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4 HEARING BIOTERRORISM, CONTROLLED SUBSTANCES AND PUBLIC HEALTH
5 ISSUES

6 THURSDAY, JULY 21, 2011

7 House of Representatives,

8 Subcommittee on Health

9 Committee on Energy and Commerce

10 Washington, D.C.

11 The subcommittee met, pursuant to call, at 10:03 a.m.,
12 in Room 2123 of the Rayburn House Office Building, Hon.
13 Joseph Pitts [Chairman of the Subcommittee] presiding.

14 Members present: Representatives Pitts, Burgess,
15 Shimkus, Rogers, Myrick, Murphy, Gingrey, Latta, McMorris
16 Rodgers, Cassidy, Guthrie, Upton (ex officio), Pallone,
17 Dingell, Towns, Capps, Baldwin, Green, and Waxman (ex
18 officio).

19 Staff present: Clay Alspach, Counsel, Health; Gary
20 Adnres, Staff Director; Jim Barnette, General Counsel; Sean
21 Bonyun, Deputy Communications Director; Andy Duberstein,
22 Special Assistant to Chairman Upton; Debbie Keller, Press
23 Secretary; Ryan Long, Chief Counsel, Health; Carly
24 McWilliams, Legislative Clerk; Andrew Powaleny, Press
25 Assistant; Chris Sarley, Policy Coordinator, Environment and
26 Economy; Heidi Stirrup, Health Policy Coordinator; Phil
27 Barnett, Democratic Staff Director; Stephen Cha, Democratic
28 Senior Professional Staff Member; Alli Corr, Democratic
29 Policy Analyst; Eric Flamm, FDA Detailee; Ruth Katz,
30 Democratic Chief Public Health Counsel; Karen Lightfoot,
31 Democratic Communications Director, and Senior Policy
32 Advisor; and Karen Nelson, Democratic Deputy Committee Staff
33 Director for Health.

|
34 Mr. {Pitts.} The subcommittee will come to order. The
35 chair will recognize himself for 5 minutes for an opening
36 statement.

37 Today's legislative hearing will focus on H.R. 2405, the
38 Pandemic and All-Hazards Preparedness Act of 2011; H.R. 1254,
39 the Synthetic Drug Control Act of 2011; and the Enhancing
40 Disease Coordination Activities Act of 2011.

41 Our witness for the first panel will be my friend and
42 fellow Pennsylvanian, Representative Charlie Dent. His bill,
43 H.R. 1254, the Synthetic Drug Control Act, addresses a
44 growing problem in many States and gives law enforcement
45 additional tools to deal with the very real dangers of
46 synthetic drugs.

47 H.R. 1254 would prohibit the sale of synthetic drugs
48 that imitate the hallucinogenic and stimulant properties of
49 drugs like marijuana, cocaine, and methamphetamines. While
50 these drugs are synthetic, they are just as dangerous as the
51 real thing, but they are not illegal.

52 Along with banning these synthetic drugs, the bill would
53 also allow the Drug Enforcement Administration (DEA) to
54 temporarily schedule a new substance for up to 3 years
55 instead of the current standard of up to 18 months.

56 Next, the subcommittee will examine Representative

57 Rogers' bill, H.R. 2405, the Pandemic and All-Hazards
58 Preparedness Act of 2011, which would reauthorize certain
59 provisions of the Project Bioshield Act of 2004 and Pandemic
60 and All-Hazards Preparedness Act of 2006 (PAHPA). These laws
61 help protect our country against pandemics and attacks from
62 chemical, biological, radiological, and nuclear weapons.

63 Among the reauthorizations in the bill are the
64 Biomedical Advanced Research and Development Authority
65 (BARDA), which helps to ensure that early-stage research
66 leads to tangible medical countermeasures that can be used to
67 save lives in an emergency, and the reauthorization of
68 Project Bioshield's Special Reserve Fund, which helps procure
69 medical countermeasures against anthrax, smallpox, botulism,
70 and other threats for the Strategic National Stockpile.

71 Finally, the Enhancing Disease Coordination Activities
72 Act of 2011 would allow the Secretary of Health and Human
73 Services to establish committees based on existing
74 interagency coordinating models that will help coordinate
75 disease-specific research and other activities currently
76 spread across the department.

77 I would like to thank all of our witnesses today, and I
78 would like to yield the remainder of my time to
79 Representative Rogers.

80 [The prepared statement of Mr. Pitts follows:]

81 ***** COMMITTEE INSERT *****

|
82 Mr. {Rogers.} Thank you, Mr. Chairman, for holding this
83 very important hearing.

84 Last month, I introduced H.R. 2405, legislation to
85 reauthorize the Pandemic All-Hazards Preparedness Act. I
86 want to thank Gene Green and Sue Myrick for being original
87 cosponsors on this bill, which will also reauthorize Project
88 Bioshield's Special Reserve Fund.

89 It has been almost 10 years since 9/11 and the anthrax
90 attacks that followed, and while they haven't had a
91 successful terrorist attack on U.S. soil, our enemies are
92 still working every single day to kill innocent Americans.
93 Bioterrorism remains a very real threat to our country, which
94 is why I think this bipartisan legislation is so important.

95 Over the last 10 years, we have made significant
96 progress in our ability to protect the public from CBRN
97 threats. Congress created Project Bioshield in 2004,
98 creating a market guarantee that prompted the private sector
99 to develop countermeasures for the Federal Government. In
100 2006, we also created the Biomedical Advanced Research and
101 Development Authority (BARDA), which helped bridge the
102 ``valley of death'' that prevented many countermeasure
103 developers from being successful.

104 Today, we have numerous vaccines and treatments in the

105 Strategic National Stockpile that will save lives in the
106 event of an attack. And while we hope that we never have to
107 use these medical countermeasures, they are essential to
108 protecting the public health from a bioterrorism attack.
109 Simply put, we must always be prepared.

110 I would also like to thank Mr. Pallone and Mr. Waxman
111 for working with us on this bipartisan basis to move this
112 legislation through the committee. The issue has always been
113 a bipartisan effort, and I appreciate their willingness to
114 partner with us. I also look forward to hearing from Dr.
115 Nicole Lurie, the HHS Assistant Secretary for Preparedness
116 and Response who oversees the entire medical countermeasure
117 enterprise. It is an important role in protecting the
118 country and I am pleased that they have also worked with us
119 on this critical legislation.

120 Thank you again for holding this hearing, Mr. Chairman,
121 and I yield back my time.

122 [The prepared statement of Mr. Rogers follows:]

123 ***** COMMITTEE INSERT *****

|
124 Mr. {Pitts.} The chair thanks the gentleman and asks
125 unanimous consent to enter the statement of Joe Rannazzisi of
126 the Drug Enforcement Administration into the record. Without
127 objection, so ordered.

128 [The information follows:]

129 ***** COMMITTEE INSERT *****

|
130 Mr. {Pitts.} The chair recognizes the ranking member of
131 the subcommittee, Mr. Pallone, for 5 minutes for opening
132 statement.

133 Mr. {Pallone.} Thank you, Chairman Pitts, and thank you
134 for holding today's hearing on these important health bills.
135 I am encouraged that this hearing marks two bipartisan
136 hearings in a row for this subcommittee and I support all
137 three bills under consideration. And I thank our witnesses
138 for joining us today.

139 Over the past 10 years, this Congress--rightfully so--
140 has placed a high priority on biodefense. In 2004, we passed
141 the Project Bioshield Act with tremendous bipartisan support.
142 Democrats and Republicans worked together to establish a
143 process that would help our Nation respond to bioterrorism
144 threats and attacks. This goal was to encourage the
145 development of new bioterrorism countermeasures.

146 Unfortunately, at first the program had limited success.
147 This committee recognized its shortfalls and in 2006 worked
148 to amend the program to help fix some of the problems.
149 Specifically, it provided the Department of Health and Human
150 Services with the additional authorities and resources
151 necessary to rapidly develop drugs and vaccines to protect
152 citizens from deliberate, accidental, and natural medical

153 incidents involving biological pathogens, as well as chemical
154 and radiological agents. It also helped to build the
155 Nation's health infrastructure.

156 In addition, a single point of authority within HHS was
157 created for the advanced research and development of medical
158 countermeasures to quickly make important procurement
159 decisions. The new position of assistant secretary for
160 preparedness and response (ASPR) has since led the Federal
161 Government's effort.

162 And today we consider H.R. 2405, the Pandemic and All-
163 Hazards Preparedness Act of 2011, which attempts to further
164 strengthen these programs. Specifically, it clarifies ASPR's
165 role in these efforts and attempts to improve coordination
166 and accountability.

167 We have worked very closely with the Republicans on this
168 bill, and while there are still some minor outstanding
169 issues, I am confident they can be settled. I know some of
170 my colleagues also have issues they would like to see
171 addressed--specifically, the ways in which we can enhance the
172 Nation's ability to care for pediatric populations and the
173 critically ill or injured in the event of a public health
174 emergency, and I hope we can incorporate these important
175 ideas in some way into the reauthorization bill.

176 Another bill we are considering today is the Synthetic

177 Drug Control Act introduced by Representative Charles Dent,
178 who joins us today. It is quite alarming to hear some of the
179 stories you have shared, as well as other members, whose
180 constituents have been able to utilize these products to the
181 detriment of their mental and physical health, and in some
182 cases, costing them their lives. It appears these imitation
183 drugs are not illegal and I support strengthening the Federal
184 Government's ability to keep these harmful and dangerous
185 drugs off the street.

186 Lastly, we are discussing the Enhancing Disease
187 Coordination Activities Act of 2011. This year, HHS is
188 devoting over \$900 million and 72,000 full-time employees to
189 carrying out their mission ``to help provide the building
190 blocks that Americans need to live healthy, successful
191 lives.'' As such, tackling the countless diseases we face is
192 a major component of their work. For a large and complex
193 organization with an even greater charge, the flexibility to
194 form coordinating bodies to better organize research and
195 public health activities is ideal.

196 The committee recently considered the Combating Autism
197 Reauthorization Act of 2011, a bill that seeks to address
198 autism spectrum disorders, a major public health problem in
199 New Jersey and across the Nation. The original program
200 created the interagency Autism Coordinating Committee, which,

201 as we heard last week, has been largely successful. So I am
202 encouraged that it can and should serve as a model for the
203 creation of other disease-specific coordinating committees.
204 The Enhancing Disease Coordination Activities Act of 2011
205 will give the secretary explicit authority to create
206 committees that would not only streamline activities within
207 the Department but also would stimulate partnerships between
208 public and private organizations. Especially at a time when
209 we are faced with such limited resources, coordinating
210 activities across public and private sectors is critical.

211 So I look forward to working with you, Chairman Pitts,
212 as we move on these critical pieces of legislation through
213 this committee and onto the House Floor.

214 And I now would like to yield what time I have left to
215 Ms. Baldwin.

216 [The prepared statement of Mr. Pallone follows:]

217 ***** COMMITTEE INSERT *****

|
218 Ms. {Baldwin.} Thank you. I want to thank you, Mr.
219 Chairman and Ranking Member Pallone, for holding this
220 important hearing on bipartisan measures that focus on our
221 Nation's public health preparedness. I am not going to be
222 able to offer my entire opening statement, so I ask unanimous
223 consent to insert that for the record in its entirety.

224 Mr. {Pitts.} Without objection, so ordered.

225 Ms. {Baldwin.} Thank you. But I did want to point out
226 that earlier this year I introduced a bipartisan bill called
227 the Critical Care Assessment and Improvement Act with my
228 colleague from Minnesota Erik Paulsen. The bill seeks to
229 identify gaps in the current critical care delivery model and
230 bolster our capabilities to meet future demands. I am
231 hopeful that we will be able to incorporate some of the
232 relevant provisions of that act into the Pandemic and All-
233 Hazards Preparedness Act as we look towards that
234 reauthorization. And in that vein I look forward to working
235 with my colleagues on both sides of the aisle to do so as
236 this legislation moves forward.

237 Again, Mr. Chairman and Mr. Pallone, thank you so much
238 for holding this bipartisan hearing. I yield back.

239 [The prepared statement of Ms. Baldwin follows:]

240 ***** COMMITTEE INSERT *****

|
241 Mr. {Pitts.} The chair thanks the gentlelady and now
242 recognizes the chairman of the full committee, Mr. Upton, for
243 5 minutes.

244 The {Chairman.} Well, thank you, Mr. Chairman. And
245 first I want to congratulate you and your wife on 50 years of
246 bliss tomorrow. Formally, 50 years. Yeah. I also want to
247 thank you for holding today's hearing on bioterrorism,
248 controlled substances, and public health legislation. I look
249 forward to hearing from the witnesses on these important
250 pieces of legislation, particularly our good friend, Mr. Dent
251 of Pennsylvania.

252 Congressman Mike Rogers--the good Mike Rogers--recently
253 introduced H.R. 2405, the Pandemic and All-Hazards
254 Preparedness Act of 2011. This bill reauthorizes provisions
255 of the Project Bioshield Act of '04 and Pandemic and All-
256 Hazards Preparedness Act of '06, laws we passed in the wake
257 of September 11 to build the Nation's health infrastructure
258 and foster the development of medical countermeasures so the
259 Nation could better respond to terrorist attack.

260 Congressman Dent introduced H.R. 1254, the Synthetic
261 Drug Control Act, to prohibit the sale of synthetic drugs
262 that imitate the effects of drugs like marijuana, cocaine,
263 and other methamphetamines. These synthetic drugs are

264 certainly just as harmful and dangerous as those drugs, but
265 due to a loophole in the law they are not illegal. This bill
266 solves that problem.

267 Finally, the Enhancing Disease Coordination Activities
268 Act of 2011 would improve the coordination of research and
269 other activities conducted or supported by HHS. Inspired by
270 the success of the Interagency Autism Coordinating Committee,
271 the bill would allow the HHS secretary to establish
272 committees that coordinate research and other activities on
273 specific diseases and conditions. The bill also would enable
274 the HHS secretary to conduct a review of existing, disease-
275 specific committees at HHS to determine the benefits of
276 maintaining them. So as I said at last week's hearing, we
277 must find a way to have our agencies work better together
278 with a common strategic vision, and I think these bills do
279 that.

280 I yield the balance of my time to Dr. Burgess.

281 [The prepared statement of Mr. Upton follows:]

282 ***** COMMITTEE INSERT *****

|
283 Dr. {Burgess.} I thank the chairman for yielding.

284 I appreciate the fact that we are having a legislative
285 hearing, and certainly I hope the committee will move
286 expeditiously on all three.

287 Let me comment, because of the briefness of the time, on
288 the Pandemic and All-Hazards Preparedness Act of 2011. This
289 program was launched after the terrorist attacks in 2001 and
290 set the framework for new medical countermeasures to respond
291 to any attacks in the future. This program encourages and
292 spurs market entry and competition and ingenuity into the
293 private market. In the aftermath of an attack, we need to be
294 assured that there is an adequate supply of countermeasures
295 for the Strategic National Stockpile, and this program helps
296 to accomplish that goal.

297 I certainly want to thank Congressman Rogers from
298 Michigan for his hard work on this legislation, for his
299 willingness to walk through the shallow of the valley of
300 death, literally, and move this bill along. I also want to
301 thank him for his inclusion of H.R. 570, the Dental Emergency
302 Responders Act, which provides clear authority for dental
303 professionals to participate in supporting medical and public
304 health measures in response to disasters.

305 So I certainly look forward to working with the chairman

306 and to Mr. Rogers on this bill and see to the passage of H.R.
307 2405 as well as the other bills before us. I will be happy
308 to yield any time I have remaining to any other member on the
309 Republican side who wishes to comment or an opening
310 statement. If not, Mr. Chairman, I will yield back to you.

311 [The prepared statement of Dr. Burgess follows:]

312 ***** COMMITTEE INSERT *****

|
313 Mr. {Pitts.} The chair thanks the gentleman and now
314 recognizes the ranking member of the full committee, Mr.
315 Waxman, for 5 minutes.

316 Mr. {Waxman.} Thank you, Mr. Chairman, for holding
317 today's hearing on three important pieces of public health
318 legislation, H.R. 2405, the Pandemic and All-Hazards
319 Preparedness Reauthorization Act of 2011; H.R. 1254, the
320 Synthetic Control Drug Act of 2011; and the soon-to-be-
321 introduced Enhancing Disease Coordination Activities Act of
322 2011. I am pleased that we have once again come together on
323 a bipartisan basis to move forward with these bills.
324 Although our work is not quite complete, I feel confident
325 that we will work out the substance of these bills for
326 further discussion.

327 I want to thank you, Mr. Chairman, and your staff, as
328 well as all the members of the subcommittee for working with
329 us to make this happen. This bipartisan approach has been
330 the foundation upon which each of the proposals we will
331 discuss today have been developed.

332 The Pandemic and All-Hazards Preparedness
333 Reauthorization Act reauthorizes programs and activities
334 first established in the 2004 Project Bioshield Act. These
335 programs are critically important to help ensure that our

336 Nation is well prepared to successfully manage the effects of
337 natural disasters, infectious disease outbreaks, and acts of
338 bioterrorism. In reauthorizing these programs and
339 activities, there are a number of issues we are exploring and
340 would like to hear about during today's hearing. In my view,
341 surge capacity, the ability of our healthcare system to
342 respond to mass casualty emergencies and biosurveillance--the
343 ability to detect natural or manmade hazardous or natural
344 events as soon as possible--deserves special attention, so
345 does the state and local public health infrastructure needed
346 to support these kinds of efforts.

347 The role of the FDA in dealing with various public
348 health emergencies of great enormity is especially critical.
349 I have concerns about the new Regulatory Management Plan that
350 is proposed in 2405, but I believe we can achieve the balance
351 necessary to make certain that the communications process
352 functions as it should--on the one hand, allowing FDA the
353 flexibility it needs to deal with regulatory science issues
354 of great complexity; on the other, we should also consider
355 the idea of allocating some of the Bioshield funds to FDA in
356 support of its Countermeasure Review Process. This approach
357 would allow FDA's work to complement the efforts of both NIH
358 and BARDA. Clearly, we cannot permit resource constraints to
359 stand in the way of FDA's ability to complete its reviews,

360 putting in potential jeopardy the entire Bioshield
361 enterprise.

362 Other subjects we would want to look at include the
363 unique needs of children in disasters, an issue that
364 Congresswoman Eshoo has been championing, the
365 administration's Strategic Investor Proposal. And like the
366 other issues I have just mentioned, I am confident that all
367 these matters will be resolved in a bipartisan negotiation.

368 Let me now speak briefly about the two other bills in
369 our hearing today: the Synthetic Drug Control Act adds
370 specified synthetic versions of drugs abused to Schedule 1.
371 These designer drugs can be very unsafe causing convulsions,
372 anxiety attacks, and dangerously elevated heart rates, among
373 other conditions. This bill would enable the Drug
374 Enforcement Agency to take appropriate enforcement actions to
375 get them off the street and away from our Nation's youth.

376 Finally, the Enhancing Disease Coordination Activities
377 Act provides direct authority to the secretary of HHS to
378 establish disease-specific interagency coordination
379 committees and lays out the parameters for these committees.
380 This will be modeled on the highly successful interagency
381 Autism Coordinating Committee, which we learned about in last
382 week's hearing.

383 Again, I want to thank you, Mr. Chairman and the members

384 of the subcommittee for cooperation with which we have worked
385 on all three bills under consideration. I look forward to
386 the hearing today and to working out our issues. And I have
387 less than a minute if anybody on our side would like a
388 minute? If not, I yield back the time.

389 [The prepared statement of Mr. Waxman follows:]

390 ***** COMMITTEE INSERT *****

|

391 Mr. {Pitts.} The chair thanks the gentleman. That
392 concludes the members' opening statements. I would like to
393 thank all the witnesses on both panels for agreeing to appear
394 before the committee today. We will go to Panel I.
395 Congressman Charlie Dent represents Pennsylvania's 15th
396 Congressional District. He is the author of H.R. 1254, the
397 Synthetic Drug Control Act. Representative Dent, you may
398 begin your prepared testimony.

|
399 ^STATEMENT OF HON. CHARLES DENT, A REPRESENTATIVE IN CONGRESS
400 FROM THE STATE OF PENNSYLVANIA

401 } Mr. {Dent.} First, I want to thank the committee and
402 the subcommittee. Thank you, Chairman Pitts, Ranking Member
403 Pallone, Chairman Upton, Ranking Member Waxman, for this
404 opportunity to talk to you today about this very important
405 issue.

406 Now, it was a little under a year ago at this time that
407 the issue of synthetic drugs or designer drugs was first
408 brought to my attention by a constituent named Alana
409 Marshall, whose son had been abusing legal substitutes for
410 marijuana. And in fact, just a couple of months ago I went
411 to the Children's Hospital of Philadelphia where they had
412 seen very little of this issues in synthetic drugs, bath
413 salts, et cetera, and now they are seeing a case every single
414 day. That is how prevalent this has become in such a very
415 short period of time.

416 These synthetic cannabinoids affect the brain in a
417 manner similar to marijuana, but they can actually be much
418 more harmful. Synthetic marijuana or cannabinoids are just
419 one category of designer drugs. Even more potent substances
420 have properties similar to cocaine, methamphetamine, LSD, and

421 other hard street drugs. These substances are marketed as
422 innocent products like bath salts, plant food, incense, and
423 they are sold under brand names familiar to their users such
424 as K2 Spice, Vanilla Sky, Ivory Wave, but these are total
425 misnomers. They are designed to facilitate their legal sale.
426 These drugs have really no legitimate purpose. And these
427 bath salts, by the way, are things you would never put in
428 your tub. Some people are confused by that that actually
429 think they are what people put in their tub. That is not the
430 case at all.

431 Over the past year, there has been a sharp increase in
432 the number of reports detailing horrific stories of
433 individuals high on synthetic drugs. A man in Scranton,
434 Pennsylvania, stabbed a priest and another jumped out a
435 three-story window. Both were high on bath salts. Several
436 deaths from West Virginia to Florida have been attributed to
437 overdoses of synthetic drugs. Senator Grassley of Iowa has
438 introduced a bill with provisions similar to the one in this
439 one, H.R. 1254, named after one of his young constituents who
440 tragically took his own life while high on synthetic
441 marijuana. A man in my district was arrested this past May
442 for firing a gun out of a window in a university
443 neighborhood. The police charges indicate that the
444 individual injected himself with bath salts and he later told

445 the police he thought there were people on the roof watching
446 him.

447 Finally, you know, I was approached by another
448 distraught mother from my district whose son was hospitalized
449 for over 2 weeks after suffering liver failure and other
450 complications after injecting himself with bath salts. These
451 substances pose a substantial risk both to the physical
452 health of the user as well as to the safety of those around
453 them when these drugs contribute to dangerous psychotic
454 behavior, suicide, and public endangerment. The fact that
455 these drugs are legal in many States contributes to the
456 misconception that they are safe and the use of these easily
457 recognizable brand names and logos on the packaging promotes
458 the concept of a consistent product. Significant variation
459 of potency from one unit to the next has led recurrent users
460 to inadvertently overdose.

461 You know, and one of the major difficulties in combating
462 these designer drugs is the ability of the producers to skirt
463 the law with different chemical variations. You know, by
464 modifying the formula in some minor way, producers can
465 generate a new compound which circumvents legal prohibitions
466 but has similar narcotic events. And that is why we have
467 H.R. 1254, this Synthetic Drug Control Act of 2011, and we
468 drafted this in consultation with other law enforcement

469 officials, particularly the DEA, and this legislation has
470 three principle components: prohibition of broad structural
471 classes of synthetic marijuana or the cannabinoids;
472 prohibition of other designer drugs such as bath salts--that
473 is methylenedioxypropylone (MDPV) and others--and there is
474 an expansion of the DEA's existing authority temporary ban of
475 substance from 1-1/2 to 3 years. And that is very, very
476 significant, that additional time.

477 Under current law, if the DEA and the Department of HHS
478 can prove that a substance is dangerous, that is important,
479 but they also are lacking in legitimate value while it is
480 temporarily banned. So the prohibition becomes extremely
481 important. I can't emphasize this enough, this authority for
482 DEA. You know, I should mention, too, that there are a lot
483 of States out there right now to pass laws. Pennsylvania, my
484 State, just passed a law last month that had banned many
485 forms of these synthetic drugs, but federal action is
486 certainly necessary to prevent these drugs from being
487 obtained by simply crossing state lines or increasingly
488 ordering them over the internet.

489 And I think every state representative on this panel--
490 except Ohio, but Representative Latta will fix that--has
491 enacted laws restricting some synthetic drugs in one form or
492 another. So all your States have already taken some action,

493 and that I think you should be commended. So Texas,
494 Michigan, Kentucky, New Jersey, Illinois, New York, North
495 Carolina, Georgia, Wisconsin, Washington State, you know,
496 they are all really taking some action--Louisiana, Arkansas,
497 Utah. So state-by-state differences in which individual
498 substances are controlled and how strongly makes for a
499 confusing legal patchwork, and this bill will provide for a
500 national ban on these dangerous drugs.

501 You know, as we speak, the Senate Judiciary Committee
502 right now is marking up a companion synthetic drug
503 legislation, and so I really would encourage this
504 subcommittee, then the full committee to take up H.R. 1254 as
505 soon as possible and report it. I do really appreciate this.
506 This is a very serious public health issue and it is just
507 getting worse by the day. These drugs come into this country
508 usually by Europe, start in Asia, head to Europe, so we
509 usually have a good idea of what is coming here. The DEA is
510 on top of this but they really do need this additional
511 authority. And again, I appreciate your consideration.

512 Thank you again, Chairman Pitts, Ranking Member Pallone.

513 [The prepared statement of Mr. Dent follows:]

514 ***** INSERT 1, 2 *****

|
515 Mr. {Pitts.} The chair thanks the gentleman for his
516 testimony and thanks him for his leadership on the issue. We
517 look forward to working with you on the legislation. And you
518 may be excused at this time.

519 And we will call Panel II to the witness table. Our
520 second panel consists of two witnesses. Dr. Nicole Lurie is
521 the Assistant Secretary for Preparedness and Response of the
522 Department of Health and Human Services; and our second
523 witness, Dr. Howard Koh, is the Assistant Secretary for
524 Health of the Department of Health and Human Services. Thank
525 you for coming this morning. Dr. Lurie, you may begin your
526 testimony.

|
527 ^STATEMENTS OF DR. NICOLE LURIE, ASSISTANT SECRETARY FOR
528 PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND
529 HUMAN SERVICES; AND DR. HOWARD K. KOH, ASSISTANT SECRETARY
530 FOR HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

|
531 ^STATEMENT OF DR. NICOLE LURIE

532 } Dr. {Lurie.} Good morning, Chairman Pitts and Ranking
533 Member Pallone and distinguished members of the subcommittee.

534 In 2006, the Congress understood the critical need to
535 strengthen our public health and medical preparedness
536 activities enacting the Pandemic and All-Hazards Preparedness
537 Act, or PAHPA as it is affectionately known. Recent events
538 remind us of the significant challenges that we continue to
539 face from ever-present and always-evolving terrorist threats
540 to unprecedented natural emergencies and how quickly and
541 unpredictably the call comes to respond and support the
542 American people.

543 Within HHS, PAHPA established the Assistant Secretary
544 for Preparedness and Response as the lead in coordinating
545 federal health response to disasters. In 2009, I had the
546 privilege of being asked to lead ASPR, a still-young
547 organization with a vital mission to lead the country in

548 preparing for, responding to, and recovering from the adverse
549 health effects of emergencies and disasters. And since that
550 time, ASPR has risen to the challenge in the face of
551 unprecedented events. As we responded, capturing lessons
552 learned along the way, we kept careful note of where
553 legislative changes would enhance our response to efforts in
554 the future. I would like to take a few minutes now to walk
555 you through some of them.

556 The H1N1 pandemic tested our ability to adapt and
557 respond to a novel influenza strain and required all parts of
558 the healthcare, public health, and response systems to work
559 together and to innovate. One of the most important lessons
560 learned came from seeing that at every step along the way we
561 needed to be able to rapidly get resources to where they
562 needed to go. Consequently, we are interested in authority
563 to temporarily allow States to reassign certain HHS-funded
564 personnel to critical areas of need during a public health
565 emergency.

566 Both H1N1 and the Japanese nuclear crisis demonstrated
567 the importance of getting countermeasures to those who need
568 them as quickly as possible. Often the speed with which
569 countermeasures are administered is the difference between
570 life and death, and so we would like the authority to issue
571 Emergency Use Authorizations, or EUAs, prior to an event.

572 This would minimize delays in making critical countermeasures
573 available when needed.

574 In addition, clarifying FDA's authorities to extend the
575 timeline for safe and effective products through the Shelf-
576 Life Extension Program will facilitate using these products
577 when needed and will make investments go further helping save
578 taxpayer dollars on replacement costs and stockpiling
579 practices.

580 We have been successful in developing promising safe and
581 effective medical countermeasures and the Bioshield Program
582 has indeed been a critical tool. As demonstrated by the
583 language included in H.R. 2405, your continued support to
584 this program is a clear commitment to the Nation's
585 preparedness.

586 I would want to highlight that we embrace the whole-
587 community approach articulated by FEMA, particularly in
588 planning for all at-risk individuals. In the countermeasure
589 arena, we have become very aggressive about pursuing medical
590 countermeasure products for children.

591 The secretary's Medical Countermeasure Enterprise Review
592 recognized that to achieve a modern and flexible enterprise
593 that can quickly develop and produce safe and effective
594 products, we must strengthen each of the enterprise's major
595 components. One recommendation, the Strategic Investor

596 Initiative, will support and accelerate the activities of
597 companies that have innovative products while reducing the
598 probability that the companies will fail because of their
599 inability to manage their business risks.

600 H.R. 2405 reauthorizes two critical elements of our
601 preparedness enterprise: the Hospital Preparedness and the
602 Public Health Emergency Preparedness Cooperative Agreement
603 Programs. When I visited Missouri after Joplin and witnessed
604 the ongoing response and recover efforts from the tornadoes
605 in May and similarly with the tornadoes in the South before
606 that, it was again clear to me why we need both medical care
607 and public health capabilities.

608 A central priority for me is the alignment of these two
609 programs, as well as similar grant programs throughout the
610 government to efficiently use limited resources, eliminate
611 duplicative or conflicting programmatic guidance, and reduce
612 the administrative burden for grantees. We anticipate that
613 the PHEP and HPP programs will be aligned in time for the
614 2012 Grant Guidance. Reauthorizing other programs, including
615 BARDA, the Medical Reserve Corps, the National Disaster
616 Medical System, and the Emergency System for the Advanced
617 Registration of Volunteer Healthcare Personnel will ensure
618 investments continue to support and foster resilient
619 communities.

620 As identified in the original PAHPA legislation, HHS and
621 specifically ASPR has the lead for coordinating the federal
622 health response efforts during public health emergencies. In
623 my time as serving as assistant secretary, ASPR has
624 strengthened its leadership role within HHS as well as
625 nationally. Along with our federal partners, we have
626 improved our coordination of preparedness and response
627 operations, and we have also gotten better at how we
628 coordinate. Our continued progress and improvements along
629 with clarifying and strengthening authorities that I have
630 talked about today will ensure ASPR and HHS have the tools
631 necessary to protect the Nation against public health
632 threats.

633 We applaud Congress' leadership and vision for enacting
634 PAHPA as the foundation for effective response and recovery
635 to public health emergencies, and I look forward to working
636 with you as PAHPA is reauthorized in this congressional
637 session. Thank you.

638 [The prepared statement of Dr. Lurie follows:]

639 ***** INSERT 3 *****

|

640 Mr. {Pitts.} The chair thanks the gentlelady.

641 Dr. Koh, you are recognized for your opening statement.

|
642 ^STATEMENT OF DR. HOWARD K. KOH

643 } Dr. {Koh.} Thank you very much, Chairman Pitts, Ranking
644 Member Pallone, and distinguished members of the committee.
645 I am Dr. Howard Koh, the Assistant Secretary for Health for
646 HHS and I am very pleased to be here to testify on the
647 legislation entitled ``Enhancing Disease Coordination
648 Activities Act of 2011.''

649 As the Assistant Secretary for Health, I have the honor
650 of overseeing some 14 core public health offices, 10 regional
651 health administrators and their staffs, and 10 secretarial
652 and presidential advisory committees. Collectively, our
653 Office of the Assistant Secretary for Health implements an
654 array of interdisciplinary programs relating to ensuring the
655 Nation's public health. And in fact our portfolio includes
656 programs in many areas such as disease prevention, health
657 promotion, women's health, minority health, adolescent
658 health, vaccines, fitness, sports, and nutrition, human
659 research protection, among other areas. The mission
660 statement of our offices in fact is ``Mobilizing leadership
661 in science and prevention for a healthier Nation.''

662 We are very proud of this mission and we are very proud of the
663 efforts of the Department all public health colleagues in

664 fact in helping all Americans reach their highest attainable
665 standard of health.

666 So in that context, I am very pleased to add some
667 comments about the draft legislation here before us to
668 improve the coordination of research and other activities
669 conducted or supported by HHS that are specific to a disease
670 or condition. I thought it would be useful to share our
671 experience in coordination efforts at HHS because over recent
672 months, our office has helped put forward strategic plans in
673 coordination in a number of areas including tobacco, HIV,
674 racial-ethnic disparities, viral hepatitis, vaccines,
675 multiple chronic conditions, health literacy, and other
676 areas.

677 I would like to focus on one particular plan as an
678 example of our coordination efforts at the Department and
679 that has to do with tobacco. As you all know, tobacco
680 addiction is one of the most troubling public health
681 challenges of our time, and in fact in the 21st Century it is
682 forecast that tobacco use globally will cause some one
683 billion preventable deaths. And that is a stunning fact that
684 demands our attention and our action.

685 So to address this public health challenge, the
686 Department last year released its first-ever comprehensive
687 tobacco control strategy called ``Ending the Tobacco

688 Epidemic: A Tobacco Control Strategic Plan.' ' This process
689 in fact began in the spring of 2010 when the secretary
690 charged me to convene a coordinating committee across the
691 Department consisting of leaders from every agency to
692 inventory the activities and efforts that were underway and
693 then leverage them together to have maximum impact with our
694 current resources. And we were very pleased to unveil that
695 plan last fall with activities focused on four pillars:
696 engaging the public, supporting state and local efforts,
697 advancing research, and having HHS lead by example.

698 I am very pleased to report to this committee that
699 already we have seen some results accomplished that would not
700 have been possible without this high level of coordination
701 and collaboration. For example, just several weeks ago on
702 July 1, the secretary announced that HHS was now completely
703 tobacco-free. And also in recent weeks our Centers for
704 Medicare and Medicaid Services (CMS) has released formal
705 guidance on the Affordable Care Act's expansion of smoking
706 cessation benefits for pregnant women enrolled in Medicaid.
707 Also, CMS has formally announced new options for Medicaid
708 beneficiaries such that administrative reimbursement for quit
709 lines could be put forward. So that is a very important
710 resource to help smokers quit.

711 We are also pleased to report that this action plan has

712 garnered a lot of support from the general community. For
713 example, just last week, there was a scientific report
714 released showing a significant decrease in smoking in the
715 movies, which contributes to changing the social norm about
716 this very important public health issue. That report cited
717 the HHS tobacco action plan as an example of bringing more
718 attention to mass media efforts around tobacco control as
719 well. So we look forward to presenting more progress on
720 plans like tobacco and many others as an example of our
721 commitment to collaboration and coordination.

722 The draft legislation here today--`Enhancing Disease
723 Coordination Activities of 2011'`--recognizes that important
724 role of cross-departmental coordination and collaboration,
725 and we want to thank the committee for your thoughtfulness
726 and insight in putting that effort forward. I should note,
727 however, that Section 222 of the Public Health Services Act
728 already has the secretary with the authority to create
729 advisory councils and committees and appoint members to those
730 groups. So with that authority, the Department has
731 established a number of advisory committees which allow the
732 Department to get input from external experts and then also
733 allows for the public to engage in the work and policy-
734 development process that occurs at the Department.

735 The proposed legislation supports very strongly the

736 efforts of coordination collaboration and that spirit, but I
737 do want to note that it may introduce some unintended
738 redundancies. For example, the legislation requires that
739 each coordination committee have a strategic plan every 2
740 years and update that plan every 2 years. And under the
741 current structure, we have our advisory committees
742 establishing their own priorities and updating plans on a
743 flexible schedule, so the bill's requirement for an every-
744 two-year timetable could take away time and resources that
745 could be better used for implementation.

746 Another area I do want to mention is potential costs to
747 the Department that could be associated with this
748 legislation. The Department already commits significant
749 resources to existing advisory committees and having to spend
750 even more funds on many more committees could potentially
751 take away dollars from other important endeavors and
752 potentially represent duplication of efforts.

753 So in closing, I want to thank the committee for its
754 recognition and promotion of the important role that cross-
755 agency collaboration and coordination play in developing
756 strong policy. I would urge the committee to take into
757 account the current system that exists and I believe works
758 well at HHS for establishing and managing advisory groups.
759 And as always, we at the Department look forward to working

760 closely with you on many, many important areas in public
761 health. Thank you very much and, of course, I am happy to
762 take any questions on these issues.

763 [The prepared statement of Dr. Koh follows:]

764 ***** INSERT 4 *****

|
765 Mr. {Pitts.} The chair thanks the gentleman and thanks
766 both of our witnesses for your testimony. I will now begin
767 the questioning and recognize myself for 5 minutes for that
768 purpose.

769 We begin, Dr. Lurie, with you. Congress enacted the
770 Project Bioshield Act of 2004 and the Preparedness and All-
771 Hazards Preparedness Act of 2006 to build the Nation's
772 preparedness infrastructure and foster the development of
773 chemical, biological, radioactive, and nuclear medical
774 countermeasures so the Nation could better respond to
775 attacks. Would you please expand on your comments on how
776 these laws have helped prepare our Nation?

777 Dr. {Lurie.} Certainly. Thanks for that question.

778 As I think we know, the development of medical
779 countermeasures has been a particularly vexing problem
780 because there is by and large not a commercial market for
781 these products. So through these laws, we have a) provided
782 funding to develop these countermeasures, b) provided the
783 assurance that the Federal Government will be a good partner
784 and will purchase these products if in fact private companies
785 come to make them. In doing all of this work and through the
786 enterprise, over time we have continued to strengthen our
787 efforts both to identify what needs to be developed, to

788 identify how it is developed, to strengthen our work with
789 developers and companies, and now to move forward to
790 coordinate the efforts with BARDA in the lead, with FDA, CDC,
791 NIH, and BARDA so that we now have a much more seamless
792 process for countermeasure development.

793 At the end of the day, however, this stuff takes a long
794 time, it is really expensive, and we have an obligation to
795 the American people to be sure we are prepared. When we
796 started all of this and when you all decided to help cross
797 this so-called ``valley of death,' ' we had almost no products
798 in the development pipeline. Now, I am proud to say we have
799 over 70 CBRM products in development and a slue more in the
800 flu area and we have moved forward to procure a number of
801 countermeasures for the Strategic National Stockpile for
802 smallpox, anthrax, botulism, red nuke threats, et cetera. I
803 could go on and on.

804 Mr. {Pitts.} Thank you. Your position, the Assistant
805 Secretary for Preparedness and Response, was created in the
806 Pandemic and All-Hazard Preparedness Act of 2006 to lead the
807 oversight and coordination of the entire medical
808 countermeasure enterprise through HHS. Would you give us
809 your insight on the challenges you have faced in leading this
810 enterprise, what we can do to help you in your position, and
811 in the aftermath of the natural disasters and pandemics of

812 the past few years, can you describe some of the challenges
813 that you and your staff have faced, especially related to
814 coordination, flexibility, and communication?

815 Dr. {Lurie.} Great. No, I very much appreciate that
816 question as well. You know, I came into this position early
817 on in H1N1 and the importance of coordinating across all of
818 HHS was terribly important, whether it was our public health
819 response or our healthcare response or our countermeasure
820 response, all of those things kneaded together. So through
821 my office and because of the authorities of my office, we
822 have been able in a very regular way to pull together all of
823 the parties end to end on the countermeasures side and
824 through the response side to be sure everybody is working
825 together.

826 You know, as do we all, some of the programs are at CDC,
827 some of the programs are at HRSA, some of the programs are at
828 NIH or FDA, and we all meet together under my leadership to
829 identify gaps and to solve problems. I do sit on the
830 secretary's Budget Council. I do have the opportunity to
831 review and provide input into the budget process through that
832 mechanism.

833 An area that has worked particularly well has been the
834 PHEMCE, or the Public Health Emergency Countermeasures
835 Enterprise, which I lead and chair. And again, through the

836 Medical Countermeasure Review, we have really enhanced the
837 coordination of all of the parties so that now everybody sits
838 at the table and sits at the table with product developers at
839 the beginning, identifies the plan, identifies the gaps, and
840 works together going forward. I would also comment that DOD
841 and DHS participate in this, so our role coordinating there
842 is much broader in fact than just at HHS.

843 Similarly, on the healthcare delivery system side where
844 we have responsibilities as Mr. Waxman pointed out for
845 medical surge and for working through issues in the emergency
846 care system, we coordinate and work closely with our
847 colleagues at CDC and HRSA and CMS, the National Disaster
848 Medical System and Hospital Preparedness Programs, you know,
849 being two major centerpieces of those.

850 Mr. {Pitts.} Thank you. My time has expired. I yield
851 to the ranking member of the subcommittee, Mr. Pallone, for 5
852 minutes for questions.

853 Mr. {Pallone.} Thank you, Mr. Chairman.

854 Dr. Koh, if I could start with you, you noted in your
855 testimony that under Section 222 of the Public Health Service
856 Act, the secretary already has the authority to create
857 advisory councils and other committees and to appoint
858 members. As I understand it, the intent of the Enhancing
859 Disease Coordination Activities Act, which is before us

860 today, is not to duplicate that authority but rather to
861 outline the structure and functions of committees' focus on
862 coordinating a specific disease or health condition. The
863 provisions of that bill are modeled on those in the Autism
864 Coordinating Committee, and as we heard in our hearing last
865 week, that has been very successful.

866 So as we consider this new bill, I wanted to be sure
867 that if and when the secretary elects to establish another
868 disease-related coordinating committee that it operates in an
869 effective and productive way. So based on the experiences
870 you shared in your testimony, are there certain elements of
871 success that have gone into these efforts that should be
872 reflected in the legislation?

873 Dr. {Koh.} Well, thank you for that question,
874 Congressman, and also thank you for your commitment to public
875 health in general.

876 So as I mentioned, we always review the landscape in
877 terms of evolving public health challenges in a magnitude of
878 new issues and then assess the resources and the
879 responsibilities of the various parts of HHS and see how we
880 can coordinate that to the best of our ability. In the
881 examples I cited, many of these had strategic plans which
882 were very, very valuable because it explicitly put forward
883 the resources we had agency by agency and also put forward

884 common goals and measures by which we would work together and
885 measure success. So that is an effort that I think has been
886 very, very valuable in many of the areas that I have pointed
887 out. And in the interagency Autism Committee, there is an
888 excellent strategic plan that has also been developed with
889 goals and targets that is being followed. So I think the
890 more explicit the coordination and the goal-setting is, that
891 is a major element of success moving forward.

892 Mr. {Pallone.} Now, let me ask Dr. Lurie, my colleagues
893 on the subcommittee--most notably Representative Eshoo--have
894 some concerns that the current programs do not adequately
895 address the needs of the pediatric population and would like
896 to see some enhancements that would assist in the Nation's
897 ability to care for kids in the event of a public health
898 emergency. Kids make up 25 percent of the Nation's
899 population, so it only seems natural to me that we should
900 prepare for their unique needs in the case of an emergency or
901 disaster. So in that regard, I would like to issue some
902 questions.

903 First, is the Strategic National Stockpile adequately
904 stocked for pediatric populations? If not, how can the
905 Pandemic and All-Hazards Preparedness Act before us today be
906 strengthened to ensure that the SNS has adequate supplies for
907 pediatric populations? And we will start with that, but I

908 have got three questions.

909 Dr. {Lurie.} Sure. I think those are great questions.
910 And you know, when I came into this position, I came in
911 facing a pandemic that a) was primarily killing children, and
912 b) I came into it as a mom and looked at this set of issues
913 that relate to strengthening our ability to respond to
914 pediatric issues in all areas. Since this experience, we
915 have done a number of things to strengthen our pediatric
916 footprint. We have hired pediatricians within BARDA and we
917 have also hired and brought on a chief medical officer to
918 really pay attention to the countermeasure development needs.
919 In addition, we have developed a pediatric NOB, interagency
920 workgroup that advises now each stage of development for
921 countermeasure requirement-setting all the way through
922 development and procurement so that we strengthen the
923 pediatric footprint there.

924 And finally, I have directed my staff to look at every
925 new contract we let to be sure that the development of
926 pediatric countermeasures is there from the get-go so we now
927 have a smallpox antiviral contract that supports pediatric
928 formulation, the new advanced research and development
929 contracts for new broad-spectrum antimicrobials, support
930 pediatric populations. We have funded the development of the
931 palatability studies so that we can--

932 Mr. {Pallone.} Well, let me finish this because my time
933 is almost up.

934 Dr. {Lurie.} Yeah.

935 Mr. {Pallone.} Is there anything that we don't have in
936 the law that would prevent you from integrating kids into the
937 national preparedness goals? Is there something that we need
938 in the law?

939 Dr. {Lurie.} I tried to think hard about that because I
940 am always a big fan of getting the authorities we need. My
941 view right now is that we have made enormous progress with
942 the authorities we have and there doesn't seem to be anything
943 in the way for me or us continuing to make more progress in
944 these areas. At the end of the day, I will point out that
945 pediatric countermeasures are expensive to develop and test
946 and the market issues there are like the market issues in the
947 rest of the countermeasures sphere but more profound. So
948 from an authorization perspective, I feel like I have what I
949 need.

950 Mr. {Pallone.} Mr. Chairman, I know that time has run
951 out but just when she was saying she was hiring those
952 pediatricians, all I kept thinking was that we better pass
953 our bill with the Graduate Medical, the GMEs, otherwise there
954 won't be any physicians to hire.

955 Mr. {Pitts.} I was thinking the same thing.

956 Dr. {Lurie.} There we go.

957 Mr. {Pitts.} The chair thanks the gentleman and
958 recognizes the vice chairman of the committee, Dr. Burgess,
959 for 5 minutes for questioning.

960 Dr. {Burgess.} Thank you, Mr. Chairman. And Dr. Lurie,
961 thank you for being here. Thank you for helping our office
962 when you first took your position and the H1N1 was clearly
963 making its presence felt in the State of Texas. We felt it
964 acutely. Appreciate the efforts from your office to help us
965 discuss that with the Fort Worth Independent School District
966 during the summer. You were concerned about kids; I was
967 concerned about pregnant women, schoolteachers in particular
968 who would be exposed to large numbers of children during the
969 beginning of the next school year. And it is one thing to
970 close down the schools in May; it is another thing to close
971 them down in September where so much instructional time could
972 be lost in the year going forward. And although, certainly,
973 I know there have been criticisms about how all of that was
974 handled. I think it certainly could have been much more
975 disruptive than it was, and I think that is largely due to
976 your efforts.

977 The issue of pediatric dosages being available was
978 something I became acutely aware of when contacted by the
979 Tarrant County Health Department that they did not have

980 antivirals available in children's doses and were simply
981 having to make it up as they went along, and that is clearly
982 uncomfortable.

983 I have got some questions for you about the National
984 Strategic Stockpile. I need to set it up a little bit so
985 bear with me. In July of 2010, I sent a letter to the
986 National Strategic Stockpile, myself and Joe Barton as the
987 ranking member of the full committee and Subcommittee on
988 Oversight and Investigations talking about the preparedness
989 through the National Strategic Stockpile. Ten items were in
990 that letter. Number five was dealing with the stockpile's
991 ability to deliver threat-appropriate materials in the event
992 of something that required national activation. So we were
993 interested in the methods to secure delivery of threat-
994 appropriate materials from both domestic and foreign
995 manufacturing sites in the stockpile activation. The
996 material provided back to me by Dr. Friedan of the CDC on
997 issue number five detailed some of the things that they were
998 doing.

999 As part of that response, Dr. Friedan referenced the
1000 Executive Order 12919, that HHS with the approval of DHS and
1001 FEMA may utilize the Defense Production Act authority with
1002 respect to health resources. That is pretty broad authority.
1003 Essentially, the Federal Government could take over those

1004 things if necessary at the time of a national emergency. But
1005 then the question comes up, you know, we have authority over
1006 foreign manufacturers and we do rely on foreign manufacturers
1007 for materials, masks, gloves, active pharmaceutical
1008 ingredients for some of these materials. So, again, the
1009 question, then, can you give us a description of how your
1010 office coordinates the movement and delivery of special
1011 medical countermeasures to ensure the delivery of threat-
1012 appropriate materials in the event of a National Stockpile
1013 activation? That is one.

1014 And the second is in the event of a global pandemic, can
1015 you assure the committee that there are the resources
1016 available to ensure threat-appropriate materials will be able
1017 to be disseminated among the population?

1018 Dr. {Lurie.} Great. Well, thank you for both the set
1019 up and for the question. But first, let me also thank you
1020 for your leadership during the pandemic and your leadership
1021 both with the pediatric and the OB community. I think
1022 largely because of your efforts in highlighting this issue,
1023 we now have record numbers of pregnant women vaccinated for
1024 influenza. I think it has made a huge difference. It also
1025 led us to think very hard about including OB issues in this
1026 pediatric interagency working group so that we are sure that
1027 we really nail those issues for both the pregnant women and

1028 children as we develop countermeasures moving forward.

1029 Dr. {Burgess.} Mr. Chairman, let me just ask unanimous
1030 consent. I would like to make copies of Ranking Member
1031 Barton's and my letter available to the record as well as the
1032 response we got from Dr. Friedan. Let me get this material
1033 to you, Dr. Lurie, because this requires some thought and
1034 perhaps some research in delivering an answer. But it is
1035 important. And really the essential issue is how do we
1036 assure that we are going to be able to deliver threat-
1037 appropriate materials to the correct places? Yes, we can
1038 have broad authority in this country--

1039 Dr. {Lurie.} Yeah.

1040 Dr. {Burgess.} --but what do we do if we are getting
1041 that stuff from Mexico, the Philippines, China--fill in the
1042 blanks? And that is really my main consideration.

1043 Dr. {Lurie.} It is an important question. It is
1044 something that I think we have a number of answers to and we
1045 are continuing to work on, but I think it might use up an
1046 awful lot of time.

1047 Dr. {Burgess.} All right. We will get that to you in
1048 writing.

1049 Dr. {Lurie.} So if you want to get that to us, we will
1050 be happy to get back to you on it.

1051 Dr. {Burgess.} Dr. Koh, let me just briefly ask you.

1052 You referenced quit lines in your testimony. Is that like a
1053 1-800 number?

1054 Dr. {Koh.} I think the number is 1-800-QUIT-NOW and it
1055 is a coordinated national effort.

1056 Dr. {Burgess.} Have you done any studies to see the
1057 efficacy of a quit line as opposed to, perhaps, a medically
1058 supervised program of Chantix, Wellbutrin, or even medical
1059 hypnosis in regards to smoking cessation? I appreciate your
1060 leading by example. I think that is great that HHS is smoke-
1061 free. We need to work on the White House and the U.S. House,
1062 but those are separate considerations of leading by example.
1063 I would appreciate you helping me with that. But I would
1064 also appreciate if you could give us some information about
1065 what research you have done as to the efficacy of the quit
1066 lines as opposed to medical therapy. I was always disturbed
1067 in my practice and I was never reimbursed for helping someone
1068 with smoking cessation, and yet it might be the single-most
1069 thing that you could do to help with their future health if
1070 you could get them to quit smoking.

1071 So thank you, Mr. Chairman, for your indulgence. I will
1072 yield back.

1073 Dr. {Koh.} Thank you, Congressman. You raise many good
1074 points in your question. And first, I should say that we are
1075 very pleased at the increasing attention on prevention in

1076 general in the country and with the passage of the Affordable
1077 Care Act, there are many preventative benefits that are begin
1078 afforded to people, especially in the area of tobacco
1079 cessation and tobacco counseling.

1080 Smoking quit lines have been studied very, very
1081 carefully and in excellent randomized trials, and those
1082 studies showed the benefit have led to the expansion of quit
1083 lines across the country. And this 1-800-QUIT-NOW number
1084 that is available to anybody in the U.S., and in general, we
1085 support using all these measures together--quit line
1086 services, counseling, medications when appropriate. We want
1087 prevention to be a multi-dimensional effort so we can move
1088 people to a tobacco-free future.

1089 Mr. {Pitts.} The chair thanks the gentleman. Without
1090 objection, the letters that you have submitted will be
1091 entered into the record. So ordered.

1092 [The information follows:]

1093 ***** COMMITTEE INSERT *****

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1094 Mr. {Pitts.} And the chair now recognizes the ranking
1095 member emeritus, Mr. Dingell, for 5 minutes for questions.

1096 Mr. {Dingell.} Mr. Chairman, thank you for your
1097 courtesy. I will be focusing my questions today on the
1098 Pandemic and All-Hazards Preparedness Act. My questions will
1099 be directed to Dr. Lurie, and I would like a yes or no
1100 response if that be possible.

1101 We have made progress but we know from recent events
1102 such as the H1N1 pandemic that more of us be done to ensure
1103 our Nation's readiness to respond and recognize such events.
1104 It is also important to note, as Secretary Napolitano
1105 recently did, that one of the evolving threats to our Nation
1106 is the use of chemical, biological, or radiological devices.

1107 Now, first question, in your role as Assistant Secretary
1108 for Preparedness and Response, you have a responsibility for
1109 the preparations to address the threat of bioterrorism. Do
1110 you believe that a bioterrorism even from a biological weapon
1111 remains at or near the top of the Nation's most serious
1112 threats? Yes or no?

1113 Dr. {Lurie.} Yes.

1114 Mr. {Dingell.} Next question, do you believe that we
1115 currently have the necessary medical countermeasures
1116 stockpiled to respond to a bioterrorist event? Yes or no?

1117 Dr. {Lurie.} Not completely.

1118 Mr. {Dingell.} Okay. Would you submit to us a
1119 statement showing where you feel we need to have more of
1120 these kinds of agents stockpiled?

1121 Do you believe that the U.S. is now in a position to
1122 recognize and respond to threats such as a bioterrorist event
1123 or an emerging infectious disease outbreak similar to H1N1?
1124 Yes or no?

1125 Dr. {Lurie.} I think we have made a lot of progress.
1126 We have more ground to cover.

1127 Mr. {Dingell.} But the answer is no?

1128 Dr. {Lurie.} The answer is no.

1129 Mr. {Dingell.} Do you believe that the Congress has
1130 allocated sufficient funding to develop and procure proper
1131 medical countermeasures? Yes or no?

1132 Dr. {Lurie.} I think we have made a lot of progress.
1133 We have more to--

1134 Mr. {Dingell.} The answer is still no?

1135 Dr. {Lurie.} The answer is still no.

1136 Mr. {Dingell.} One of the greatest problems we faced
1137 during the H1N1 pandemic was delays and interruptions in the
1138 production of a vaccine, which has been an ongoing and
1139 continuing problem for many reasons. Your testimony mentions
1140 the Centers for Innovation in Advanced Development and

1141 Manufacturing as one way to increase domestic manufacturing
1142 and surge capacity for medical countermeasures. ASPR put out
1143 a request for proposals in March. How many centers will ASPR
1144 support?

1145 Dr. {Lurie.} Well, I should tell you that the deadline
1146 for submission is today. We have already been receiving
1147 submissions.

1148 Mr. {Dingell.} Would you give us, then, for the record
1149 an answer to that question?

1150 Dr. {Lurie.} Sure.

1151 Mr. {Dingell.} Now, you state in your testimony that
1152 the centers will also be available to manufacture vaccines in
1153 the event of a pandemic. Given this, will you take into
1154 consideration geographic questions when choosing where to
1155 establish these centers? Yes or no? In other words, are you
1156 going to consider geographic questions as to where you are
1157 going to locate the centers?

1158 Dr. {Lurie.} I think the most important factor to
1159 consider is whether the proposers can do the job.

1160 Mr. {Dingell.} Of course. Now, do you believe that the
1161 centers will help reduce U.S. reliance on vaccine
1162 manufacturers based overseas? Yes or no?

1163 Dr. {Lurie.} Yes.

1164 Mr. {Dingell.} Would you submit for the record a little

1165 monograph as to why you feel that would be so?

1166 Dr. {Lurie.} Certainly.

1167 Mr. {Dingell.} Do you believe that these centers will
1168 have a role in supporting small companies who have developed
1169 or are currently developing medical countermeasures? Yes or
1170 no?

1171 Dr. {Lurie.} Yes.

1172 Mr. {Dingell.} And in the case of places like the
1173 University of Michigan or other universities where they have
1174 substantial spinoffs, this would be a very big help? Do you
1175 agree?

1176 Dr. {Lurie.} Yes.

1177 Mr. {Dingell.} Now, Doctor, as you know, the Department
1178 of Defense has put out a request for proposals advanced
1179 development and manufacturing of medical countermeasures.
1180 Have you been working closely with DOD to minimize any
1181 potential duplication between these centers? Yes or no?

1182 Dr. {Lurie.} Yes. We have been working very closely
1183 from the very beginning, they with our proposal and us with
1184 them.

1185 Mr. {Dingell.} Would you submit to us, please, a brief
1186 statement as to what you are doing and how you expect this to
1187 assist you and DOD in avoiding duplications--

1188 Dr. {Lurie.} Sure.

1189 Mr. {Dingell.} --and other kinds of unfortunate events,
1190 please?

1191 Mr. Chairman, I thank you for your courtesy. I yield
1192 back the balance of my time.

1193 Mr. {Pitts.} The chair thanks the gentleman and
1194 recognizes the gentleman from Illinois, Representative
1195 Shimkus, for 5 minutes.

1196 Mr. {Shimkus.} Thank you, Mr. Chairman. Thank you for
1197 attending. I am going to kind of stay on my focus on Dr.
1198 Lurie also.

1199 And my first question deals with your proposal to extend
1200 the shelf life on NCMs. Why is that important and can you go
1201 in a little bit more detail?

1202 Dr. {Lurie.} Sure. Well, right now--

1203 Mr. {Shimkus.} And I think for those who aren't
1204 physicians, shelf life, there is an issue there and we don't
1205 know really much about the details.

1206 Dr. {Lurie.} Right. Well, first, let me say that in
1207 all of this our primary concern is continuing to make
1208 available safe and effective medical products and
1209 countermeasures for the American people in an emergency.
1210 Particularly with some of the newer countermeasures that have
1211 developed, as well as antibiotics and other things that have
1212 been around for a long time, if they are stored properly and

1213 according to standards, they remain safe and effective. It
1214 turns out that many of them remain safe and effective and
1215 maintain their potency beyond the initial date at which
1216 everyone thought that they could guarantee their safety and
1217 effectiveness. As long as they still work, as long as they
1218 are still tested--

1219 Mr. {Shimkus.} And we know that by pulling them all
1220 randomly and checking--

1221 Dr. {Lurie.} We know by them pulling them off randomly.
1222 We know them by testing. And there is a very extensive
1223 testing process that goes on.

1224 Mr. {Shimkus.} And the stored agents are basically the
1225 ones that we most assume we will need readily available.

1226 Dr. {Lurie.} So they might be vaccines, they might
1227 antimicrobials, they might be antitoxins. So we test all of
1228 these regularly as part of our stockpile maintenance.

1229 Mr. {Shimkus.} Let me go to a lot of concerns is what
1230 you have on hand and may be used that is not on hand, and the
1231 ramp-up of something not expected. And in your testimony you
1232 talked about the idea of a strategic investor.

1233 Dr. {Lurie.} Um-hum.

1234 Mr. {Shimkus.} How does that differ from--well, what is
1235 that by definition? Because it is a little vague. And is
1236 that similar to a private venture capital firm or are you

1237 proposing that the government take the role of a venture
1238 capitalist in this and that is what this strategic investor
1239 is?

1240 Dr. {Lurie.} So the strategic investor is a
1241 nongovernment, private, not-for-profit entity that does some
1242 of the things that venture capital companies do but focuses
1243 strategically to meet the Federal Government's needs in areas
1244 that is not met now. You know, these Centers for Advanced
1245 Development help us with the technical problems companies
1246 face.

1247 It is also the case as we have looked at our experiments
1248 that a lot of companies fail for business reasons or because
1249 they can't leverage other resources that accelerate really
1250 great ideas. You know, the intelligence community uses this
1251 kind of mechanism to get things that it needs. NASA uses
1252 this to get what it needs. And we have researched, I think,
1253 this very carefully and think that as one of the components
1254 of the Medical Countermeasure Review, making sure the
1255 companies succeed or helping companies succeed for business
1256 reasons is terribly important. Now, this is envisioned as a
1257 private, not-for-profit entity not run by the Federal
1258 Government. It is not like the Federal Government is going
1259 to get into the VC business.

1260 Mr. {Shimkus.} And that is why we ask these questions--

1261 Dr. {Lurie.} Yeah.

1262 Mr. {Shimkus.} --because I think if I was going down
1263 and trying to figure out who is this? Who manages this? How
1264 is this controlled? And I think you answered that question.

1265 Dr. {Lurie.} Okay.

1266 Mr. {Shimkus.} And I appreciate it.

1267 The last question I have is on the Medical Reserve
1268 Corps. How effective has that been in current disasters and
1269 how does the Emergency System for Advanced Registration of
1270 Volunteer Health Professionals--is that segued into that? Is
1271 it fully complementary? And are we seeing some positive
1272 results from that?

1273 Dr. {Lurie.} Sure. So the Medical Reserve Corps is a
1274 volunteer cadre of people who sign up in their communities to
1275 volunteer in case of emergencies, and they have training and
1276 they meet regularly and they are rostered and they are
1277 available when something happens. They are not a federal
1278 asset. They are a state and local asset.

1279 Mr. {Shimkus.} And the question is have we seen them
1280 called out? I mean is it 5 years old.

1281 Dr. {Lurie.} They respond a lot to local events--

1282 Mr. {Shimkus.} Right.

1283 Dr. {Lurie.} --and in fact make it often so states and
1284 locals can handle things on their own and don't need the

1285 Federal Government. So yes.

1286 Mr. {Shimkus.} And then how does the Emergency System
1287 for Advanced Registration and Volunteer Health Professionals
1288 segue into that?

1289 Dr. {Lurie.} So you know that whenever either a State
1290 or the Federal Government calls people up, we want to be sure
1291 that their credentialed, they are who they say they are, they
1292 have got the skills and the credentials for who they say they
1293 are. In an emergency, it is not the time to figure that out.
1294 You really want to figure that out beforehand.

1295 You know, I will just point to our experience during
1296 Haiti where we have thousands of people who wanted to help.
1297 They were all well intentioned. Many of them were extremely
1298 well qualified, but we couldn't process and certify all of
1299 those people in the middle of a disaster. You have to do
1300 that in advance so that you are ready to go when you have a
1301 disaster.

1302 Mr. {Shimkus.} I know my time has expired, but the
1303 question is is it working? Are we doing it? I know what the
1304 real world we want it to be but is it working?

1305 Dr. {Lurie.} So some States have very, very strong
1306 advanced registration credentialing programs, and those are
1307 working quite well. We are continuing to provide technical
1308 assistance and supports to other States to get up to speed.

1309 Mr. {Pitts.} The chair thanks the gentleman and
1310 recognizes the gentlelady from California, Mrs. Capps, for 5
1311 minutes for questions.

1312 Mrs. {Capps.} Thank you, Chairman Pitts and Ranking
1313 Member Pallone for holding this very important hearing.

1314 All too often, disaster preparedness is addressed in
1315 hindsight once a disaster has already taken place rather than
1316 before when it could have been more effective. I am proud of
1317 the work that this committee has done to ensure that we are
1318 better prepared today and look forward to reauthorizing PAHPA
1319 to ensure that we are even more ready if and when disaster
1320 strikes.

1321 Today, we are here working together to ensure that
1322 important safeguards are in place and that as the result of
1323 this work communities will be able to better respond to and
1324 recover from public health emergencies. Dr. Lurie, as you
1325 might be aware, my district is home to one of two nuclear
1326 power plants that the Nuclear Regulatory Commission recently
1327 confirmed are located in the highest seismic-risk areas in
1328 the country. In Japan, an earthquake and tsunami breached
1329 all the safeguards at Fukushima Power Plant and put numerous
1330 communities at risk. Needless to say, my constituents are
1331 very concerned about a similar potential threat in their
1332 backyards. And even the NRC has a recent report pointing out

1333 numerous safety deficiencies in nuclear plant oversight.

1334 So my concern and question for you is what is the
1335 current status of our country's preparedness from your
1336 vantage point to adequately address radiation exposure? Are
1337 there some particular steps we should be taking that we are
1338 not and just your general response?

1339 Dr. {Lurie.} You know, it is a great question, and I
1340 think you know that as a Federal Government we did a nuclear
1341 power plant accident exercise a couple of months before the
1342 Japan event confirming that nothing is really unthinkable.
1343 Since both of those events, we have gone back and we are in
1344 the middle of a systematic review of all of our public health
1345 gaps in radiologic preparedness. So that is right now
1346 underway. That is including an assessment of whether we need
1347 to be stockpiling potassium iodide for children and going
1348 back and reviewing all of the science related to that.

1349 At the same time, we are very aggressively developing a
1350 set of countermeasures for radiologic emergencies not only
1351 for the blood and bone marrow suppression but for lung, for
1352 the intestinal system, and for skin.

1353 Mrs. {Capps.} Well, I am going to be very interested in
1354 what you come up with and I would like to ask if it would be
1355 okay with the chairman if we ask for that report to be made
1356 available to this committee as soon as it is completed.

1357 Dr. {Lurie.} We would be delighted to come and brief
1358 you about what we have learned--

1359 Mrs. {Capps.} That would even be better.

1360 Dr. {Lurie.} Yeah.

1361 Mrs. {Capps.} You know, just in one general area,
1362 potassium iodide tablets have been available to my community
1363 members in the surrounding region, but since we saw the
1364 markers of mild considered exposed in Japan to have increased
1365 dramatically. That is one question that I think is certainly
1366 in the minds of my constituents as they will also look
1367 forward to the results of your study and hope that it will be
1368 completed at the earliest possible time.

1369 Dr. {Lurie.} Right.

1370 Mrs. {Capps.} There is another related but not
1371 necessarily just confined to nuclear exposure but surge
1372 capacity is another topic that is very much on my mind. I
1373 have a background in healthcare and that, of course, is the
1374 ability to respond in case of a mass casualty event, whether
1375 that be a tornado, a bombing, an outbreak of an infectious
1376 disease. The ability of any community to respond to a
1377 massive influx of casualties' capacity depends on care across
1378 the system, including ambulatory care, hospital care,
1379 critical care, trauma and emergency care. Some mass casualty
1380 events takes weeks or months to develop such as a pandemic

1381 flu or a biologic attack, but many events provide no such
1382 warning, as you know.

1383 After a terrorist bomb explosion or a natural disaster
1384 such as an earthquake, hospitals and the community would have
1385 to be able to respond without any assistance in the immediate
1386 minutes and hours without any assistance from state or
1387 federal authorities. Such assistance cannot arrive in time,
1388 and that is why I believe surge capacity is so critical to
1389 response capabilities.

1390 So there is not enough time to go into this in depth,
1391 but could you talk a little bit about the Hospital
1392 Preparedness Program and anything else you want to bring up?

1393 Dr. {Lurie.} Sure. No, thank you. So the Hospital
1394 Preparedness Program has been central to getting hospitals
1395 prepared to surge in case of emergencies. We also recognize
1396 two things that are really important. It is not about only
1397 the individual hospital. It is about all the entities in the
1398 community being able to do this. And at the end of the day,
1399 if we are going to be able to have the surge capacity we
1400 need, it has to be built on the back of strong day-to-day
1401 systems, especially for those no-notice events you talk
1402 about.

1403 So dealing with issues like emergency department
1404 boarding and crowding, which I know this committee has had

1405 hearings on in the past, central issue here, getting people
1406 to the next-lowest level of safe and appropriate care in an
1407 emergency, something else that is really central. So as we
1408 are moving with the next generation of the HPP program, that
1409 set of issues about surge capacity is front and center, being
1410 sure that we have the ability to work within the HPP program
1411 to innovate and be flexible and test some new models, and
1412 that is also really critical.

1413 Mrs. {Capps.} Thank you. And Mr. Chairman, if I could
1414 just beg for one follow-up that anything you could do to help
1415 our communities just as you had an evaluation or training of
1416 facilities, I think our communities would like to train and
1417 go through some preparations to be prepared.

1418 Dr. {Lurie.} That is a great comment and in the program
1419 we do continue to support training and exercising all the
1420 time.

1421 I would make one last comment. As I have looked at the
1422 no-notice disasters that have struck this country since I
1423 have been in this, there are many times when States and
1424 communities have not needed to call the National Disaster
1425 Medical System to provide medical care. They surged and
1426 handled it on their own. And I continue to hear it was the
1427 Hospital Preparedness Program that got us ready. It was that
1428 training and exercising that I really didn't want to do but

1429 we did anyone and it really helped.

1430 Most recently in Joplin, you know, we saw them be able
1431 to stand up a temporary hospital extremely rapidly after a
1432 disaster. And that was done with a lot of support as a
1433 result of the kinds of things that HPP does. Similarly, with
1434 a lot of the flooding events and others that have happened.
1435 So in all of the major events that I have been here to see, I
1436 hear from emergency doctors, hospital administrators, state
1437 and local public health about this very issue. We did it
1438 because.

1439 Mrs. {Capps.} Excellent. Thank you very much. Thank
1440 you, Mr. Chairman.

1441 Mr. {Pitts.} Thank you. The chair thanks the
1442 gentlelady and recognizes the gentleman from Michigan, Mr.
1443 Rogers, for 5 minutes for questions.

1444 Mr. {Rogers.} Thank you, Dr. Lurie, and thanks for
1445 working with us on this piece of legislation. Hopefully, we
1446 can continue to work together to perfect it in a way that we
1447 can here in Congress if there is such a thing.

1448 And I just want to follow up on Mrs. Capps' line of
1449 questioning. There is a point of issue that I hope you can
1450 help us with is during an emergency from a terrorist attack
1451 or, as we saw with H1N1, it is critical that there is a point
1452 person, somebody that makes the decision, somebody that is

1453 absolutely in charge. It is not CDC, it is not NIH, it is
1454 not the FDA or anyone else. It is you.

1455 Dr. {Lurie.} That is right.

1456 Mr. {Rogers.} How can we improve the functions at HHS
1457 to ensure that you are, in fact, in charge of the
1458 preparedness efforts? And we understand HHS does work on a
1459 consensus model brought by peer review and other things, but
1460 in this particular case, I think it is incredibly important
1461 that there is a person in charge or it takes longer, as you
1462 know. How can we help you clarify that?

1463 Dr. {Lurie.} Thank you. And I very much appreciate the
1464 question. The original intent of the legislation was to do
1465 just that. And I have found through this experience that
1466 indeed I have the authorities that I need to be in charge.
1467 We have strengthened our policy coordination and our
1468 preparedness planning with all of the entities involved. So,
1469 you know, being in charge during a response also requires
1470 sort of being in charge and providing that policy direction
1471 in all of the preparations so that when the balloon goes up,
1472 you are really ready.

1473 Mr. {Rogers.} And do you find you have that?

1474 Dr. {Lurie.} And I find that the collaboration with the
1475 sister agencies and HHS, I don't think it has ever been
1476 better. We are working extremely closely together. I think

1477 they recognize and respect the fact that we provide policy
1478 direction and are in charge. And I think all of the efforts
1479 that we have undertaken to coordinate across HHS have done
1480 that.

1481 You know, during response, you know, it is really the
1482 secretary's operations center run by the Office of
1483 Preparedness and Emergency Operations in my office that is
1484 the bellybutton for those activities, the central
1485 coordinating point for our operational response, and it is my
1486 office as well that is the central coordinating point for the
1487 strategic and policy response. And that has all become
1488 increasingly recognized with each of the events that we have
1489 dealt with this year. And I very much understand that I am
1490 in charge that I am accountable and I think I have the
1491 authorities that I need to do that.

1492 Mr. {Rogers.} Well, I am not so interested if you know
1493 you are in charge because I think you do. It is the other
1494 folks at the table I want to understand that you are--

1495 Dr. {Lurie.} Right. Right. Right. I appreciate that.

1496 Mr. {Rogers.} Yeah, thank you. I am going to move to
1497 the FDA here for a minute. Last year the HHS conducted a
1498 comprehensive medical countermeasure review. In that review
1499 you identified the need to improve regulatory science at the
1500 FDA to ensure medical countermeasures are given a priority.

1501 Specifically, you said the FDA needs ``to work with sponsors
1502 to identify and help resolve scientific issues as early and
1503 efficiently as possible.'' And I couldn't agree more with
1504 that statement. And I think that is absolutely critical.
1505 Countermeasures are different than the next generation of--
1506 you know, they are different from Viagra. They are different
1507 from--clearly. And so having the FDA involved early, to me,
1508 is incredibly important.

1509 Can you explain why improving regulatory science at the
1510 FDA is so important in your view?

1511 Dr. {Lurie.} Sure.

1512 Mr. {Rogers.} And why early intervention may be
1513 different and is important in countermeasures as it is
1514 different from other drugs?

1515 Dr. {Lurie.} Let me do the early intervention part
1516 first if I can because I think it will help explain better
1517 the regulatory science piece.

1518 You know, if a company is developing a product and gets
1519 either hung up scientifically or has a pathway to regulation
1520 that is not as clear as it could be, it is really hard for
1521 that company to go forward. We have--as I think you know or
1522 have heard--really transformed the way in which we work with
1523 companies so that now, at the beginning, at the get-go, we do
1524 what I affectionately as a primary-care doctor call ``case

1525 management.' ' We sit down with scientists from FDA, NIH,
1526 CDC, BARDA. We look at what the plan is, we provide
1527 scientific input and expertise and then now on a very regular
1528 basis, we sit down, review the process and the progress with
1529 those companies and try to troubleshoot. And FDA is now at
1530 the table and a very active participant. It has been very
1531 welcomed by companies and I get feedback about that all the
1532 time.

1533 Now, if in fact you are moving along on a plan to
1534 develop a product and to get it approved or authorized by the
1535 FDA and, for example, you don't have the tests necessary to
1536 know how effective it is going to be, the time to develop
1537 those tests isn't when the company is ready to submit a
1538 dossier to the FDA. The time is very early on in the
1539 development process. A great example of that has been, you
1540 know, the sterility testing for a flu vaccine, which hadn't
1541 changed for 30 or 40 years. Now, you know, we are doing
1542 things early on to work with FDA and companies to change that
1543 process.

1544 So what you need are the tools. You need the scientific
1545 tools to evaluate whether a product is going to be safe and
1546 effective, and the science has changed so rapidly that we
1547 need to be able and we have to ask FDA to use new science,
1548 not antiquated science, to do its job. That means that it

1549 has to be at least at the pace of or a step or two ahead of
1550 where all of these companies are so that when the companies
1551 are ready to have their products evaluated, the science is
1552 there to do that.

1553 Animal models are another great example. We are working
1554 hand-in-glove with NIH and FDA on developing those kinds of
1555 animal models so that at the end of the day if an animal
1556 model is an appropriate way to move forward, we could do it.
1557 So regulatory science becomes central to being able to get a
1558 product approved and to clarifying and I think speeding up a
1559 regulatory pathway.

1560 Mr. {Rogers.} And early intervention with those folks
1561 is--

1562 Dr. {Lurie.} Much earlier intervention. And we have
1563 been doing that, as I said, since the secretary's
1564 countermeasure review. It seems to be working quite well.
1565 In that early intervention, we sort of make a plan. On the
1566 vaccine front, we have moved forward with also working on
1567 some timelines so that we and the BARDA, the sponsor, FDA
1568 agree on the plan, agree on timelines, and we manage to
1569 those.

1570 Mr. {Rogers.} Good. Thank you.

1571 Mr. {Pitts.} The chair thanks the gentleman and
1572 recognizes the gentleman from Louisiana, Dr. Cassidy, for 5

1573 minutes for questions.

1574 Dr. {Cassidy.} I thought I was third in line.

1575 So Dr. Koh, I appreciate the anti-tobacco efforts, but
1576 let me just be a contrarian for a second. We just raised
1577 taxes tremendously on tobacco. Do we know that the effects
1578 of this taskforce, which I am sure consume a fair amount of
1579 resources--are they responsible for our decrease in tobacco
1580 usage or would it just be the fact that we are taxing the
1581 heck out of it and that it making it less affordable for
1582 people to smoke?

1583 Dr. {Koh.} Well, there are many parts to tobacco
1584 control, Congressman, and the plan that we have put together
1585 really accomplishes a multi-pronged approach. So you
1586 mentioned one, which is raising the price and just about
1587 every State has done that in the last 10-plus years.

1588 Dr. {Cassidy.} So let me ask you, has there been any
1589 sort of, for example, regression and analysis to see if there
1590 is a secular trend that is just continuing downward usage as
1591 we increase taxes versus this kind of significant commitment
1592 of federal resources which, frankly, I like, but I am
1593 wondering could we redirect those resources if taxes are
1594 doing it all for us?

1595 Dr. {Koh.} Well, Congressman, this is one area in
1596 public health that we have tremendous science; we have

1597 tremendous data. We know what works. We know raising the
1598 price works. We know that community-based interventions
1599 work. We know that quit lines work. We know that providing
1600 cessation services to smokers who want to quit is extremely
1601 helpful. So the challenge is to put it all together so that
1602 we can have a country where we are reducing the suffering
1603 here. We do know that tobacco usage, which was declining for
1604 many years has stalled over the last 7 or 8 years, and that
1605 is actually why the secretary asked me to convene this group.
1606 And so we hope we can--

1607 Dr. {Cassidy.} Well, let me ask you because, again, I
1608 think as part of the CHIP reauthorization last year, there
1609 was a dollar a pack placed. Now, was there any sort of
1610 downtick in tobacco usage with that dollar-a-pack tax? And
1611 did that precede the efforts of your interagency--

1612 Dr. {Koh.} It preceded the efforts of our group. And
1613 the economics of raising tobacco prices has been extremely
1614 well studied. In fact, we know that raising the price about
1615 10 percent decreases consumption 4 percent for adults and
1616 even higher for children. So that was a federal effort from
1617 several years ago. I think you are referring also to State
1618 efforts. And each governor of both parties actually in just
1619 about every State has raised taxes over the last decade or
1620 so.

1621 But I do want to stress again, Congressman, that is an
1622 important and well studied intervention, but it is only one
1623 intervention.

1624 Dr. {Cassidy.} I guess but what I am wondering is does
1625 that overwhelm the efficacy of all the others?

1626 Dr. {Koh.} We need all the efforts. I am a physician.
1627 I--

1628 Dr. {Cassidy.} No, I accept that, but I am just
1629 wondering, again, as we have scarce resources, I guess I am
1630 asking is there a secular trend whereby all others pale in
1631 significance. Sure, if taxes are not raised, then we need
1632 the others, but if taxes are raised, the others are obviated?

1633 Dr. {Koh.} The price can increase can help to some
1634 degree and I have presented the numbers to you, but we also
1635 know that tobacco addiction is a really tough addiction. I
1636 know you know that as a health professional, Congressman.
1637 And so do I. I am a physician who has cared for patients for
1638 over 30 years. So when you see people who are hooked and
1639 they want to quit and they haven't been able to, you need
1640 every resource and you also need additional resources to
1641 prevent the next generation from taking up--

1642 Dr. {Cassidy.} I am just asking is there statistical
1643 data to show that these other interventions help over and
1644 above--

1645 Dr. {Koh.} Absolutely.

1646 Dr. {Cassidy.} --but I am also out of time, so let me
1647 just kind of try--

1648 Dr. {Koh.} Yeah, and let me just say, Congressman, this
1649 area has been extremely well studied. I would be glad to
1650 provide you more materials, but we need many approaches here
1651 to tackle this problem.

1652 Dr. {Cassidy.} That would be good if you could. And
1653 again, I am not saying we shouldn't do it. I am just saying
1654 if we have got limited resources, where do we spend it sort
1655 of thing.

1656 Let me ask you also, just broadly, as long as I have
1657 you--and either of you can answer--but I am struck that
1658 sometimes it seems--as perhaps you know, I am a doctor that
1659 treats diseases of the liver--

1660 Dr. {Koh.} Right.

1661 Dr. {Cassidy.} --and societal and economic impact is
1662 tremendous, and yet the amount of funding from the Federal
1663 Government kind of pales in significant to some other
1664 illnesses which, arguably, don't cost more if you will. Is
1665 there any sort of metric as we do funding for federal
1666 activities that I can imagine a metric named morbidity,
1667 mortality, years of life lost, potential--because smallpox
1668 clearly doesn't kill anybody now but the potential death is

1669 tremendous--is there any sort of metric applied to this or is
1670 it more or less historical funding moving forward?

1671 Dr. {Koh.} I can start and, Congressman, I really
1672 appreciate your support of the Viral Hepatitis Strategic
1673 Plan. I remember when you testified and presented in front
1674 of our congressional briefing, and I know you have spent much
1675 of your career caring for patients with hepatitis, so we
1676 really appreciate that.

1677 And you all know that if you intervene on hepatitis, you
1678 can prevent liver cancer and prevent liver transplant, all of
1679 which drives up healthcare costs in this country.

1680 So with respect to your question, obviously, these are
1681 very challenging budget times. We have launched this plan to
1682 address a rising public health need. We do need to bring in
1683 as many resources on the table from many parts of our--

1684 Dr. {Cassidy.} Well, let me ask you because I am
1685 frankly out of time but I am asking do we have any sort of
1686 metric by which federal funding for addressing illnesses
1687 applied or it historical funding that kind of continues for
1688 it? Is it active politicians determining how we spend our
1689 dollars or is there a metric that is applied that
1690 scientifically says we should put X number of dollars here, Y
1691 there, and Z here?

1692 Dr. {Koh.} Well, those metrics have been well defined

1693 for tobacco. For hepatitis less so.

1694 Dr. {Cassidy.} Well, I am just saying globally. Okay,
1695 we have this death rate from HIV, this from breast cancer,
1696 this from prostate, this from hepatitis, this from smallpox--

1697 Dr. {Koh.} Right.

1698 Dr. {Cassidy.} And do we have a metric that then
1699 determines how we do our spending?

1700 Dr. {Koh.} Again, they are state-by-state guidelines
1701 for spending on tobacco that are very well defined from
1702 scientific data but on hepatitis there is less so.

1703 Dr. {Cassidy.} Okay. I yield back. I think I know
1704 what the answer is.

1705 Mr. {Pitts.} The chair thanks the gentleman and
1706 recognizes the gentleman from Georgia, Dr. Gingrey, for 5
1707 minutes for questions.

1708 Dr. {Gingrey.} Mr. Chairman, thank you so very much.
1709 And I was going to direct my question to Dr. Koh, but as
1710 usual, my good friend and colleague from Louisiana stole all
1711 my thunder and I will have to then direct my question--I will
1712 let you take a breath, Dr. Koh, and I will direct mine to Dr.
1713 Lurie.

1714 Dr. Lurie, you mentioned in your testimony about the
1715 Emergency Medical Countermeasures Enterprise Review, MCM
1716 Review in August of last year that articulated ``a vision for

1717 a nimble, flexible infrastructure to produce MCMs rapidly in
1718 the face of an attack or threat, including a novel,
1719 previously unrecognized naturally occurring emerging
1720 infectious disease''--that terrorists or hostile governments
1721 might use a drug-resistant form of bacteria or other
1722 infectious disease as a weapon against us, against the United
1723 States?

1724 Dr. {Lurie.} Well, one of the great things is that the
1725 scientific methods and tools to do all kinds of things we
1726 call synthetic biology has progressed tremendously. One of
1727 the very scary things is it has become a lot more automated
1728 and a lot easier--I don't know if you have seen these
1729 articles about the DIY, the do-it-yourself, you know, garage
1730 manufacturing of--

1731 Dr. {Gingrey.} Yeah, we actually heard a little bit
1732 about that activity from our first witness, our colleague,
1733 Charlie Dent, in regard to some of these--

1734 Dr. {Lurie.} Good point.

1735 Dr. {Gingrey.} --synthetic drugs--

1736 Dr. {Lurie.} And so, you know, the technology to
1737 genetically engineer all kinds of deadly organisms is there.
1738 It is available. It is becoming more available and we have
1739 to be very prepared for those kinds of things.

1740 Dr. {Gingrey.} So a real threat.

1741 Dr. {Lurie.} Yeah, it is a real threat.

1742 Dr. {Gingrey.} Well, look, let me ask you this, then.
1743 If we ever meet these emerging threats, we need more novel
1744 antibiotics, yet our current development is not as robust as
1745 it needs to be. And you mentioned in your testimony that MCM
1746 Review had identified choke points where product development
1747 was--and I will quote you--``stalling or failing.''

1748 Dr. {Lurie.} Yeah.

1749 Dr. {Gingrey.} Can you take a moment and describe some
1750 of these choke points and disincentives in the current
1751 antibiotic development pipeline? Because I think you know I
1752 had some real interest in this area.

1753 Dr. {Lurie.} Right. No, I appreciate that and I am
1754 glad you have interest in this area because antimicrobial
1755 resistance is terribly, terribly important.

1756 In the medical countermeasure arena, we focus on
1757 antimicrobial resistance for two reasons. One is because of
1758 the genetically engineered set of issues. The other, quite
1759 honestly is because antimicrobial resistance complicates our
1760 ability to treat and save lives from trauma, from H1N1 where
1761 something like 40 percent of kids died from methicillin-
1762 resistant staph complicating their H1N1 infection, et cetera.
1763 So if we are going to meet our mission in the countermeasure
1764 arena and in the preparedness arena, we have to have novel

1765 antibiotics. Now, to the sets of issues about the choke
1766 points--

1767 Dr. {Gingrey.} It might be little off the subject
1768 matter of the day, but I mean it would be true, too, in
1769 cancer to chemotherapy patients, you know, whose immune
1770 system is beaten down, they have no platelets, they have no
1771 T-cell lymphocytes and then all of a sudden their own enteric
1772 bacteria is a tremendous threat to them and they need more
1773 than just the usual off-the-shelf, third-generation wonder
1774 drugs.

1775 Dr. {Lurie.} But one of the things that I think is not
1776 as appreciated about this whole medical countermeasure
1777 enterprise that we are embarked on is that an awful lot of
1778 the developments that are coming through this pipeline,
1779 whether it is novel antimicrobials or a next-generation
1780 ventilator, actually have benefits to a broader population in
1781 this country even if we are never attacked, for example, or
1782 don't have a new kind of threat. And a goal is for us to do
1783 those multi-use and dual-use things as much as we can.

1784 Dr. {Gingrey.} Sure. Absolutely.

1785 Dr. {Lurie.} Our primary mission is to meet our
1786 counterterrorism and biological--

1787 Dr. {Gingrey.} I have got 30 seconds left so I am going
1788 to shift just for a second. Mr. Shimkus was asking you a

1789 little bit about our preparedness for a disaster of any kind.
1790 And I am thinking Katrina because I remember jumping on a
1791 plane. I had been out of the practice of medicine for a
1792 couple of 3 years and flying down to Louisiana and just say
1793 here I am, I have got my white coat, my stethoscope, and here
1794 is my medical license. It is still active. Let me help out.
1795 I don't think the Red Cross had any way, shape, or form of
1796 checking on me to see if anything had been suspended or
1797 whether I truly was an OB/GYN or maybe somebody with a
1798 criminal background indeed.

1799 But in any regard, I think what he was trying to get at
1800 was at the federal level--you said the States and I think the
1801 States are indeed doing a good job in regard to that,
1802 hopefully all of them will--but we need to get that data,
1803 don't you think, at the federal level where somebody on the
1804 ground when the next--Mrs. Capps talked about if another--
1805 obviously, we all know another disaster is going to occur in
1806 some shape or form, be it an earthquake or whatever. But we
1807 need that information and if you could just comment very
1808 quickly.

1809 Mr. Chairman, if you will let her do that and then I
1810 will yield back.

1811 Dr. {Lurie.} First, I just want to comment that when
1812 Katrina hit and people came here, I walked into the armory

1813 with a stethoscope around my neck. They said are you a
1814 doctor? I said yes, and they set me loose. I didn't even
1815 show a license. So I do think that we have to protect people
1816 and let them know--you know, be sure that they are who they
1817 say they are and they are really qualified to practice
1818 whatever their profession is.

1819 I do think we need a national system to be able to
1820 rapidly look at somebody's credentials and give them the
1821 okay. You know, we also have a set of challenges that we
1822 continue to face because State by State, you know, there is
1823 not license reciprocity across all States. So a governor
1824 can, you know, use their--I think we talked about it in
1825 another meeting--the metric smoke stick and say in an
1826 emergency, you know, situation I will accept licensed
1827 providers from another State and do that, but everybody
1828 needs, then, that mechanism to know are they licensed
1829 providers and to have that work in a hurry.

1830 On a federal level, we credential everybody you know in
1831 advance through the National Disaster Medical System and we
1832 have been working very aggressively since the Haiti
1833 earthquake to be able to credential people in other
1834 specialties, particularly in the critical care area and some
1835 of the specialty surgical areas and trauma areas where we
1836 don't necessarily have a full cadre of people on each team so

1837 that when a disaster happens, we can pull those volunteers
1838 from anywhere in the country and put them to work joining our
1839 NDMS teams. And that is actively underway.

1840 Mr. {Pitts.} The chair thanks the gentleman and
1841 recognizes the gentlelady from North Carolina, Mrs. Myrick,
1842 for 5 minutes for questions.

1843 Mrs. {Myrick.} Thank you. I appreciate it. And thank
1844 you both for being here. I am sorry I have to leave for a
1845 few minutes. I understand that there are like 44 million
1846 doses of the first-generation anthrax vaccine for the
1847 Strategic National Stockpile for civilian use. Is that
1848 roughly about right?

1849 Dr. {Lurie.} I would have to check on exactly what the
1850 number of doses in the stockpile is now but we are continuing
1851 to add to it.

1852 Mrs. {Myrick.} Well, I know that is a lot of the budget
1853 obviously.

1854 Dr. {Lurie.} Yeah. Right.

1855 Mrs. {Myrick.} And I know back in 2004, HHS issued a
1856 requirement to purchase 75 million doses of a second-
1857 generation anthrax vaccine. How are you going to move
1858 forward on that? Do you know? I mean is that something you
1859 have looked into?

1860 Dr. {Lurie.} Well, so issuing the requirement, you

1861 know, really means that we have a public health and
1862 preparedness need for that.

1863 Mrs. {Myrick.} Um-hum.

1864 Dr. {Lurie.} Sometimes when we issue a requirement,
1865 there is something kind of off the shelf already licensed
1866 that we can go buy. Sometimes when we issue a requirement,
1867 that product doesn't exist and we have to make it. That is
1868 what the advanced development piece is really about.

1869 Mrs. {Myrick.} Um-hum.

1870 Dr. {Lurie.} And so we have invested in the advanced
1871 development of a next-generation anthrax vaccine largely
1872 because the current vaccine, you know, really takes multiple
1873 doses--

1874 Mrs. {Myrick.} Yeah.

1875 Dr. {Lurie.} --to develop immunity and isn't ideal from
1876 the perspective of needing to respond to a public health
1877 emergency involving millions of people.

1878 Mrs. {Myrick.} But a second generation that is being
1879 developed, is that--

1880 Dr. {Lurie.} We are seeking next-generation vaccines
1881 that would, you know, when they are developed--and the
1882 requirements is that they have to meet certain, you know,
1883 specifications so that ideally we would like something, you
1884 know, that is one shot and works quickly. We are not there

1885 yet in the development process. This is a great example of
1886 where science is hard. The development process is cumbersome
1887 and it takes really all the best scientific minds and the
1888 creativity of many of our industry partners to do that.

1889 Mrs. {Myrick.} Well, is this another area where you
1890 have to have investors that are willing to do this? I mean I
1891 know all of this, if you produce these countermeasures, is
1892 very expensive. What kind of tools do you have at your
1893 disposal?

1894 Dr. {Lurie.} It is a great question. So right now we
1895 use advanced research and development funds to be able to do
1896 that. And as you probably recall, PAHPA gave us the
1897 authority to spend money on these advanced research and
1898 develop purposes, and that is what we need to do.

1899 The strategic investor seeks to do two other things that
1900 are really important to think about. One is that, you know,
1901 some of these companies have great scientific ideas but not a
1902 lot of business expertise and so fail not for scientific
1903 reasons but for business reasons. And so the strategic
1904 investor, first of all, seeks to help them with those
1905 business issues. And secondly, it seeks to identify
1906 companies that might be working on something for a commercial
1907 application. They don't want to work on anthrax because
1908 there is not a good market for it, but they could say you

1909 have got a really great idea and something innovative. And
1910 we are going to take us in our venture-capital-like state, we
1911 are going to sort of take a risk, invest in you, and working
1912 with us say we want you to take this platform, this idea and
1913 apply it to the anthrax problem. That is exactly what it is
1914 intended to do.

1915 Mrs. {Myrick.} Yeah, you have answered some of this
1916 while I was gone, I apologize. I can always look at your
1917 testimony. But the strategic investor is actually working
1918 with HHS or for HHS? Is that what I understand?

1919 Dr. {Lurie.} The strategic investor, as I explained to
1920 Mr. Rogers and I am happy to again would be a private,
1921 nonprofit entity that exists outside of government.

1922 Mrs. {Myrick.} Okay.

1923 Dr. {Lurie.} But what we have to do is say here are the
1924 kinds of things that we need you to invest in. We have a
1925 requirement for a next-generation vaccine whether it is for
1926 anthrax or purple spots and please, you know, go stimulate
1927 the development of those things through the ways in which you
1928 work as a strategic investor.

1929 Mrs. {Myrick.} And maybe he asked the same question,
1930 but about the strategic investor--

1931 Dr. {Lurie.} Yeah.

1932 Mrs. {Myrick.} --is that someone that is actually like

1933 a consultant to HHS or something? Is that--

1934 Dr. {Lurie.} No, it is not.

1935 Mrs. {Myrick.} It is a volunteer or a--

1936 Dr. {Lurie.} No, I think it would be a private, not-
1937 for-profit company ideally, and it would act in many ways
1938 like venture capital companies act--

1939 Mrs. {Myrick.} Right.

1940 Dr. {Lurie.} --but also act to invest strategically.

1941 So one of the things I explained is that the intelligence
1942 community does that now. NASA has done that in the past.

1943 Mrs. {Myrick.} Right.

1944 Dr. {Lurie.} There are a number of examples across
1945 government where that has been very successful. We didn't
1946 dream it up ourselves.

1947 Mrs. {Myrick.} Is that the type of thing that you would
1948 be looking at, then, on the--

1949 Dr. {Lurie.} Yes. We are looking for the authority to
1950 start a strategic investor so that we can use this additional
1951 tool to get the kinds of products we need.

1952 Mrs. {Myrick.} Thank you very much.

1953 Dr. {Lurie.} Yeah.

1954 Mrs. {Myrick.} Thank you, Mr. Chairman.

1955 Dr. {Burgess.} [Presiding] The gentlelady yields back.

1956 The gentlelady from Washington State is recognized for 5

1957 minutes for the purposes of questions.

1958 Mrs. {McMorris Rodgers.} Thank you, Mr. Chairman.

1959 My questions relate to the Enhancing Disease
1960 Coordination Activities Act of 2011, and I wanted to ask how
1961 the committees for specific diseases and conditions will be
1962 established and then how the bill changes the current
1963 process.

1964 Dr. {Koh.} Well, first of all, Congresswoman, thank you
1965 for your interest in the support of public health. I know
1966 you have been a leader in many areas, and we appreciate that.
1967 In my testimony, I did review a number of areas where we have
1968 strategic plans and implementation efforts and then also did
1969 review that we have actually many advisory committees up and
1970 running. So the proposed legislation supports that general
1971 theme, which we applaud. And in fact the mission of my
1972 office, the Secretary for Health's office is to advance that
1973 coordination on behalf of the Department and the country.

1974 The provisions in the proposed legislation that require
1975 a strategic plan update every 2 years might hold us to a
1976 level where we are perhaps spending too much time on that
1977 effort and not enough on implementation. So that current
1978 status that we have offers us more flexibility.

1979 And then I did review and mention that the unintended
1980 consequences of a legislation like this might be to drive up

1981 cost because putting together committees and running them
1982 adds to our budget issues. So those are some of the areas
1983 that we reviewed for you.

1984 Mrs. {McMorris Rodgers.} In our experience in
1985 developing a strategic plan for Down syndrome, the patient
1986 advocacy organizations and private research foundations
1987 provide critical insight into what is needed to move a
1988 research agenda forward. And for example, as we speak, the
1989 Down syndrome community is in the process of working with the
1990 National Institute of Child Health and Human Development to
1991 establish a consortium that includes patient advocacy
1992 organizations and researchers. This interaction is critical
1993 to furthering one agenda. And I have a little bit of a
1994 concern that the draft bill we are discussing today keeps too
1995 much authority with the federal agencies with respect to the
1996 development of a research strategy, possibly to the detriment
1997 of the collective goal of finding a cure or treatment. And I
1998 just wanted to ask you to comment and could the legislation
1999 be strengthened by including a role for stakeholders?

2000 Dr. {Koh.} Well, thank you for raising attention to
2001 that particular issue. And we are pleased to report the
2002 evolution of that consortium as you just mentioned, and there
2003 is a very concerted effort at NIH to have a cross-trans-NIH
2004 coordinating committee on Down syndrome, which I understand

2005 is up and running and moving very, very well. In all these
2006 efforts, current and proposed, we make special efforts to
2007 bring in the best experts in the country so that we can do
2008 our work really informed by people who are learned and have
2009 spent their career studying these issues. And then we want
2010 the portfolio and the public health areas addressed to focus
2011 not just on research but on services and public health
2012 dimensions in the broadest sense. So that is what we try to
2013 do. Currently, I think the proposed legislation really
2014 resonates with that theme as well.

2015 Mrs. {McMorris Rodgers.} Okay. Thank you. I
2016 appreciate you answering those questions.

2017 Dr. {Koh.} Thank you.

2018 Dr. {Burgess.} I am sorry. I didn't see you. You came
2019 in so quietly.

2020 The chair now recognizes Mr. Green from Texas for the
2021 purposes of questions.

2022 Mr. {Green.} Thank you, Mr. Chairman, and I know it is
2023 unusual for a Texan to sit quietly but I want to thank each
2024 of you for being here. This is my first term in Congress at
2025 least on the Energy and Commerce Committee. I haven't been
2026 on the Health Subcommittee and I appreciate the opportunity
2027 to weigh in on the hearing on H.R. 2405 introduced by both
2028 Congressman Rogers, a number of members, and myself. I am an

2029 original cosponsor of the legislation. I am pleased it is a
2030 bipartisan piece of legislation. It appears there are a few
2031 issues germane that need to be worked about before this bill
2032 moves to subcommittee markup. I know there is an interest in
2033 the sharing special considerations given to children during
2034 national emergencies, and I hope we will resolve this issue
2035 before the markup.

2036 The University of Texas Medical Branch's Galveston
2037 National Lab is one of the two national biocontainment labs
2038 constructed under grants awarded by the National Institute of
2039 Allergy and Infectious Disease and the National Institute of
2040 Health and I am proud much of this research is literally
2041 performed in the backyard of my district in Houston. And I
2042 was happy during Hurricane Ike that there was lots of damage
2043 but the lab was very safe.

2044 At this BSL-4 lab research is conducted to develop
2045 therapies and vaccines and tests for diseases like anthrax,
2046 Avian flu, the bubonic plague, hemorrhagic fever such as
2047 Ebola, typhus, West Nile virus, influenza, and drug-resistant
2048 tuberculosis.

2049 I have a personal interest in this legislation because
2050 my daughter was actually at UTMB during her fellowship and
2051 did some work there in studies at the BSL lab, and believe
2052 me, when you talk about my concern from our colleague from

2053 Georgia, Dr. Gingrey, about--I was at the Astrodome when we
2054 evacuated a quarter of a million people from New Orleans, and
2055 you are right, Doctor, there were folks running around
2056 everywhere because the medical community in Houston literally
2057 came together, and I was amazed at what happened. And as we
2058 know, medical facilities, nonprofits, and profits sometimes
2059 compete with each other and their neighbors, but I watched
2060 them that doing such a great job on triaging these folks who
2061 literally were picked up in New Orleans and had no
2062 medication, no medical records unless they were veterans. In
2063 those cases we were very lucky.

2064 But my concern today is that Texas A&M, University of
2065 Texas, and Baylor College of Medicine, along with Texas
2066 Children's Hospital in Houston, along with GlaxoSmithKline,
2067 along with many other distinguished partners in a newly
2068 established and developed National Center for Innovation and
2069 Advanced Development and Manufacturing in Texas. The purpose
2070 of the center will be to develop medical countermeasures to
2071 ensure domestic vaccine manufacturing serve capacity for
2072 emerging and infectious diseases, pandemic, influenza, and
2073 other threats during public health emergencies utilizing
2074 flexible and multi-product technologies. These public and
2075 private partnerships along with academic research
2076 institutions are vitally important both in the Federal

2077 Government and the private companies as we work to develop
2078 novel bioterrorism measures. Solicitations for these efforts
2079 were issued by HHS on March 30 of 2011.

2080 My first question is can you discuss the Center for
2081 Innovation and Advanced Development and Manufacturing and the
2082 process going forward for these important institutions, Dr.
2083 Lurie? And I believe these centers will be at the forefront
2084 of developing medical countermeasures needed by our country
2085 in the event of a bioterrorism event.

2086 Dr. {Lurie.} Thanks so much for your question and for
2087 your recognition of Advanced Development and Manufacturing
2088 facilities. You know, they were another critical piece of
2089 the recommendations of the secretary's Medical Countermeasure
2090 Review, and they are intended to provide technical expertise
2091 and core services to the small companies that get into the
2092 countermeasures space and need help. You are right, we did
2093 issue the request for proposals, and the deadline for
2094 proposals is today. We are receiving applications and we are
2095 very excited about that. And we will be reviewing those
2096 applications over the course of the year working to be sure
2097 that we can identify the very best entities to do that job
2098 and then after that hope to make one or more awards.

2099 Mr. {Green.} One of the concerns I have is BARDA has
2100 issued contracts that are fulfilled by international

2101 companies with production facilities in Europe. This leaves
2102 open the question of supply security and job creation in our
2103 own country. Is BARDA committed to allowing contract
2104 modifications for pandemic flu vaccine development that will
2105 bring some of those jobs back to the U.S. so you can supply
2106 us with these contract modifications?

2107 Dr. {Lurie.} We are very focused on domestic
2108 manufacturing of our critical countermeasures, including
2109 pandemic vaccines. And that has been the focus of much of
2110 our work.

2111 Mr. {Green.} Okay.

2112 Dr. {Lurie.} And I think certainly what happened in the
2113 pandemic very much showed us the criticality of domestic
2114 manufacturing.

2115 Mr. {Green.} Okay. Thank you.

2116 Mr. Chairman, thank you.

2117 Mr. {Pitts.} The chair thanks the gentleman. That
2118 concludes our first round of questioning. We will go to one
2119 follow-up on each side. Dr. Burgess is recognized for a
2120 follow-up.

2121 Dr. {Burgess.} Thank you, Mr. Chairman.

2122 Dr. Lurie, Representative Markey of this committee
2123 amended the Public Health Security and Bioterrorism
2124 Preparedness Response Act in 2002 to make potassium iodide

2125 available to state and local governments to meet the needs of
2126 all persons living within a 20-mile radius of a nuclear power
2127 plant. However, the Nuclear Regulatory Commission in both
2128 the previous administration and in this administration has
2129 not enforced this provision. Have there been any studies
2130 done on the health effects of the difference on health
2131 effects done at different differences and will we have a
2132 large enough supply of potassium iodide to provide for us in
2133 a 20-mile radius?

2134 Dr. {Lurie.} Thank you for that question and I think it
2135 is a question that has been on everybody's minds since
2136 Fukushima. And certainly planning for a radiologic disaster
2137 is part of our all-hazards preparedness. You know, that
2138 disaster has caused us to go back and try to look at what all
2139 of our public health gaps are and to try to look at, you
2140 know, should there be a requirement for potassium iodide,
2141 particularly for children in the stockpile? And then how
2142 much should we stockpile? How much should that be? So
2143 because we in public health like to apply the best available
2144 science that we can, you know, going back we have been
2145 reviewing all that. We are doing a lot of modeling right now
2146 to determine is there a requirement and how big it should be
2147 so that we can protect children. It is fair to say, I think,
2148 that Fukushima sort of challenged a number of our assumptions

2149 about an event.

2150 Dr. {Burgess.} Sure, well, let me ask you this. I mean
2151 apparently it is my understanding that you have the authority
2152 to purchase the potassium iodide. Is that correct?

2153 Dr. {Lurie.} We have the authority.

2154 Dr. {Burgess.} And you have the money? The money has
2155 been appropriated in previous Congresses. Is that correct?

2156 Dr. {Lurie.} That is right.

2157 Dr. {Burgess.} But the money has not been spent.

2158 Dr. {Lurie.} So right now we are in the process of
2159 figuring out--so we had pediatric potassium iodide in the
2160 stockpile, you know, and that is now set to expire over the
2161 next year or two. And so what we need to figure out right
2162 now is how much do we need to have in the stockpile to
2163 adequately protect the American people? And that is what we
2164 are doing right now. And once we figure that out, assuming
2165 that we agree that there needs to be potassium iodide in the
2166 stockpile, I think that we will act on that requirement.

2167 Dr. {Burgess.} Are you looking at larger radiuses than
2168 a 20-mile radius as was outlined in Mr. Markey's amendment?
2169 Has the experience in Japan taught us anything there?

2170 Dr. {Lurie.} You know, I think what we are doing is,
2171 you know, taking all of the science into account and taking
2172 what we have learned from the recent event and trying to

2173 figure out what does it best take to protect the population,
2174 whether it is going to be what the exact radius is that we
2175 are going to settle on, you know, I think that is going to
2176 really depend on what the science shows us.

2177 Dr. {Burgess.} The potassium iodide itself is a
2178 relatively stable compound. Does it really go bad?

2179 Dr. {Lurie.} You know, we just had that discussion as
2180 we looked at shelf-life extension for the pediatric potassium
2181 iodide that is in the stockpile. And FDA was really a
2182 terrific partner with us in rapidly testing the liquid to try
2183 to look at its stability over time. I think the stability of
2184 the liquid version and the tablet version are different but
2185 we do need to sort out what the shelf life of it is and when
2186 it is, you know, safe to do the shelf-life extension. It
2187 sort of highlights the need for some of the shelf-life
2188 extension authorities potentially.

2189 Dr. {Burgess.} Well, I remember in my district in the
2190 H1N1 crisis the FDA released all kinds of outdated antiviral
2191 medication and I was assured by Dr. Hamburg that it was just
2192 as good as the day it was minted and that they were revising
2193 some of those shelf-life expiration dates on a much more
2194 complex molecule than potassium iodide, which is relatively
2195 straightforward.

2196 Let me just ask you a question. Do you have any concern

2197 about the availability of potassium iodide? As I understand
2198 it, it is the only treatment that is currently available for
2199 prevention of uptake of radioactive iodine by the thyroid and
2200 particularly in young populations. Are you concerned about
2201 the availability of potassium iodide?

2202 Dr. {Lurie.} Well, I think what one of the things that
2203 we said during the Fukushima event was this incredible
2204 epidemic of fear in the United States and there was a huge
2205 run on the companies. And so people bought up short-term the
2206 available--

2207 Dr. {Burgess.} Yeah, that is kind of the point.

2208 Dr. {Lurie.} --supply.

2209 Dr. {Burgess.} That is kind of the point.

2210 Dr. {Lurie.} Yeah.

2211 Dr. {Burgess.} We assure people that we have--

2212 Dr. {Lurie.} What we need to do is be sure that we have
2213 it where we need it, that it is stockpiled where we need it.
2214 You know, there have been plans to stockpile it around
2215 nuclear power plants. It is exercised differently in
2216 different States. That is one of the things that we looked
2217 at.

2218 Dr. {Burgess.} My understanding is that Janet
2219 Napolitano just today released information that was gathered
2220 in the Osama bin Laden compound about al-Qaeda's desiring to

2221 infiltrate nuclear power plants in this country and reek some
2222 sort of damage. So this is not just a theoretic concern. If
2223 the Secretary of Homeland Security is out there talking about
2224 this, then our National Strategic Stockpile should reflect
2225 that level of concern. And really I urge you to spend some
2226 energy on doing that.

2227 Dr. {Lurie.} No, I appreciate that. And I think we all
2228 very much appreciate the concern and that is why we are in
2229 the midst, I think, almost a closure on coming up with, you
2230 know, the recommendations about how much we should stockpile.
2231 I don't think any of us has any question that this is a
2232 concern and I don't think any of us have any question that we
2233 need to protect the American people in this way.

2234 Dr. {Burgess.} Thanks, Mr. Chairman. I will yield
2235 back.

2236 Mr. {Pitts.} The chair thanks the gentleman and yields
2237 to Mr. Pallone for follow-up.

2238 Mr. {Pallone.} Thank you, Mr. Chairman.

2239 Dr. Lurie, I was going to ask you this before so I
2240 didn't have a chance. I wanted to ask about our current
2241 efforts on biosurveillance. As you know, in many cases of
2242 bioterrorism or natural disease outbreaks the first clue is
2243 that people seek medical care for their condition. And
2244 sometimes the condition may appear like other common

2245 conditions and could be missed unless there is a system to
2246 detect unique features of an outbreak. And biosurveillance
2247 is the ability of our system to detect these ongoing
2248 outbreaks whether natural or manmade. I am concerned because
2249 there was a recent GAO report in December that suggests that
2250 HHS should be doing more to provide a strategic plan for
2251 situational awareness.

2252 So I have two questions. I will mention both. In your
2253 professional opinion, do we have adequate capabilities for
2254 biosurveillance and what are we doing to enhance these
2255 capabilities? And can you tell us how the public health
2256 infrastructure relates to the biosurveillance infrastructure?

2257 Dr. {Lurie.} Sure. Great questions and issues that I
2258 think are very much on my mind all the time. I appreciate
2259 that.

2260 You know, surveillance and recognition of outbreaks is
2261 most often something that happens locally. Sometimes it
2262 happens through an astute clinician who happens to see
2263 something more than once. Sometimes it happens through other
2264 surveillance systems that are in place in health departments
2265 and hospitals throughout the country. At the end of the day,
2266 our preparedness in this country, particularly in this area
2267 is built on the back of strong day-to-day systems. We see
2268 around the country right now, because of the economic

2269 situation, real threats to public health, an erosion of public
2270 health capabilities. So something like 40,000 jobs in the
2271 state and local level in public health have been compromised
2272 over the past couple of years. They have either been lost or
2273 been cut back drastically.

2274 Mr. {Pallone.} They lost their jobs, then.

2275 Dr. {Lurie.} So people have lost their jobs, they are
2276 working part-time, and right now it is often only money that
2277 is coming through a public health preparedness vehicle that
2278 is holding that surveillance capability together at the state
2279 and local level. So when you say do we have biosurveillance
2280 capability and how good is it? We know the techniques, we
2281 have the tools, and we know what to do, but we have to make
2282 it work and be sure it works day to day on a state and local
2283 level and doesn't get eroded as we are falling on hard times
2284 because this erosion at the end of the day compromises our
2285 national security.

2286 Mr. {Pallone.} I mean it is true, you know, I mean it
2287 is a long time since I was a councilman, but I was at one
2288 time, and I remember going over the budget and it was often
2289 the case that, you know, somebody that would say let us cut
2290 back on, you know, the health department because, you know,
2291 nobody really knew what they did and also, you know, if you
2292 are talking about something that may happen in the future, it

2293 is easy to say, well, I don't know if that is going to happen
2294 so why should I deal with the preparedness? I mean I see
2295 that that is a significant problem.

2296 But Chairman Pitts and I were talking about how
2297 important this hearing is and how interesting it was because,
2298 you know, you can't take that attitude. You have to take the
2299 attitude that, you know, we need to prepare. But it is hard.
2300 It is hard from a political point of view because people, you
2301 know, they don't want to prepare for contingencies that may
2302 never occur and it is easy to think that they never will
2303 occur.

2304 And, you know, this is of course after the fact, but one
2305 of the things that we have in my district is we have one of
2306 the 9/11 clinics, you know, mostly first responders who
2307 sustained all kinds of health problems from 9/11. And, you
2308 know, I talk to the people that are in charge of the clinic
2309 from time to time and even today, you know, they are still
2310 coming up with diseases and disorders that, you know, are
2311 unforeseen or that, you know, manifest themselves years
2312 later. So it is just so important. But it is difficult, you
2313 know, to deal with this issue and to be prepared. I mean I
2314 am only looking at it after the fact but obviously when you
2315 talk about it before the fact, I think it is even more
2316 difficult.

2317 Dr. {Lurie.} And, you know, I think this reluctance of
2318 people to always want to think about the unthinkable even
2319 though it has happened an awful lot since I have been here is
2320 in part human nature and it is part something we have to work
2321 against. But it also, I think, shows us the importance of
2322 being sure that the day-to-day systems are really strong so
2323 that the systems that detect your foodborne outbreaks, the
2324 systems that detect seasonal flu, the systems that do these
2325 other things and function in the background day-to-day to
2326 prevent us from infectious diseases and do that kind of
2327 surveillance have to be strong if we are going to be able to
2328 detect a bioterror event or a new emerging disease. We are
2329 working, you know, again through BARDA on the diagnostics end
2330 of this, but there is that whole local infrastructure that
2331 has to be on the ground to make this work.

2332 Mr. {Pallone.} Thank you. Thank you, Mr. Chairman.

2333 Mr. {Pitts.} The chair thanks the gentleman, also
2334 thanks the witnesses. Excellent panel, great testimony.
2335 Thank you very much for answering our questions.

2336 In conclusion, I would like to thank the witnesses and
2337 the members for participating in today's hearing. I remind
2338 members that they have 10 business days to submit questions
2339 for the record, and I ask the witnesses to respond promptly
2340 to the questions. Members should submit their questions by

2341 the close of business on August 4.

2342 This subcommittee is adjourned.

2343 [The information follows:]

2344 ***** INSERT 5, 6, 7 *****

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2345 [Whereupon, at 12:06 p.m., the subcommittee was
2346 adjourned.]