you, Dr. Shah.

2795

Dr. Berrey, you're recognized for five minutes, please.

2796 STATEMENT OF DR. BERREY

2797

2798 Dr. Berrey. Good morning. My name is Michelle Berrey.

2799 I would like to thank Chairman Burgess and Ranking Member Green,
2800 other members of the committee, for the opportunity to speak to
2801 you today.

2802 I am here in support of reauthorization of PAHPA and to
2803 highlight the important components of successful public-private
2804 relationships to develop medical countermeasures from the
2805 perspective of a small biotechnology company.

2806 I am a board-certified infectious disease and public health
2807 physician. I spent the last 20 years developing new drugs for
2808 viral diseases.

2809 I currently serve as CEO of Chimerix, a small publicly-traded
2810 biotech of 85 employees in Durham, North Carolina. We are one
2811 of many companies currently collaborating with BARDA in
2812 development of medical countermeasures against CBRN threats.

2813 We are here today as members of the Alliance for Biosecurity
2814 as a strong supporter of reauthorization of PAHPA.

2815 Our lead candidate, brincidofovir, or brinci for short, is
2816 an anti-viral with activity against a broad range of viruses.

2817 It is in late stage development for treatment of small pox.

2818 Brinci is one of a handful of dual-use agents, meaning it
2819 is in development both as a medical countermeasure for protection
2820 of the public health and to address some of the most common viruses

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2821 in patients with urgent needs for new treatments.

2822 For brinci, this is for children undergoing bone marrow
2823 transplants. It was federal funding that allowed us to jumpstart
2824 our smallpox program and to progress to full development and our
2825 currently collaboration with BARDA.

2826 When smallpox was eradicated in the 1970s, routine
2827 vaccinations ceased. Without broad immunity, weaponized
2828 smallpox could be devastating to the global population and thus
2829 it became an appealing potential biological weapon.

2830 It is a highly infectious easily transmitted airborne virus
2831 with at least a 30 percent mortality rate. As the first line
2832 of defence for smallpox exposure, vaccines are stockpiled by BARDA
2833 for every American including the one in five Americans who would
2834 require a next-generation or attenuated vaccine.

2835 So why did the Institute of Medicine also recommend that
2836 the U.S. stockpile two different smallpox antivirals with
2837 different mechanisms of action?

2838 The reason that antivirals are critical is for three separate
2839 populations -- one, those who remain ineligible for vaccine; two,
2840 patients with severe side effects from the vaccine; and three,
2841 those with symptomatic smallpox.

2842 Like the flu, once symptoms begin it is too late for a
2843 vaccine. Specifically for brinci, we have completed over a dozen
2844 efficacy studies for the treatment of smallpox under the FDA's
2845 animal rule. In our largest rabbit pox study, we demonstrated

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2846 100 percent survival in animals that we began dosing at the time
2847 we confirmed infection.

2848 Our studies have also shown that brinci may also reduce
2849 transmission of smallpox by accelerating clearance of virus.
2850 This point could be critical in stopping an outbreak.

2851 Chimerix has worked closely with our colleagues at the
2852 Division of Antivirals at the FDA to progress this challenging
2853 program. Just this morning, we received orphan drug designation
2854 from the FDA, which provides a waiver for FDUFA fees and will
2855 thus provide further savings for BARDA.

2856 Developing countermeasures as dual-use compounds allows us
2857 to stretch precious federal resources and to ensure
2858 sustainability of the enterprise.

2859 We've also seen that brinci's development for the treatment
2860 of life-threatening antiviral infections has provided
2861 innovations for drug formulations that are paid for fully by
2862 private sector dollars and this has reaped additional benefits
2863 for compounds that are included in the medical countermeasures
2864 and the stockpile.

2865 The passage of Project BioShield and PAHPA created a market
2866 for medical countermeasures where one did not previously exist.

2867 Knowing that there is a fund dedicated to support stockpiling
2868 provides for our common defense. This is critical. We are
2869 developing a solution for a problem that we all hope never presents
2870 itself.

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2871 But not being prepared for a smallpox event is not an option.
2872 We commend the committee for the bipartisan collaboration on
2873 PAHPA reauthorization and in particular for the 10-year advance
2874 appropriation for the Project BioShield special reserve fund.

2875

2876 Companies like Chimerix rely on the existence of a government
2877 market for medical countermeasures in order to sustain the
2878 long-term investment in research and development for these
2879 critical.

2880 I will be happy to welcome any your questions.

2881 [The prepared statement of Dr. Berrey follows:]

2882

2883 *****INSERT 5*****

2884

Mr. Burgess. Thank you, Dr. Berrey.

2885

Mr. Decker, you're recognized for five minutes, please.

2886 STATEMENT OF MR. DECKER

2887

2888 Mr. Decker. Thank you, Chairman Burgess, Ranking Member
2889 Green, and members of the subcommittee. It's an honor to testify
2890 concerning the reauthorization of PAHPA.

2891 I am the chief security and privacy officer for the
2892 University of Chicago Medicine. I also serve as the chairman
2893 of the advisory board for the Associations of Executives and
2894 Health Care Information Security, otherwise known as AHIS.

2895 AHIS is an association that represents more than 850 senior
2896 security leaders within health care. Lastly, I serve as the
2897 industry lead and co-chair of a public private partnership task
2898 group sponsored by the Department of Health and Human Services
2899 for establishing cybersecurity best practices within the health
2900 care sector.

2901 This group is the result of a legislative imperative of the
2902 Cybersecurity Act of 2015, Section 405(d) and authorized under
2903 the National Infrastructure Protection Plan.

2904 We are organized under the joint cybersecurity working group
2905 within the Healthcare Sector Coordinating Council and the
2906 Government Coordinating Council.

2907 We support the reauthorization of PAHPA. Specifically, we
2908 support the inclusion of cybersecurity as an identified hazard
2909 and the need to designate a sector-specific agency such as ASPR
2910 to interface with the health care industry.

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2911 Over the last decade, the health care sector has witnessed
2912 the evolution of cyber-attacks against our health systems.
2913 Today's cyber-attacks have become more numerous and sophisticated
2914 from the establishment of underground markets for the exchange
2915 of stolen sensitive information to the creation of a "hacking
2916 as a service industry."

2917 In the hyper connected world of health care, the digital
2918 footprint has exploded, creating more points of entry than ever
2919 for attacks to be successful.

2920 As was evidenced by the WannaCry ransomware attack that was
2921 launched in May of 2017, we must recognize that cyber-attacks
2922 are a real and present danger. With the recent WannaCry incident
2923 has signalled to the industry that attacks are no longer localized
2924 to one particular health system or another but can impact us
2925 locally, regionally, and nationally.

2926 We need a system of prevention and response that is similar
2927 to the disease prevention and infection control practices within
2928 the health care industry.

2929 This system should encourage and incentivize the adoption
2930 of standard cyber hygiene practices, as our clinicians do with
2931 washing their hands, and that is capable of coordinating
2932 large-scale emergency response to cyber threats as HHS has done
2933 with the Ebola and Zika outbreaks.

2934 We feel that this is the perfect moment to introduce the
2935 inclusion of cybersecurity to PAHPA and strengthen the

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2936 partnership with the federal government. Specifically, we feel
2937 that ASPR, in combination with the right cybersecurity expertise,
2938 capabilities, and funding will serve as an impartial partner to
2939 help bolster the industry's cyber capabilities.

2940 I would like to offer a few methods that ASPR could deploy
2941 to achieve these outcomes. Number one, encourage the adoption
2942 of a cybersecurity framework and a soon to be released top ten
2943 cybersecurity best practices within health care.

2944 Number two, bolster the importance of cybersecurity
2945 technical -- of sharing technical cybersecurity threat
2946 intelligence information through the use of a national healthcare
2947 ISAC, otherwise called NHISAC. Ensure that this information is
2948 protected from regulators.

2949 Number three, offer enforcement relief for organizations
2950 that demonstrate the adoption of the cyber framework -- the
2951 aforementioned best practices and participation within NHISAC.

2952 And number four, establish a national response program in
2953 partnership with NHISAC and potentially DHS that is capable of
2954 facilitating a response to the national threat.

2955 I sincerely thank the committee for allowing me to speak
2956 on this important topic and I look forward to answering your
2957 questions.

2958 [The prepared statement of Mr. Decker follows:]

2959

2960 *****INSERT 6*****

2961 Mr. Burgess. And I thank all of our witnesses for their
2962 testimony. We will proceed into the question and answer portion
2963 of the hearing. I will recognize myself five minutes for
2964 questions.

2965 And Dr. Shah, again, thank you. Before I go to you, Dr.
2966 Shah, I wanted to introduce the Shattuck Lecture that was printed
2967 in the New England Journal of Medicine given by Bill Gates,
2968 specifically the comments about the early detection system and
2969 BioWatch.

2970 So I will be asking unanimous consent to make that as part
2971 of the record. Without objection, so ordered.

2972 [The information follows:]

2973

2974 *****INSERT 7*****

2975 So now, Dr. Shah, again, I appreciate you being here today.
2976 Appreciate all the work that you have done for the county of
2977 Harris where I lived for a while while I was in medical school.
2978 So I am very familiar with the issues that you -- that you
2979 elucidated in your testimony.

2980 We talked a little bit about BioWatch. I think Dr. Kadlec
2981 mentioned that in his testimony. So do you see a need to update
2982 the technology currently used in the BioWatch program and is the
2983 guidance provided by Health and Human Services and Department
2984 of Homeland Security appropriate for our local responses?

2985 Dr. Shah. Thank you, Mr. Chairman.

2986 So let me answer that with going back a little bit in the
2987 history. So as the first BioWatch hit that we had in Houston
2988 in our community and then over the years having multiple BioWatch
2989 actionable results at the bars. What we've seen over the years
2990 is that there has been a shift in the way BioWatch was actually
2991 looked at.

2992 Initially, it was you have a hit, it is an act of intent
2993 and you have to launch an all public health response to it. That
2994 has now shifted, fortunately, in a way that it is a laboratory
2995 confirmation -- a sensor positive that doesn't necessarily mean
2996 that it's a public health positive, and this is the difference
2997 between the science of public health and the art of public health
2998 where we have to put all the other epidemiologic data, all the
2999 other environmental health data, all of the other factors in so

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3000 we can make a determination whether this is truly a terrorist
3001 attack or a terrorist threat, and that, I think, is the way to
3002 go.

3003 But what that really implies is that we have to make sure
3004 that the technology is as strong as it can be, it's as certain
3005 as possible to give us the right result.

3006 And so we, certainly at the local level and even really
3007 thinking about this more from a physician standpoint, we really
3008 want to make sure that if you ask for a test that you know what
3009 you're going to do with the result and that's the first thing
3010 -- the first adage in medicine and that's what applies for here
3011 is that we want to make sure that the technology is certain, gives
3012 us the right results, and then we can use all of the other
3013 information that we have at our disposal to make a determination.

3014 So we support better technology. We also support better
3015 guidance because continuation of changing shifting guidance over
3016 the years means that we have to relook at what kind of guidance
3017 has been given to local health departments and state health
3018 departments so we could relook at this program and make sure that
3019 it really meets the needs of today and not just yesterday.

3020 Mr. Burgess. So what is -- if I could ask, what is the state
3021 of the art? The level of precision that is now technically
3022 available is -- obviously, you can work with that at the local
3023 level?

3024 Dr. Shah. Yes, we can. There are -- there are some

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3025 challenges with the, you know, proposed some technologies that
3026 were there.

3027 The initial technology would allow for more information
3028 about what the results were and how there was some move towards
3029 saying it was more or less, for all intents and purposes, a
3030 positive or a negative and not giving you all the factors that
3031 were in play.

3032 And, fortunately, DHS has moved away from that. But that
3033 was a challenge and so we are really recognizing that it's really
3034 important to work with federal, state, and local partners in a
3035 transparent way so that we can actually understand the science
3036 because we too can interpret information and we are partners as
3037 part of that system.

3038 Mr. Burgess. Thank you for that answer.

3039 Dr. Berrey, I referenced I went to medical school in Houston.
3040 It was a number of years ago. The New England Journal of Medicine
3041 back in 1974 or 1975 or 1976 talked about the fact that smallpox
3042 was going to be eradicated from the face of the earth.

3043 As I sat in my study cubicle that day in the mid-1970s I
3044 thought it was until I arrived here a number of years later as
3045 a member of Congress and found out that it wasn't.

3046 But I just want to mention that as a thanks to you and your
3047 company for working on those agents. Right after 9/11 when people
3048 were concerned about biologic agents there was really an open
3049 question as to whether or not we were prepared because of the

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3050 nonvaccination of the population and the lack of a substantial
3051 stockpile to deal with a -- what could have been a significant
3052 attack.

3053 So you're welcome to respond to that but I just wanted to
3054 thank you for the work that your company has done.

3055 Dr. Berrey. Thank you, Chairman Burgess, and we appreciate
3056 the opportunity to speak here today. We do believe the
3057 eradication of naturally-occurring smallpox remains probably the
3058 greatest contribution of medicine to humankind on the planet.

3059 It is unfortunate that the technologies available to
3060 would-be attackers have kept a step ahead and we are hoping that
3061 we are keeping on lockstep with them.

3062 I really commend BARDA for their foresight in moving forward
3063 not just with vaccination and being at the ready but their close
3064 work with CDC to be prepared to implement ring vaccination, to
3065 be able to control another outbreak that could begin from either
3066 naturally occurring or more likely from an attack of smallpox.

3067 Some of the more recent information available about the
3068 likelihood of being able to implement synthetic smallpox is
3069 something we've had a lot of discussions about with our colleagues
3070 at BARDA and really hope to, by having multiple therapeutics
3071 available within the stockpile, to be prepared in the event to
3072 face whatever form that that smallpox could take.

3073 Mr. Burgess. Thank you for that.

3074 My time has expired. I will recognize the gentleman from

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3075 Texas, Mr. Green, five minutes for questions, please.

3076 Mr. Green. Thank you, Mr. Chairman, and again, Dr. Shah,
3077 and our whole panel, thank you for being here.

3078 I know in the Houston areas that I represent we have a
3079 coordinated effort. Both our county judge, Ed Emmett in the city
3080 of Houston and Harris County and some of the responses that we've
3081 had necessitate the deployment of the national strategic
3082 stockpile.

3083 In your statement, you made reference, Dr. Shah, to the fact
3084 that the response to Hurricane Harvey was more than an acute
3085 response but was instead the result of years of planning and
3086 coordination.

3087 With the likely transfer of SNS from CDC to ASPR, do you
3088 foresee any possible disruptions to the planning, coordination,
3089 and development of the SNS in future events, given that
3090 predictable -- that frequency, intensity of weather-related
3091 events will only increase?

3092 Dr. Shah. First of all, Congressman Green, thank you so
3093 much for your service and for the continued partnership that you
3094 have given to our health department and our community in general.

3095 What I would say is that Hurricane Harvey was the culmination
3096 and the continuation of a lot of the lessons that we have learned
3097 over the decade plus since Tropical Storm Allison.

3098 And, fortunately, we have learned those lessons and there
3099 has been incredible amount of investment in both public health

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3100 and health care. With respect to the SNS, as you heard from the
3101 earlier panel, there -- you know, there certainly are challenges
3102 as we think about a transfer and there's some uncertainty at least
3103 at the local level of what exactly this means when they say it's
3104 being moved from the CDC to ASPR.

3105 The biggest concern that I would -- I would put out there
3106 is the fact that we know that ASPR is responsible for hospital
3107 readiness and health care readiness, and we also know that
3108 oftentimes public health gets drowned out by the hospitals and
3109 healthcare system.

3110 And so one of the biggest challenges we would have as moving
3111 SNS over to ASPR is to ensure that it does not get lost in all
3112 the public health activities that we at the local level and the
3113 state level, that we require from an SNS as well -- from our federal
3114 partners.

3115 And so ensuring that the legislation has that built in is
3116 absolutely critical. The other aspect of this is the federal
3117 medical station that was deployed during SNS for Hurricane Harvey
3118 response was very much about really having a field hospital that
3119 we were able to rely on.

3120 Unfortunately, Florida and Hurricane Irma happened right
3121 afterwards and it started to move. And so one of our big
3122 challenges is to ensure that when we have multiple emergencies
3123 happening how do we really try to figure out what those federal
3124 assets are and how we can use them locally as well as across the

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3125 system. I think that's another challenge.

3126 Mr. Green. Well, I appreciate it, because I know the
3127 response with Hurricane Harvey and Katrina -- when the CDC came
3128 in we were treating a lot of our visitors, who are now Texans,
3129 from Louisiana. CDC can bring other resources including the
3130 public health service and I just didn't want to disrupt some of
3131 the good things we had.

3132 If you have any suggestions on how we may make sure that
3133 that process will not lose the success we have now, I would be
3134 glad to see what we can do when we are marking up the bill, because
3135 that's my concern -- the change from CDC to ASPR, which is a great
3136 agency, but I don't want to lose that effort.

3137 The -- one of the -- Dr. Shah, one of the other concerns
3138 I have is we spent some today discussing the importance of
3139 well-funded public health infrastructure for preparedness and
3140 response.

3141 A related discussion in the provision of the bill would allow
3142 the secretary to transfer 1 percent of any appropriation to the
3143 public health emergency response fund. The intent of the fund
3144 is to provide a source of extra funding for responding to public
3145 emergencies like Katrina or Harvey -- in extra funding.

3146 However, in your written testimony, you indicated that you
3147 had significant concerns about the transfer authority.
3148 Specifically, you mentioned that the authority will take away
3149 vital dollars from other public health programs.

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3150 And my question is from the perspective of the local public
3151 health officials on the ground can you describe the challenges
3152 that would occur from allowing the secretary to transfer 1 percent
3153 of HHS funding to the public health emergency response in case
3154 of a public health emergency declaration?

3155 Dr. Shah. Thank you again for that question.

3156 What I would say is that we recognize the importance of having
3157 a fund because in the midst of an emergency you have to have that
3158 funding ready right then. You cannot wait months or some period
3159 of time to get those dollars back into the system.

3160 The challenge that we have is that while we were looking
3161 at what happened during Zika, we started to go back and pull
3162 dollars from Ebola. But Ebola was still a threat while we were
3163 also trying to find the dollars over to Zika.

3164 And at our own health department, for example, we had hired
3165 a physician for chronic disease prevention for diabetes and high
3166 blood pressure and immediately because we did not have those funds
3167 we had to move that physician over to be the response -- part
3168 of the response system for Zika.

3169 And so I think it's a real challenge that we have to remember
3170 that there are multiple challenges and issues the public health
3171 departments at the local level are facing all the time.

3172 What we don't want to have happen is in mid-cycle dollars
3173 are shifted from one place to another and you now start to lose
3174 infrastructure in that existing area that is equally important.

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3175 And we also have to remember that multiple emergencies can
3176 happen at the same time. So yes, those are our concerns,
3177 Congressman, that we are interested in discussing.

3178 Mr. Green. Thank you. I know I am out of time but that's
3179 another issue we'll look at because I still have my constituents
3180 waiting for FEMA assistance 10 months now since Harvey and I would
3181 not like to have our public health have to wait that long because
3182 then we could end up with epidemics.

3183 Thank you, Mr. Chairman.

3184 Dr. Shah. When you wait for dollars that can cost lives,
3185 and so that's very important. Thank you.

3186 Mr. Burgess. The chair thanks the gentleman.

3187 The chair recognizes the gentlelady from Indiana five
3188 minutes for questions, please.

3189 Mrs. Brooks. Thank you, Mr. Chairman.

3190 Dr. Berrey, in 2004 Congress passed the Project BioShield
3191 Act, which created the special reserve fund of \$5.6 billion made
3192 available over a 10-year period to help create stability and ease
3193 concerns from companies about the likelihood of, you know, help
3194 them decide about whether or not to get into the market for medical
3195 countermeasures. That has traditionally been unprofitable, and
3196 once this initial funding expired, Congress reverted to
3197 appropriating for the program on an annual basis, which I
3198 understand has created less long-term certainty.

3199 Do you agree that recommitting to a multi-year funding

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3200 approach for medical countermeasures development and procurement
3201 would help strengthen our nation against biological threats and
3202 could you please talk about whether or not it's incentives or
3203 how can we better prioritize our existing funding for medical
3204 countermeasures?

3205 Dr. Berrey. Absolutely. Thank you, Congresswoman Brooks,
3206 and I want to thank both you and Congresswoman Eshoo for sponsoring
3207 this bill.

3208 I will say without question that having federal moneys
3209 available for support of these long-term research and development
3210 projects is absolutely critical.

3211 We know that the private sector does not establish the same
3212 value -- does not support those programs, especially these
3213 longer-term programs, and thus it is critical that we have federal
3214 moneys available.

3215 We've seen the impact in other small and large companies
3216 that are committed to this space. But without a multi-year
3217 authorization have seen the dollar value and the size of those
3218 procurement contracts decrease because BARDA does not have that
3219 capability of having the security of a longer-term multi-year
3220 commitment there.

3221 Having that dedicated fund is absolutely critical. We
3222 believe in dual use and the -- both the economic and the medical
3223 benefits that dual-use compounds can bring.

3224 We've seen benefits to our medical countermeasure program

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3225 that have been exclusively paid for through our private sector
3226 dollars.

3227 One specific example is optimization of our pediatric
3228 suspension. We now have a suspension that is -- has no need for
3229 refrigeration, which is ideal for the SNS, and because we are
3230 treating children through our clinical program for adenovirus,
3231 we have real-world data that can support the dosing information
3232 specific for pediatric use in the event of a smallpox outbreak.

3233

3234 I believe that both the long-term funding and continued
3235 support through PAHPA reauthorization are critical for that but,
3236 secondly, I wanted to make the point that I do believe dual-use
3237 compounds, even though they do bring additional challenges, have
3238 additional economic benefits.

3239 Mrs. Brooks. Thank you.

3240 Mr. Decker, the Blue Ribbon Study Panel on Biodefense called
3241 for the development and implementation of a government-wide
3242 security strategy for stored pathogen data that incorporates
3243 deterrent and enforcement measures, oversight, and inspection.

3244 Would you be willing or interested in contributing to such
3245 a process and do you believe a strategy like this would improve
3246 the security of sensitive public health information?

3247 Mr. Decker. Well, certainly, I think that focusing any
3248 amount of preparation and effort on securing sensitive
3249 information is going to be -- is going to be important.

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3250 I am not familiar with that particular provision so I am
3251 happy to take that back and provide an answer to you, if you'd
3252 like.

3253 Mrs. Brooks. Are you familiar with the Blue Ribbon Study
3254 Panel on Biodefense and recommendations they made?

3255 Mr. Decker. No, I am not.

3256 Mrs. Brooks. Okay. Well, we would welcome the opportunity
3257 to work with you on that and to get your further thoughts on what
3258 they recommended.

3259 And finally, Dr. Shah, if we could just go in a little bit
3260 with respect -- can you help us understand the role that CDC --
3261 we've certainly had quite a debate and discussion this morning
3262 about CDC's role and what would you say?

3263 Are there any additional tools CDC needs that -- or resources
3264 that they need that we ought to be providing as we explore what
3265 their role is, going forward, relative to ASPR's?

3266 Dr. Shah. Yes, that's a -- that's a tough one. Thank you
3267 for that question.

3268 That's a tough one only because we -- there are a number
3269 of needs that public health in general has at the federal, state,
3270 and local level. And so I could really, you know, have a nice
3271 --

3272 Mrs. Brooks. That's a huge lecture. I understand that.

3273 Dr. Shah. Yes. Yes. Exactly. Exactly.

3274 That said, I do think that, you know, outside of supply chain

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3275 logistics and those kinds of things that, obviously, and ASPR
3276 would be -- would be very good at doing, there would be an
3277 opportunity really to be looking at the real consultation and
3278 the technical assistance --

3279 Mrs. Brooks. Right.

3280 Dr. Shah. -- and the support that's given to local and
3281 state health departments. Really, that's what CDC is really,
3282 really good at -- technical assistance and really being able to,
3283 you know, pick up a phone and call and/or even deploy in if you
3284 need help and assistance and want to make sure that that
3285 consultation piece is available.

3286 But also the real piece about the support that is given to
3287 local health departments as they're doing their work. If this
3288 shifts over to ASPR and that piece is not so strong then at the
3289 end of the day the last mile is really the most important piece
3290 about SNS is how do you get medications into the -- you know,
3291 into the mouths of people and you want to make sure that local
3292 health departments have the support to be able to get that done
3293 well and that, obviously, would mean that we would continue to
3294 have that support from whomever is going to be providing it.

3295 So those guardrails really need to be in place.

3296 Mrs. Brooks. Thank you. I agree. I yield back.

3297 Mr. Guthrie. [Presiding.] The gentlelady yields back and
3298 I will recognize myself for five minutes to ask questions, and
3299 thank you all for being here today.

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3300 And Dr. Shah, this is for you. During an Ebola outbreak
3301 in West Africa -- the Ebola outbreak in 2014, much was made about
3302 the lack of standards and guidelines for the use of personal
3303 protective equipment in hospitals that were treating infected
3304 patients.

3305 What are your thoughts on establishing reasonable personal
3306 protective equipment guidelines and requirements for emergency
3307 medical service personnel in advance of a biological event based
3308 on existing research and lessons learned?

3309 Dr. Shah. Thank you for that question.

3310 I would say, first of all, there a few things about Ebola.
3311 I think Ebola and Zika and H1N1, the pandemic, teach us that
3312 global health is very much connected with domestic health and
3313 we have to keep that in mind.

3314 So, really, the way to be able to interrupt the transmission
3315 or get to zero risk for the American people is to be able to
3316 interrupt transmission in global communities, for example, in
3317 West Africa in 2014 or in the case of Zika in Latin American and
3318 Caribbean countries.

3319 That also, obviously, is a concern now with the Democratic
3320 Republic of Congo with DRC because the concern now is does this
3321 get into an urban environment that potentially you could get
3322 spread and get on a plane and you can now get to North America
3323 and here we are, we are back and playing for years later a very
3324 similar situation.

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3325 So we work very closely with our environmental health folks.
3326 I mean, the environmental health field is amazing when it comes
3327 to really helping us as well as the occupational health field
3328 when it comes to those personal protective equipment and those
3329 environment changes that need to be made and we really believe
3330 with a disease like Ebola, because it's so meticulous that you
3331 have to use personal protective equipment every single time, we
3332 have to recognize the absolute importance of ensuring that we
3333 are working with our private sector that are designing these
3334 suits, designing those gloves, designing those masks, designing
3335 all those -- all those materials but we also train local
3336 practitioners so they know what they're doing, how they're doing
3337 it, how they're putting it on, how they're using it so they are
3338 meticulous.

3339 One example I will give you is from Hurricane Harvey. We
3340 have J.R. Atkins, who was an EMS responder, who volunteered.
3341 In the middle of -- he was meticulous about using personal
3342 protective equipment except one time where he was bitten by a
3343 mosquito -- it was a spider, most likely, and he wound up having
3344 necrotizing fasciitis, a flesh-eating bacteria, and we wound up
3345 going to the operating room three to five times.

3346 So we have to be meticulous when it comes to infectious
3347 disease control and we certainly support that.

3348 Mr. Guthrie. Okay. Thank you very much.

3349 And also -- and this for you but anybody on the panel that

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3350 would like to address it -- the public health emergency
3351 preparedness cooperative agreement is an annual source of direct
3352 funding for state and local public health systems.

3353 Can you speak about the importance of these agreements in
3354 terms of capability to address biological threats and how do
3355 state, local, and territorial public officials leverage the
3356 federal support and how does it help prepare the country for the
3357 next outbreak?

3358 Dr. Shah. Thank you again for that question.

3359 What I would say is that we recognize that there is a lot
3360 of capacity already at the local and state level. There is a
3361 lot that's already being done with the resources that we have
3362 in state and local communities.

3363 But it would be important to say that public health emergency
3364 preparedness funding -- that 55 percent of local health
3365 departments are actually relying on those dollars for their
3366 preparedness work.

3367 It is so critical to many of our local health departments,
3368 especially the smaller local health departments, the more
3369 frontier local health departments. We have to make sure that
3370 those dollars are available and that they can support and really
3371 augment what's already happening at the local level.

3372 The other piece around the biologics is that we want to make
3373 sure that there is improved recognition of quicker digital systems
3374 and recognition of surveillance systems that really allow us to

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3375 do disease pattern recognition.

3376 The final point that I would make in the interest of time
3377 is the fact that we have to really be thinking about where the
3378 risk is, where the threats are, and really ensuring that those
3379 dollars are going not just to certain areas of a community but
3380 all of a community to make sure that those dollars are really
3381 reaching those local health agencies that are boots on the ground
3382 to ensure that they can do the work that they're doing.

3383 Mr. Guthrie. Thank you.

3384 Anybody comment? I know that's more his area but anybody
3385 want to comment on that as well?

3386 Dr. Berrey. The only additional point that I would make
3387 is as we look back on smallpox and as Chairman Burgess noted
3388 earlier that we haven't seen smallpox since the 1970s. So when
3389 you think about the physicians that are currently staffing
3390 emergency rooms, it's very unlikely that any of the physicians
3391 who are currently serving in those first response settings have
3392 actually seen smallpox.

3393 So a big component not just in diagnosis is first to think
3394 about this could be a bioweapon, could be a chemical weapon,
3395 reflect recently on coverage of the nurses who was treating the
3396 Russian spy and his daughter who, when they first were -- entered
3397 into the emergency room considered it was mostly likely an opioid
3398 overdose, and only an hour later as the physically -- the police
3399 officer was brought in with similar symptoms did they realize

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3400 that this was not in fact an opioid overdose.

3401 So we really have to go back to thinking about those zebras.

3402 When you hear hoof beats, don't always think of zebras, but today
3403 might be the day for us to begin remembering those zebras. We
3404 can be educating our physicians to think about early diagnosis
3405 and give them the tools to make sure that diagnosis can occur
3406 rapidly.

3407 Mr. Guthrie. Thank you. My time is expired.

3408 I will recognize the gentleman from Missouri, Mr. Long, for
3409 five minutes for questions.

3410 Mr. Long. Thank you, Mr. Chairman.

3411 Doctor -- Mr. Decker, did you participate in the industry
3412 calls that HHS led during the WannaCry cyber-attack?

3413 Mr. Decker. Yes, I did.

3414 Mr. Long. Did you find them valuable?

3415 Mr. Decker. Yes, I did. I mean, what was -- what was
3416 valuable was getting the information out to all the health systems
3417 so that we could understand what was happening -- if we were being
3418 impacted. There was also -- having a sort of a pulse on what
3419 was going on in Europe and the U.K. at the time and if that was
3420 coming over across the pond was important.

3421 There was some confusion on some of the calls -- some
3422 information that came out of those calls that was technical in
3423 nature and it was not necessarily related to the actual technical
3424 nature of the attack that was occurring. But the coordinated

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3425 and facilitation effort of what those calls were doing was highly
3426 useful.

3427 Mr. Long. So I am assuming that you did find it valuable
3428 to interact with HHS in real time?

3429 Mr. Decker. Absolutely.

3430 Mr. Long. Do you think that if another WannaCry attack took
3431 place today HHS would be able to serve a similar kind of function?

3432 Mr. Decker. I think they would stand up a similar type of
3433 activity -- an incident response function like that. I think
3434 it would be beneficial for the preparedness of that response to
3435 be a little more coordinated.

3436 The means by which HHS is facilitating the process versus
3437 the means by which information sharing and analysis centers
3438 facilitate technical and distribute technical information down
3439 to the health systems, I think there's some better coordination
3440 that could occur there as well as some further monitoring of the
3441 other critical infrastructures that's occurring.

3442 But, ultimately, you know, having HHS serve as the focal
3443 point and facilitation point and the coordination point for a
3444 national response so that we can have an open line of communication
3445 with them in case we need help is, I think, incredibly important.

3446 Mr. Long. If another cybersecurity incident like WannaCry
3447 were to take place, would you want to contact HHS for guidance
3448 and additional information?

3449 Mr. Decker. We would -- personally, yes. I think there's

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3450 also a bit of hesitancy from some of our constituents on HHS being
3451 a regulator as well as an office that provides support and
3452 resources.

3453 I think there's a hesitancy for some to not open up the lines
3454 of communication. So I think that further bolstering the
3455 knowledge of who that sector-specific agency is, what the
3456 protection is --

3457 Mr. Long. Knowledge of what? I am sorry.

3458 Mr. Decker. Of who the sector-specific agency is and how
3459 we can communicate with them under protection is something that
3460 would help with disseminating that information.

3461 Mr. Long. If it did happen again, who would you want to
3462 contact at HHS and how do you know that that would be the right
3463 person to contact?

3464 Mr. Decker. Yes. So contacting ASPR would be on the list
3465 as well -- now, ASPR would probably be the main focus point, or
3466 the MCIC within the Department of Health and Human -- or DHS.

3467 Mr. Long. You mentioned some people might have concerns
3468 about sharing information with HHS since HHS is your regulator
3469 --

3470 Mr. Decker. Yes.

3471 Mr. Long. -- in addition to your sector-specific agency.
3472 You said other people had that concern. Do you share that
3473 concern?

3474 Mr. Decker. Do I share that concern?

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3475 I think there is a clear line between which operating
3476 division is responsible for interfacing with industry and which
3477 is responsible for regulating the industry.

3478 But I don't think that is common knowledge throughout all
3479 the healthcare industry. I think people see HHS as the regulator.
3480 They don't understand the intricacies inside of HHS.

3481 So though I understand the difference between what ASPR is,
3482 what OCR, what ONC, CMS, et cetera, are, I think that's -- it's
3483 not a common knowledge.

3484 Mr. Long. What steps could HHS take to address some of the
3485 concerns that you detail?

3486 Mr. Decker. A lot of focused education and awareness I think
3487 would be important. Designating a very specific agency that's
3488 going to be responsible for coordinating with the sector -- with
3489 the industry is, I think, very important.

3490 Being able to facilitate the various guidance between OCR,
3491 FDA, ONC, CMS, et cetera, because all of those operating divisions
3492 produce guidance for cybersecurity for the health care industry.

3493
3494 But it's potentially in conflicting matters and so
3495 deconflicting the guidance that comes out and being able to really
3496 lower the barrier of entry to, you know, to the cyber space I
3497 think is going to be important, especially for the smaller
3498 practice organizations like small practice -- small practices,
3499 one- or two-physician practices, critical access hospitals,

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3500 community hospitals where they're resource strapped and every
3501 dollar that they have, if they spend it on cyber or if they spend
3502 it on public health, or they spend it on something is something
3503 they have to consider.

3504 Mr. Long. With all the players involved in the soup it
3505 sounds like acronymology to me.

3506 Mr. Decker. It is a little bit.

3507 [Laughter.]

3508 Mr. Long. Thank you, Mr. Chairman. I yield back.

3509 Mr. Burgess. [Presiding.] The chair thanks the gentleman.
3510 The gentleman yields back. We are just about to have votes on
3511 the floor so it looks like there are no further members wishing
3512 to ask questions.

3513 So I want to thank our witnesses for being here with us today.
3514 Pursuant to committee rules, I will remind members they have
3515 10 business days to submit additional questions for the record.

3516

3517 I am going to ask witnesses to submit their response within
3518 10 business days upon receipt of those questions.

3519 I would also like to submit documents from the following,
3520 for the record: American Academy of Pediatrics, the American
3521 Hospital Association, the American Society for Microbiology,
3522 America's Essential Hospitals, Global Health Technologies
3523 Coalition, Healthcare Leadership Council, Infectious Disease
3524 Society of America, International Safety Equipment Association,

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3525 and the Trust for America's Health statement.

3526 Again, members have 10 business days to submit additional
3527 questions. I ask the witnesses to submit their responses within
3528 10 business days of the receipt of those questions.

3529 Without objection, the subcommittee is adjourned.

3530 [Whereupon, at 1:13 p.m., the committee was adjourned.]

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