

**This is a preliminary transcript of a Committee hearing. It has not yet been subject to a review process to ensure that the statements within are appropriately attributed to the witness or member of Congress who made them, to determine whether there are any inconsistencies between the statement within and what was actually said at the proceeding, or to make any other corrections to ensure the accuracy of the record.**

1 {York Stenographic Services, Inc.}

2 RPTS BURDETTE

3 HIF034.020

4 EXAMINING THE U.S. PUBLIC HEALTH RESPONSE TO SEASONAL

5 INFLUENZA

6 TUESDAY, FEBRUARY 3, 2015

7 House of Representatives,

8 Subcommittee on Oversight and Investigations

9 Committee on Energy and Commerce

10 Washington, D.C.

11 The Subcommittee met, pursuant to call, at 10:02 a.m.,  
12 in Room 2123 of the Rayburn House Office Building, Hon. Tim  
13 Murphy [Chairman of the Subcommittee] presiding.

14 Members present: Representatives Murphy, McKinley,  
15 Burgess, Blackburn, Griffith, Bucshon, Flores, Brooks,  
16 Mullin, Hudson, Collins, Cramer, Upton (ex officio), DeGette,  
17 Schakowsky, Castor, Tonko, Clarke, Kennedy, Green, Welch, and  
18 Pallone (ex officio).

19           Also present: Representative Ellmers.

20           Staff present: Charlotte Baker, Deputy Communications  
21 Director; Sean Bonyun, Communications Director; Leighton  
22 Brown, Press Assistant; Noelle Clemente, Press Secretary;  
23 Brad Grantz, Policy Coordinator, Oversight and  
24 Investigations; Brittany Havens, Legislative Clerk; Charles  
25 Ingebretson, Chief Counsel, Oversight and Investigations;  
26 Emily Newman, Counsel, Oversight; Alan Slobodin, Deputy Chief  
27 Counsel, Oversight; Peter Bodner, Democratic Counsel;  
28 Elizabeth Letter, Democratic Professional Staff Member; and  
29 Nick Richter, Democratic Staff Assistant.

|

30           Mr. {Murphy.} Good morning. Today we convene the first  
31 meeting of this session of the Subcommittee on Oversight and  
32 Investigation of the 114th Congress. I welcome back Members  
33 who served here last session, particularly, my friend and  
34 colleague, Diana DeGette, the Ranking Member from Colorado,  
35 and the new members from the 114th Congress, which we hope,  
36 as we come up, you may introduce them today, and I will  
37 introduce ours on our side.

38           The Subcommittee is here to examine a very serious U.S.  
39 public health response to seasonal influenza. America is  
40 experiencing a severe flu season with an unstable predominant  
41 strain that could result in one of the deadliest and  
42 costliest flu seasons in recent memory. An estimated 50,000  
43 people will die. Over 200,000 will be hospitalized, and most  
44 of these will be senior citizens.

45           Last February, when public health officials needed to  
46 decide what strains would go into this year's seasonal flu  
47 vaccine, the FDA bet on the wrong predominant strain. Just a  
48 few weeks after the FDA's decision, doubts already were  
49 already beginning to creep in the scientific community about  
50 the FDA's decision. By September, the U.S. vaccine was such  
51 a poor match for the dominant strain of flu that the World  
52 Health Organization, with consultation from the CDC, revised

53 the vaccine formula, but not for the United States. It was  
54 changed for the southern hemisphere nations. In other words,  
55 the American people were stuck with a vaccine that wasn't  
56 going to work for nearly 4 out of 5 people, and for nearly 9  
57 out of 10 seniors. Despite a growing body of knowledge that  
58 the vaccine for the United States would not be effective,  
59 production went forward anyway for a number of reasons that  
60 we hope to discuss today.

61 With a mismatched strain, this year's vaccine is  
62 estimated to be only 23 percent effective. It is even lower  
63 for the elderly at 12 percent. While this season's vaccine  
64 has lower-than-usual effectiveness, CDC is still recommending  
65 vaccination for everyone 6 months or older. In addition to  
66 vaccination, CDC has also recommended that all high-risk  
67 patients should be treated with antiviral drugs as soon as  
68 possible when influenza is suspected.

69 So what are agencies doing to communicate with the  
70 public? Many are choosing not to vaccinate against the flu  
71 because they hear the vaccine doesn't work, so why bother.  
72 We are seeing a similar result with measles vaccinations but  
73 for every--but for very different reasons, and now we are  
74 paying the piper for more than 100 cases have been stricken  
75 with a disease of measles that had once been eradicated from  
76 our shores.

77           False rumors still exist that vaccines and a  
78 preservative for multi-dose vaccines, which once used a  
79 microscopic amount of mercury as a preservative to prevent  
80 bacteria growth, led to autism. There is no credible  
81 evidence to support that claim. In fact, mercury is not used  
82 as a preservative in the MMR vaccine, and in developing  
83 nations where vaccination rates have increased, autism rates  
84 have not changed. So in addition to understanding why this  
85 year's flu vaccine missed so badly, and what should be done  
86 to protect the public in future years, I hope we can use this  
87 platform to educate the public and advance vaccine  
88 development in the interest of public health.

89           Now on to the flu vaccine. We must know: Did the  
90 federal government do everything it could at the right time  
91 to respond to the challenge of this year's flu season? As I  
92 noted, the CDC knew in late September that there was a  
93 significant mismatch, as great as 50 percent, with the U.S.  
94 vaccine, however, the CDC did not issue a health advisory in  
95 response to this mismatch until more than 2 months later.  
96 Did the CDC make the right public health decision to delay  
97 the health advisory, especially on delaying a recommendation  
98 to treat high-risk patients with antivirals? Could vaccine  
99 manufacturers have developed a new vaccine for high-risk  
100 groups? The CDC and the FDA tell us that the significant

101 change in the strain could not have been addressed any  
102 earlier than September 2014, way too late to make changes in  
103 the U.S. vaccine. However, one flu expert at the University  
104 of Utah School of Medicine has stated on the record that  
105 there was a pretty good indication that the drifted strain by  
106 April or May 2014, that probably would have led to a decision  
107 to change at that time if strain selection decisions for  
108 manufacturing were made in May instead of February.

109         In hindsight, it was a bad decision, and thousands will  
110 die. Surely there are lessons to be learned here to do  
111 something different in the future, and we want to know how we  
112 can partner with these agencies to come up with some  
113 solutions.

114         In 2009, when there was a similar outbreak of the swine  
115 flu, federal agencies declared a public health emergency and  
116 responded by producing a monovalent, or single strain,  
117 vaccine to protect the public in a short time. In only 12  
118 weeks, they had developed this new vaccine. Here, we must  
119 know, was a monovalent rescue vaccine targeting the drifted  
120 strain a possible response? Who made the decision to not go  
121 forward with a different vaccine? If not, was this partly  
122 because the FDA and other agencies lacked emergency authority  
123 to respond? Did they recognize the problem and ask for  
124 authority to respond quicker? If an astounding 50,000 deaths

125 and 200,000-plus hospitalizations does not equal an emergency  
126 then what is? Shouldn't we be treating this problem with  
127 more urgency, and is there even a backup plan in the event a  
128 vaccine mismatch to a deadly strain exists?

129 HHS has set a goal for vaccines to vaccinate 70 percent  
130 of their population as part of the Healthy People 2020  
131 initiatives, but overall vaccination rates in the U.S. have  
132 been around 45 to 46 percent in the last few years. CDC has  
133 not even met its target of 50 percent. Does the CDC have an  
134 effective strategy to increase vaccination rates, or is there  
135 a better strategy for reducing flu deaths than seeking  
136 further increases of vaccination rates in all sub-groups?

137 So we are here today to challenge some of the policies  
138 and decisions, but in the spirit of us all working together  
139 to make improvements in the public health response to  
140 seasonal flu. I am encouraged by the potential of ongoing  
141 research and innovation. We appreciate the cooperation and  
142 attendance of these excellent witnesses from the CDC, the  
143 FDA, NIH and BARDA. We need your input to help us decide how  
144 we change this system for the better. I welcome our  
145 witnesses today, and thank them for help in this inquiry.

146 [The prepared statement of Mr. Murphy follows:]

147 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
148           Mr. {Murphy.} And I recognize the ranking member for 5  
149 minutes.

150           Ms. {DeGette.} Thank you so much, Mr. Chairman. I am  
151 really happy that our first hearing of this new Congress is  
152 on an area of bipartisan concern and interest. And I want to  
153 join you in welcoming our new members on both sides of the  
154 aisle to this committee. This is a venerable committee that  
155 has a long history of bipartisan investigations, and I think  
156 it is going to be a really important year to continue this  
157 trend.

158           Flu preparedness and response is incredibly important,  
159 and this committee has a long hearing--history of hearings  
160 and investigations on this issue. What we need to do is come  
161 together in support of a strong public health infrastructure  
162 that prevents outbreaks, and responds quickly and  
163 appropriately when they occur.

164           These past several months have been a harsh reminder  
165 that infectious disease is all around us. Last October and  
166 November, this subcommittee convened hearings on the Ebola  
167 outbreak and the dire situation in West Africa. We saw and,  
168 frankly, continue to see, the deadly consequences of a  
169 breakdown in the public health infrastructure there.  
170 Fortunately, we are now seeing the lowest number of new Ebola

171 cases since last June, largely because of international  
172 efforts both to build and operate effective Ebola treatment  
173 centers, and also education of local populations on Ebola  
174 prevention and control. But, you know, it is interesting  
175 because as much attention as we have given to Ebola in this  
176 country, far more people die every month from influenza than  
177 they do of Ebola, and this is a continuing problem.

178         This month, we are hearing about the measles outbreak  
179 which was linked to Disneyland in California, and has now  
180 spread to at least 14 states. Infectious disease experts at  
181 the CDC and the State Health Departments have mounted a fast  
182 an aggressive response to prevent this highly contagious  
183 disease from spreading.

184         And, Mr. Chairman, I know you have received a letter  
185 from me and Ranking Member Pallone and Ranking Member Green  
186 on--asking this committee to hold a targeted hearing on the  
187 measles outbreak, and the urgent public health threat. I  
188 would like to make a copy of that letter part of the record,  
189 Mr. Chairman.

190         And, you know, while that letter is pending, and I want  
191 to commend you, Dr. Fauci. I saw you on the news last night  
192 telling all of the families in America to get their measles  
193 vaccine, and I really appreciate that. I want to add from  
194 this podium, as the mother of two daughters; one of whom is

195 immunocompromised, vaccinate your children against measles.  
196 There is no reason not to, and there is every reason that  
197 they could be a threat to themselves and other children if  
198 they don't get that vaccine. So I just want to pile onto  
199 that. It is very, very important.

200 But on to the flu, which is the topic of this hearing,  
201 the predominant strain of flu is H3N2, which is resulting in  
202 increased hospitalizations, particularly for vulnerable  
203 populations like seniors and young children. And the CDC  
204 announced several weeks ago that the flu vaccine has only 23  
205 percent effectiveness. That is significantly lower in  
206 private--in--than in recent years, and as the chairman  
207 mentioned, it is largely due to changes in the virus that  
208 have resulted in a mismatch between the strain of the virus  
209 used in vaccine production and the one actually circulating.  
210 But even with a 23 percent effectiveness, we still need to  
211 protect ourselves as much as we can. Dr. Frieden recommend--  
212 reminded us several weeks ago that even a vaccine with 23  
213 percent effectiveness will still prevent millions of people  
214 from getting sick. And so, therefore, as the chairman said,  
215 people also need to get this vaccine. And it is not too  
216 late; flu season is still going on. We have to do everything  
217 we can to protect our vulnerable populations; young children,  
218 seniors, pregnant women, and others with compromised immune

219 systems.

220           So I am looking forward to hearing from our wonderful  
221 witnesses today about what we can do to mitigate the effects  
222 of this flu season, and how doctors and hospitals are  
223 prepared to respond. I also want to look to the future.  
224 What can we do to inform our prevention and response efforts  
225 in future flu seasons? I want to hear about the research and  
226 technological developments in diagnostics, antiviral  
227 treatments and vaccines.

228           In our last hearing on this topic in February 2013, we  
229 heard about FDA approval of quadrivalent vaccines and cell  
230 base technology. Today, I am hoping our witnesses can give  
231 us encouraging news about the development of a universal flu  
232 vaccine.

233           So regardless of the particular effectiveness rate in a  
234 given season, the flu vaccine remains the best tool that we  
235 have to protect as many people as possible, and we need to  
236 have ongoing work on that. This flu season reminds us that  
237 it is almost impossible to predict what the strain will be,  
238 but it underscores the importance of a strong public health  
239 infrastructure.

240           And so, Mr. Chairman, I just want to say I appreciate  
241 the witnesses coming today. I hope we can all work together  
242 to move the country toward better flu preparedness.

243 [The prepared statement of Ms. DeGette follows:]

244 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
245           Mr. {Murphy.} I thank the gentlelady. And now  
246 recognize the chairman of the full committee, Mr. Upton, for  
247 5 minutes.

248           The {Chairman.} Well, thank you, Mr. Chairman.

249           This is an important issue, that is for sure, and it has  
250 been an especially harsh flu season, and preliminary  
251 estimates show that this year's vaccine is only 23 percent  
252 effective in preventing folks from going to the doctor for  
253 treatment, even lower for high-risk groups, which is often  
254 the case I know.

255           Usually, the flu vaccine is about 50 to 60 percent  
256 effective, and I, like many folks back in Michigan and across  
257 the country, would like to see this--see us do better in  
258 addressing this major public health threat.

259           Every year, between 5 and 20 percent of Americans get  
260 the flu. In a severe flu season like this one, there could  
261 be more than 50,000 deaths, over 200,000 hospitalizations,  
262 and more than \$10 billion spent on direct medical costs. The  
263 flu is and should be a top priority for all of U.S. public  
264 health.

265           This year's vaccine, we know, is less effective because  
266 it is not a good match for the flu strain that has become  
267 dominant. The flu virus strain changed significantly during

268 the 6 months after the strain selection decision for the U.S.  
269 was made. The World Health Organization, in September,  
270 recommended changing the flu vaccine for the southern  
271 hemisphere to use in their upcoming flu season that starts in  
272 April but by the time the change in virus was evident, it was  
273 too late to change the U.S. vaccine.

274 Now, it is worth pointing out that the CDC continues to  
275 recommend vaccinations in the U.S., even with a lower  
276 effectiveness, and that high-risk patients should be treated  
277 as soon as possible with all antiviral drugs.

278 When we learned that there was a shift in the virus,  
279 what options were available to respond to the mismatch in  
280 viruses? Was there a way to deploy a rescue vaccine  
281 targeting just the changed virus? Was there a way to improve  
282 the effectiveness of this year's vaccine by adding substances  
283 to boost the immune response? Those are some of the  
284 questions that we need to have answered as we proceed with  
285 this hearing.

286 And I appreciate the folks that are testifying today and  
287 yield to Dr. Burgess and then to Marsha Blackburn.

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

289 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
290 Mr. {Burgess.} I thank the chairman for yielding. And,  
291 Mr. Chairman, thank you for holding the hearing today.

292 In fiscal year 2014, the estimated federal investment in  
293 seasonal flu preparedness exceeded \$850 million. The public-  
294 private partnership striving research and development has had  
295 successes but we must do better.

296 First, communication between agencies and with the  
297 public must improve. If there is a mismatch in the vaccine,  
298 which became apparent in May or even as late as September, it  
299 is unacceptable that advisories were not issued until  
300 December. Second, there must be transparency and consistency  
301 in the regulatory pathways for innovation in vaccines.  
302 Experts have recognized the promise of--in vaccines for over  
303 a decade, yet not one is licensed in the United States, and  
304 no guidance has been issued. Third, greater emphasis must be  
305 placed on modernizing the development of manufacture of flu  
306 vaccines. I would add my acknowledgement to the ranking  
307 member of the subcommittee, I too at one time was promised a  
308 universal flu vaccine, I think in this committee at a hearing  
309 just like this. That was probably in 2004, 2005. We are  
310 still waiting. We want to see it.

311 So I appreciate the opportunity to be able to speak on  
312 this. I look forward to hearing from our witnesses.

313           And I will yield the balance of the time to Mrs.

314 Blackburn, Vice Chair of the full committee.

315           [The prepared statement of Mr. Burgess follows:]

316 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
317 Mrs. {Blackburn.} Thank you, Mr. Chairman. And I want  
318 to continue our conversation about vaccinations. And, yes,  
319 we are talking about flu today, but there is another issue  
320 out there and Ms. DeGette mentioned this. Vaccine politics  
321 injected into 2016, measles outbreak infects politics and  
322 debate.

323 Now, this is far too serious an issue to be treated as a  
324 political football. People still die from measles. And the  
325 CDC Web site tells us it was eliminated from the U.S. in  
326 2000, but yet we are seeing this outbreak. And I have to  
327 tell you, it is of tremendous concern to me as a mother and a  
328 grandmother. I am hearing so much about this from my  
329 constituents, and they want to know some answers, they want  
330 to know how you all are addressing this. And I will tell  
331 you, when I hear about counties in California that have lower  
332 immunization rates than the Sudan and Chad, this is something  
333 that is of concern to me.

334 I am a Rotarian. We have invested decades into  
335 eliminating and wiping out polio, and then to hear this about  
336 the U.S., I am concerned.

337 We know the measles outbreak started in California. It  
338 has affected over 100 people in 14 states, and that most of  
339 those people were not vaccinated. So we do want to veer off

340 and ask you some questions in this realm today.

341 And I yield back.

342 [The prepared statement of Mrs. Blackburn follows:]

343 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
344 Mr. {Murphy.} The gentlelady yields back.

345 And now--who is the--

346 {Voice.} Pallone.

347 Mr. {Murphy.} Recognize Mr. Pallone. You are down  
348 there. Mr. Pallone for 5 minutes.

349 Mr. {Pallone.} Thank you, Mr. Chairman, and thanks for  
350 holding this hearing today.

351 I have to tell Ms. DeGette that this is actually the  
352 first time that I have been a member of the O&I subcommittee,  
353 so I am very happy.

354 Ms. {DeGette.} And we are happy to have you, Mr.  
355 Pallone.

356 Mr. {Pallone.} Thank you.

357 Mr. {Murphy.} Welcome aboard. It is the best  
358 subcommittee in Congress.

359 Mr. {Pallone.} Thank you. So this year, we are seeing  
360 a severe flu season. Across the country, hospitalization  
361 rates are higher, especially for seniors over age 65, and for  
362 young children, and public health experts predict these flu  
363 activity levels will continue and even increase in the next  
364 few weeks.

365 The Centers for Disease Control and Prevention continues  
366 to recommend that we all get the flu vaccine. Initial

367 estimates show that this year's flu vaccine is 23 percent  
368 effective, meaning that 23 percent of those vaccinated for  
369 the flu will still have to visit a doctor because of the flu.  
370 But despite being less effective this year than the recent  
371 past, flu shots will still protect against and decrease the  
372 severity of flu-related illnesses. Moreover, flu shots don't  
373 only protect the vaccinated, they also protect those who have  
374 not been vaccinated from getting sick, and as members of  
375 Congress, I think we all have to play a role to ensure that  
376 message gets out and it is not too late to get your flu  
377 vaccine.

378         This hearing is also a good opportunity to talk about  
379 how we can improve vaccination rates. We took important  
380 steps in the ACA to provide coverage for preventative  
381 services like immunizations. Since the law went into effect,  
382 nearly 76 million Americans have received no-cost coverage  
383 for preventative services, and as millions more receive  
384 coverage through the ACA, we hope to see the vaccination rate  
385 improve so that we can realize the benefits of a better-  
386 protected population. However, we still must improve public  
387 awareness, and continue to improve access to these  
388 preventative services. This is especially of concern as we  
389 hear reports of the measles outbreak that began at  
390 Disneyland, and is now spreading throughout the country.

391 Just yesterday, the President urged all parents to get their  
392 children vaccinated against measles, and I would certainly  
393 echo his comments.

394 Dr. Tom Frieden, who heads the CDC, is warning that the  
395 U.S. could see a large outbreak of measles. There are now  
396 over 100 cases in 14 states, and measles is extremely  
397 contagious, 90 percent of those exposed to the disease will  
398 be infected unless they have been vaccinated. According to  
399 Dr. Frieden, there has been growing evidence that more  
400 parents are not vaccinating their children against measles,  
401 and that these lower vaccination rates have led to the latest  
402 increase in measles cases. The CDC is further assuring  
403 families, and parents especially, that the measles vaccine is  
404 safe and effective, and we were able to eliminate measles in  
405 the U.S. in 2000, largely because of a highly-effective  
406 vaccination program. So it is important to reiterate that  
407 measles is a preventable disease for which there are safe,  
408 effective and available vaccines.

409 So I look forward to hearing from our public health  
410 officials today about how we can improve vaccination rates  
411 for the flu, but we also need to learn how we can improve  
412 vaccination rates for the future for other infectious  
413 diseases, including measles.

414 I know that Ms. DeGette mentioned that both herself and

415 Mr. Green and myself sent a letter yesterday asking for a  
416 hearing with regard to the measles public health emergency,  
417 and I hope that we can actually see that occur. I think it  
418 would be very important. And I just want to thank everyone.

419 And I would now yield the balance of my time to  
420 Representative Castor.

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

422 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
423 Ms. {Castor.} Well, thank you for yielding the time,  
424 and good morning. Thank you, Mr. Chairman and Ranking Member  
425 DeGette, for holding this important hearing to better  
426 understand the flu and the flu vaccine.

427 Vaccines are incredibly valuable tools to protect and  
428 improve the health of all of our neighbors. And as we have  
429 seen with the recent and surprising measles outbreak,  
430 vaccines protect lives. According to reports, there have  
431 been 102 cases of measles reported across 14 states, and  
432 those who do not vaccinate their children are putting them at  
433 risk, and they are putting others at risk. Vaccines are safe  
434 and effective.

435 I want to give particular thanks to Dr. Schuchat from  
436 the Centers from--for Disease Control for traveling to the  
437 Tampa Bay area a few months back to raise awareness with  
438 another important vaccine, the anti-cancer vaccine of HPV.  
439 Thank you for meeting with our public health students, and  
440 cancer--anti-cancer advocates to explain. See, Florida had  
441 one of the lowest rates of HPV vaccines, and we can save  
442 lives and prevent cancer if people will understand the  
443 importance of the HPV vaccine. Your visit was a great boost  
444 to our efforts to prevent cancer through the HPV vaccine, so  
445 thank you again for the work you do to educate the public on

446 vaccinations.

447           You know, we are so fortunate to live in America where  
448 we have studied and investigated and tested all of these  
449 vaccines to ensure that they are safe and effective. So  
450 thank you to all the panelists for all the work you do, and I  
451 look forward to your testimony.

452           I yield back.

453           [The prepared statement of Ms. Castor follows:]

454 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
455 Mr. {Murphy.} Thank you.

456 I would now like to introduce the witnesses on the panel  
457 for today's hearing. We are--first is Dr. Anne Schuchat.  
458 Did I pronounce that correctly? The director of the National  
459 Center for Immunization and Respiratory Diseases at the  
460 Center for Disease Control and Prevention. Dr. Karen Midthun  
461 is next, is the director for the Center for Biologics  
462 Evaluation and Research at the U.S. Food and Drug  
463 Administration. Dr. Robin Robinson, the director of  
464 Biomedical Advanced Research and Development Authority,  
465 otherwise known as BARDA, within the Office of the Assistant  
466 Secretary for Preparedness and Response. And Dr. Anthony  
467 Fauci is the director of the National Institute of Allergy  
468 and Infectious Diseases at the National Institutes of Health.  
469 I welcome you all here and we look forward to your testimony.

470 I will now swear in the witnesses.

471 You are aware that this committee is holding an  
472 investigative hearing, and when doing so, has the practice of  
473 taking testimony under oath. Do any of you have any  
474 objections to testifying under oath? Seeing no objections,  
475 the Chair then advises you that under the rules of the House  
476 and the rules of the committee, you are entitled to be  
477 advised by counsel. Do any of you desire to be advised by

478 counsel during your testimony today? Everybody has said no.  
479 In that case, if you would please rise and raise your right  
480 hand, I will swear you in.

481 [Witnesses sworn.]

482 Mr. {Murphy.} Thank you. You are now under oath, and  
483 subject to penalties set forth in Title XVIII, section 1001  
484 of the United States Code. You may each now give a 5-minute  
485 summary of your written statement. Make sure you pull the  
486 microphone close to you, and watch that red light.

487 Dr. Schuchat, you can begin.

|  
488 ^TESTIMONY OF DR. ANNE SCHUCHAT, DIRECTOR, NATIONAL CENTER  
489 FOR IMMUNIZATION AND RESPIRATORY DISEASES, CENTERS FOR  
490 DISEASE CONTROL AND PREVENTION; DR. KAREN MIDTHUN, DIRECTOR,  
491 CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, U.S. FOOD AND  
492 DRUG ADMINISTRATION; DR. ROBIN ROBINSON, DIRECTOR, BIOMEDICAL  
493 ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, OFFICE OF THE  
494 ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S.  
495 DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND DR. ANTHONY  
496 FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS  
497 DISEASES, NATIONAL INSTITUTES OF HEALTH

|  
498 ^TESTIMONY OF DR. ANNE SCHUCHAT

499 } Dr. {Schuchat.} Good morning, Mr. Chairman, and members  
500 of committee. I am Dr. Anne Schuchat, Director of the  
501 National Center for Immunization and Respiratory Diseases at  
502 the Centers for Disease Control and Prevention.

503 Influenza virus is a formidable adversary. Influenza's  
504 propensity to change presents unique challenges. New flu  
505 vaccines must be developed each year based on the predictions  
506 of which viruses are likely to be most common during the next  
507 season. Vaccine development is complex and time-consuming,  
508 typically requiring vaccine candidates that grow well in eggs

509 and provide immunity in humans. And while we tackle seasonal  
510 flu, we must conduct constant global surveillance and prepare  
511 for the emergence of dramatically changed or shifted  
512 influenza virus that could trigger the next pandemic.

513 Over the past decade, we have made significant  
514 improvements in our ability to detect, prevent and respond to  
515 influenza, yet, despite our improvements, the current severe  
516 influenza season has been difficult. My colleagues and I  
517 represent agencies that work together to respond to seasonal  
518 and pandemic flu. The NIH supports research on vaccines,  
519 diagnostic tools, and antiviral drugs for seasonal and  
520 pandemic influenza. The Food and Drug Administration  
521 regulates influenza vaccines, convening public health and  
522 influenza disease experts to recommend which influenza virus  
523 strains should be included in FDA-licensed vaccines.

524 The Biomedical Advanced Research and Development  
525 Authority, BARDA, supports advanced research, development and  
526 procurement of innovative medical countermeasures to address  
527 manmade and emerging infectious diseases, including influenza  
528 pandemics. And at CDC, we support surveillance and  
529 diagnostic capacity to rapidly detect, prevent and respond to  
530 annual influenza epidemics, and novel and pandemic influenza  
531 threats.

532 Our CDC systems provide the scientific basis for global

533 vaccine virus selection for seasonal flu, vaccine as well as  
534 for pandemic vaccine stockpiling. We monitor for genetic  
535 changes in the flu virus, and identify how these changes  
536 affect disease transmission and severity. We build public  
537 awareness and provide our knowledge about prevention and  
538 early treatment, and support public sector delivery of  
539 routine and emergency immunizations.

540         The 2014/'15 influenza season has proven a particularly  
541 bad season. The virus that is predominant, H3N2, is  
542 associated with more severe disease. The vaccine we are  
543 using is not well matched to circulating H3N2 strains.  
544 Antivirals can be important aids in some patients, but  
545 clinicians are underutilizing them.

546         How do we find ourselves with vaccine that isn't well  
547 matched to the circulating H3N2 viruses? When the 2014/'15  
548 flu vaccine strains were selected last February, the drifted  
549 virus we are seeing now was not yet detected. A small number  
550 of these drifted viruses were first detected in March 2014,  
551 and CDC continued to monitor them throughout the summer,  
552 looking for genetic patterns and geographic spread.

553         In September 2014, when we began promoting seasonal  
554 vaccination, about 1/2 of the H3N2 viruses circulating were  
555 like the vaccine component. When the influenza season took  
556 off at the end of November, only 1/3 of the H3N2 viruses CDC

557 detected were like the vaccine component. Our early vaccine  
558 effectiveness estimate found people vaccinated had about 23  
559 percent lower risk of influenza infection requiring a medical  
560 visit. While this is lower than we usually see, the vaccine  
561 is providing some protection.

562       Influenza viruses follow their own schedules, not ours.  
563 New strains can emerge at any time. Some appear and die out,  
564 and others persist and spread. Our actions are proportional  
565 to risks. We work year-round to detect and characterize  
566 viruses of concern that circulate globally, monitor their  
567 emergence and geographic spread, and develop viable vaccine  
568 candidates for drift viruses as they occur. When we detected  
569 relatively small numbers of the drifted H3N2 strain late last  
570 spring, CDC began preparing candidate vaccine virus strains.

571       As the Nation's public health agency, we are committed  
572 to provide the information people need to protect their  
573 patients' and families' health, and to be transparent in our  
574 assessments and the evidence base that supports our  
575 recommendations.

576       As a physician and a public health professional, I too  
577 wish we could guarantee better protection each year, yet, we  
578 have made significant advances on several fronts. Our  
579 surveillance network is characterizing more viruses with  
580 improved methods. Significantly more Americans get flu

581 vaccine each year, and information on viruses, disease and  
582 vaccination is released more rapidly.

583         In closing, this flu season has caused more suffering  
584 and serious disease than many previous years, and there will  
585 be more challenging seasons ahead, but collaboration across  
586 the agencies, and with our public and private partners, holds  
587 promise for the future, including progress toward development  
588 of universal influenza vaccines, since better, broader, and  
589 long-lasting protection could transform our approach to this  
590 challenging virus.

591         [The prepared statement of Dr. Schuchat follows:]

592 \*\*\*\*\* INSERT 1 \*\*\*\*\*

|  
593 Mr. {Murphy.} Thank you.

594 Dr. Midthun, you are recognized for 5 minutes. Thank  
595 you. Make sure the microphone is turned on and it is close  
596 to you. Thank you. You still have to turn it on. Press  
597 the--there you go.

|  
598 ^TESTIMONY OF DR. KAREN MIDTHUN

599 } Dr. {Midthun.} Thank you. Mr. Chairman and members of  
600 the subcommittee, I am Dr. Karen Midthun, Director of the  
601 Center for Biologics Evaluation and Research, the center  
602 within FDA that is responsible for regulating vaccines.  
603 Thank you for the opportunity to be here today to discuss our  
604 role in a highly collaborative, multi-partnered effort in  
605 preventing influenza through vaccination in the U.S.

606       Influenza viruses continually undergo changes in their  
607 genetic makeup, and the resulting proteins that interact with  
608 the immune system. Due to these continuous changes, the  
609 composition of influenza vaccines must be periodically  
610 updated so that they are effective against what are  
611 anticipated to be the predominant circulating viruses in the  
612 upcoming influenza season.

613       The strains of virus in the vaccine include 2 distinct  
614 subtypes of influenza A, H1N1, and H3N2, and 1 or 2 influenza  
615 B strains, depending upon whether the vaccine is trivalent or  
616 quadrivalent. To identify virus strains likely to cause  
617 illness during the upcoming season, the World Health  
618 Organization convenes influenza and public health experts to  
619 study recently circulating influenza viruses from around the

620 world, and recent global disease patterns. After careful  
621 evaluation of the assessment, WHO makes recommendations on  
622 the composition of the influenza vaccines, usually in late  
623 February for the upcoming season in the northern hemisphere,  
624 and in September for the upcoming season in the southern  
625 hemisphere. The recommendations must be made months in  
626 advance because of the time required for manufacturing,  
627 testing, release and distribution of a very large number of  
628 vaccine doses.

629         Each year, following the WHO recommendations, FDA  
630 convenes its vaccines and related biological products  
631 advisory committee, typically in late February or early  
632 March. The committee considers the WHO recommendations and  
633 reviews information regarding viruses that caused illness in  
634 the previous year, how these viruses are changing, and  
635 disease trends. Based on the data available at the time of  
636 the meeting, the committee makes recommendation for the  
637 composition of the influenza vaccines licensed by FDA for the  
638 upcoming season in the U.S. Once the strains are selected,  
639 candidate influenza viruses that are adapted for high growth  
640 are generated and accepted by WHO collaborating centers, and  
641 are provided to manufacturers who generate the seed viruses  
642 for manufacturing vaccines. The manufacturing demands are  
643 tremendous and the timelines are tight. No other vaccine is

644 produced, FDA approved and distributed every year across the  
645 U.S. within a six-month time frame.

646         This season, more than 150 million doses were  
647 manufactured. Given the yearly need for a new vaccine, there  
648 is limited flexibility in the timelines of vaccine  
649 manufacturing and availability. And parallel with vaccine  
650 manufacturing, FDA develops and calibrates reagents which are  
651 used by both FDA and the manufacturers to test vaccines for  
652 potency and identity before FDA approves the new formulation  
653 for distribution. Manufacturers submit their vaccine testing  
654 results, along with samples from each lot, to FDA for lot  
655 release. As FDA releases lots, the manufacturers can make  
656 these lots commercially available throughout the U.S.

657         In February 2014, when the strain selection  
658 recommendation for the correct influenza season was made, it  
659 reflected the circulating viruses. The drifted H3N2 viruses  
660 were first detected in March 2014 and were uncommon. Over  
661 the ensuing months, the drifted strains gradually increased.  
662 By late September, when WHO made its recommendations for the  
663 2015 southern hemisphere influenza vaccine, the drifted H3N2  
664 strains were common, prompting a recommended change in the  
665 upcoming southern hemisphere vaccine composition. Because of  
666 the manufacturing time required, there was not enough time to  
667 make a similar change to the current northern hemisphere

668 influenza season. The drifted strains have caused the  
669 majority of influenza cases this season, however, vaccination  
670 is still important to prevent disease and minimize the public  
671 health burden of influenza. Influenza vaccines contain three  
672 or four influenza viruses, so even when there is a less than  
673 ideal match or a low effectiveness against one virus, the  
674 vaccine may protect against the other viruses.

675         FDA has made progress in our preparedness efforts and  
676 collaboration with BARDA, CDC, NIH, manufacturers, and other  
677 stakeholders, and we thank Congress for your support of these  
678 efforts. New influenza vaccines have been licensed,  
679 including cell-based, recombinant protein vaccines and  
680 quadrivalent vaccines. To enhance pandemic preparedness, FDA  
681 licensed an adjuvanted H5N1 avian influenza vaccine, and has  
682 worked with U.S. Government partners and manufacturers to  
683 facilitate the development of candidate vaccines directed at  
684 H7N9 avian influenza. Surveillance efforts are more  
685 extensive than ever before, and offer the potential for early  
686 detection of emerging viruses. The number of candidate  
687 vaccine virus strains available to manufacturers has greatly  
688 increased over the last few years, providing them with more  
689 options to increase vaccine yields. We continue efforts with  
690 our government partners to develop high-yield candidate  
691 vaccine strains, as well as more modern, faster testing

692 methods for vaccine potency and sterility. To further  
693 address the challenges presented by the constantly changing  
694 nature of influenza viruses, scientists and government  
695 laboratories, academic institutions, vaccine manufacturers,  
696 are all working to develop new generation vaccines that might  
697 provide longer-lasting and broader protection against  
698 influenza viruses, including drifted strains. Although these  
699 development efforts are still in early stages, some may have  
700 the potential to increase and broaden protection against  
701 influenza.

702         FDA will continue to work with its government partners,  
703 manufacturers and other stakeholders to facilitate development  
704 of new vaccines, and identify methods that have the potential  
705 to speed the manufacturing process for existing vaccines.  
706 Our goal is to better protect the American public against  
707 influenza.

708         Thank you.

709         [The prepared statement of Dr. Midthun follows:]

710         \*\*\*\*\* INSERT 2 \*\*\*\*\*

|

711 Mr. {Murphy.} Thank you.

712 Now, Dr. Robinson, you are recognized for 5 minutes.

|  
713 ^TESTIMONY OF DR. ROBIN ROBINSON

714 } Dr. {Robinson.} Good morning, Chairman Murphy, Ranking  
715 Member DeGette, and distinguished members of the  
716 subcommittee. Thank you for the opportunity to speak with  
717 you today. I am Dr. Robin Robinson, Director of the  
718 Biomedical Advanced Research and Development Authority, of  
719 the Deputy Assistant Secretary for Preparedness and Response,  
720 as well as a former developer of influenza vaccines in  
721 industry.

722 BARDA is a federal government agency mandated to support  
723 advanced research and development, and procurement of novel  
724 and innovative medical countermeasures such as vaccines,  
725 therapeutics, diagnostics and medical devices for the entire  
726 Nation to address the medical consequences of manmade and  
727 naturally-occurring threats like the H1N1 pandemic in 2013,  
728 H7N9 influenza outbreak, and the current Ebola epidemic.

729 Pandemic influenza is one of our primary concerns. We  
730 understand that preparedness for pandemic influenza is  
731 directly tied to seasonal influenza. Medical countermeasures  
732 for seasonal influenza underpin the vaccines, antivirals and  
733 diagnostics used for pandemic influenza. BARDA has invested  
734 in the advanced development of medical countermeasures that

735 have utility for both seasonal and pandemic influenza  
736 preparedness.

737         BARDA transitions medical countermeasures from early  
738 research and development at NIH, to advanced development  
739 toward FDA approval and potential procurement. BARDA has  
740 funded and successfully managed the advanced development of  
741 more than 60 medical countermeasures for pandemic influenza.  
742 More than 20 of these medical countermeasures for influenza  
743 have been FDA approved, with 6 receiving approval in the last  
744 3 years, as Dr. Midthun indicated. Additionally, BARDA  
745 developed and procured vaccines and antivirals used in the  
746 2009 H1N1 pandemic, and stockpiled vaccines for preparedness  
747 against H5N1 and H7N9 viruses. BARDA, through partnerships  
748 with NIH, CDC and FDA, industry and academia, has met and  
749 overcome many, but not all of the challenges inherent to  
750 making medical countermeasures associated with seasonal and  
751 pandemic influenza. Specifically, BARDA, with our partners,  
752 has made major progress in the following pandemic areas.

753         First, modernization of influenza vaccine manufacturing  
754 through the development and licensure of new cell- and  
755 recombinant-based influenza vaccines, and antigen-sparing  
756 pandemic vaccines with adjuvants towards meeting our  
757 strategic goal of more and better influenza vaccines sooner.  
758 These new vaccines were part of our successful H7N9 response

759 in 2013.

760         Second, shortening influenza vaccine manufacturing time  
761 by weeks, effective through the Influenza Vaccine  
762 Manufacturing Improvement initiative, as recommended by  
763 PCAST, to optimize the generation of high-yielding vaccine  
764 seed strains, and alternative potency and sterility assays.  
765 Many of these improvements, such as biosynthetic technology,  
766 were employed during the H7N9 vaccine response in 2013, which  
767 was the fastest on record.

768         Third, establishment and maintenance of pre-pandemic  
769 influenza vaccine stockpiles for H5 and H7N9 viruses that may  
770 be used to immunize tens of millions of persons at the onset  
771 of an influenza pandemic with these viruses.

772         Fourth, and last, multi-fold expansion of domestic  
773 pandemic influenza vaccine production capacity, afforded by  
774 retrofitting of older manufacturing plants, building new  
775 state-of-the-art manufacturing facilities for making 21st  
776 century influenza vaccine, and establishing three centers for  
777 innovation and advanced development and manufacturing, with  
778 rapid, nimble and flexible manufacturing capabilities through  
779 public-private partnerships with industry.

780         The new national infrastructure responded in 2013 to the  
781 H7N9 outbreaks, and today, in the Ebola epidemic. Despite  
782 these significant accomplishments, our pandemic preparedness

783 work is not over. Making a more effective influenza vaccine  
784 remains a significant scientific challenge. Indeed, progress  
785 towards more effective influenza vaccines has been noted in  
786 recent years, but much more is needed.

787       Going forward, there is reason for hope that more  
788 effective influenza vaccines may be within our grasp. The  
789 discovery of new influenza viral targets within the last 4  
790 years has renewed interests and efforts to develop new  
791 universal influenza vaccine candidates.

792       Developing more effective pandemic influenza vaccines is  
793 one of our top priorities, and BARDA will support new methods  
794 based on evolutionary biology that may help forecast in  
795 selection of new seasonal and pandemic influenza vaccine  
796 strains.

797       In parallel, we are launching this month an initiative  
798 to support advanced development of new, more effective  
799 influenza vaccine candidates that may elicit greater,  
800 broader, longer immunity in all populations against divergent  
801 influenza virus variants, and that may serve as primers for  
802 pandemic influenza vaccines.

803       In conclusion, influenza viruses with pandemic potential  
804 continue to evolve and change, infect animals and man, and  
805 pose significant threats to global and domestic public  
806 health. This year's limited seasonal influenza vaccine

807 effectiveness, and the arrival of the first human case of  
808 H7N9 virus in North America underscore our urgent need to  
809 complete this mission. To be better prepared, our Nation  
810 must continue to invest in domestic pandemic preparedness,  
811 and work with key global partners.

812 I thank you for this opportunity to discuss how we can  
813 be better prepared for seasonal and pandemic influenza, and I  
814 look forward to your questions.

815 [The prepared statement of Dr. Robinson follows:]

816 \*\*\*\*\* INSERT 3 \*\*\*\*\*

|

817 Mr. {Murphy.} Thank you, Dr. Robinson.

818 Dr. Fauci, you are recognized for 5 minutes.

|  
819 ^TESTIMONY OF DR. ANTHONY FAUCI

820 } Dr. {Fauci.} Mr. Chairman, Ranking Member DeGette,  
821 members of the committee, I appreciate the opportunity to  
822 discuss with you today very briefly the role of the National  
823 Institute of Allergy and Infectious Diseases in research  
824 addressing both seasonal and pandemic influenza.

825 As shown on this slide, the NIH research agenda is  
826 really based on the traditional approach that the NIH has  
827 taken with all diseases, namely fundamental basic research,  
828 clinical research and field research, the provision of  
829 research resources both to the academic community, as well as  
830 to the biotech and pharmaceutical companies. The endgame is  
831 to ultimately produce interventions in the form of  
832 diagnostics, therapeutics and vaccines. You have heard about  
833 the diagnostics and therapeutics. We can talk about them a  
834 little bit later. I want to focus the remainder of my  
835 remarks on a subject of obvious importance; namely, the  
836 development of influenza vaccines.

837 Traditionally, the classic, what we call, platforms or  
838 the way you develop the vaccine, have been based on growing  
839 the virus itself either in eggs, which is somewhat  
840 cumbersome, or more recently using it in cell lines, which

841 are a bit more predictable. You either have an inactivated  
842 live vaccine, or a--excuse me, a live attenuated vaccine or  
843 an inactivated vaccine, and that has been the traditional  
844 approach towards vaccines. It is cumbersome, it takes a long  
845 period of time because you have to grow the virus.

846 Our researchers, both at the NIH and our grantees and  
847 contractors, over the last several years have been  
848 attempting, with some success, to make a conversion to what  
849 we call a recombinant DNA technology, molecular-based  
850 approach that would obviate the need to actually continue to  
851 grow the virus to make a vaccine. Several of these are  
852 illustrated on this slide. We don't have time to go into  
853 each and every one of them, but they are particularly suited  
854 to develop a vaccine that we are all hoping for, and that Dr.  
855 Burgess mentioned in his 5-minute remarks, and that is a  
856 universal influenza vaccine.

857 This is the cover of a Nature Medicine article that I  
858 wrote with my colleague, Dr. Gary Nabel, the former director  
859 of the Vaccine Research Center, namely, how we can induce  
860 what I called unnatural immunity; namely, immunity that a  
861 normal vaccine induction or the virus itself doesn't induce,  
862 and that is broad protection against subsequent exposures to  
863 different types of influenzas that have a tendency to drift  
864 over a period of years, and sometimes to even shift, which

865 gives us a pandemic.

866           Now, the reason we can do this, and I just want to point  
867 out on this slide, on the lower right is a blown-up schematic  
868 of the influenza virus. The proteins that coat the outside  
869 are referred to as hemagglutinin, and that is where we get  
870 the H for H3, H2 or H1. It is a designation of a major  
871 protein. The other one is N for neuraminidase. But notice  
872 how those proteins are clustered on the surface of the virus,  
873 so that what the immune system sees generally is just the  
874 top, what we refer to as the head or the bulb of that  
875 protein. If you look at this slide, that head is where most  
876 of the antibodies that protect you and I against influenza  
877 are made. That is the good news. The sobering news is that  
878 is a variable region, which tends to change as influenzas  
879 drift from season to season, and change an awful lot when it  
880 goes to a pandemic.

881           If you look at the little stem, the thin part of that  
882 protein, that the immune system doesn't see very well,  
883 interestingly, we found out several years ago that that is  
884 the part--that is what we called highly conserved. It  
885 doesn't change from necessarily a Texas H3N2 to a different  
886 type, a Singapore or a variety of others, they stay the same,  
887 which means that if you can induce an immune response against  
888 that unchangeable one, you might be able to get what we call

889 a broader reactivity. And over the last several years, we  
890 have made considerable progress and--let me go back here--as  
891 shown on this slide here, where a number of candidates have  
892 used molecular techniques to essentially show the body  
893 predominantly the part of that protein that doesn't change.  
894 And there are a number of ways of doing that. Instead of  
895 giving the body the entire virus, either killed or  
896 attenuated, by molecular techniques, you show the body only  
897 the part that you want it to respond to, unencumbered by the  
898 physical structures that don't allow the body to see it. And  
899 we now have done this in several candidates in mice, in  
900 ferrets, and what we call phase one studies in humans, which  
901 means we know it is safe, we know it can induce the kind of  
902 response that is more broad, and in collaboration with BARDA,  
903 we are now starting to produce that to go into larger trials.  
904 And as Dr. Burgess said, we are not there yet, but we are  
905 clearly many steps further than what we were the last time I  
906 testified before this committee.

907       So I will stop there, and be happy to answer any  
908 questions.

909       [The prepared statement of Dr. Fauci follows:]

910 \*\*\*\*\* INSERT 4 \*\*\*\*\*

|  
911 Mr. {Murphy.} Thank you.

912 I will now recognize myself opening questions for 5  
913 minutes.

914 But let me just start off, and I know that a lot of  
915 concerns about vaccines and autism. As a psychologist, I  
916 have seen many a child with autism. It is a deeply  
917 concerning problem with the families. Past publications have  
918 been discredited, and data was deemed fraudulent. Multiple  
919 studies said there is no link between developmental disorders  
920 such as autism and vaccines.

921 I want to ask each of you, do you agree, Dr. Schuchat?  
922 Dr. Midthun, do you agree? Dr. Robinson, do you agree? Dr.  
923 Fauci, do you agree? And--yeah, you can say this verbally.  
924 Should parents have their children vaccinated? Dr. Schuchat?

925 Dr. {Schuchat.} Vaccines save lives and are the best  
926 way for parents to protect their children--

927 Mr. {Murphy.} Yeah, right.

928 Dr. {Schuchat.} --from vaccine-preventable diseases.

929 Mr. {Murphy.} Dr. Midthun, yes or no? Yes?

930 Dr. {Midthun.} Yes. I have three children and they  
931 were all vaccinated on time with all the recommended  
932 vaccines.

933 Mr. {Murphy.} Dr. Robinson?

934 Dr. {Robinson.} Absolutely.

935 Mr. {Murphy.} Dr. Fauci?

936 Dr. {Fauci.} Definitely.

937 Mr. {Murphy.} Okay. Now, let us talk about--moving  
938 into this one. Dr. Schuchat, flu expert, Dr. Andrew Pavia at  
939 the University of Utah School of Medicine, said, ``By April  
940 or May, there was good evidence of the drifted A/Switzerland  
941 strain. It wasn't clear it was going to be a dominant  
942 strain, but there was a pretty good hint, we probably would  
943 have chosen the vaccine differently.'' Dr. Schuchat, do you  
944 agree that there was good evidence of the drifted strain by,  
945 say, April or May of this last year?

946 Dr. {Schuchat.} We were certainly keeping a close eye  
947 on this drifted strain last May, and that is when the CDC  
948 began to develop a candidate vaccine virus, but as you know,  
949 it can be very challenging to develop candidate vaccine  
950 viruses, and to take it from a candidate to all the way to  
951 production of vaccine, all the way to production of hundreds  
952 of millions of doses of vaccine.

953 Mr. {Murphy.} But by May, there was evidence of a 17  
954 percent mismatch. Do you think that 17 percent mismatch was  
955 a concern at that point, and were there any discussions about  
956 that at CDC?

957 Dr. {Schuchat.} Yes, there were. In fact, in March, we

958 started to reach out to the global community, the  
959 international WHO collaborating centers, when we saw the  
960 first handful of this drifted strain to ask others were they  
961 seeing it.

962 I think it is important to realize that strains emerge  
963 and can disappear, and in the spring, it is very difficult to  
964 know which ones will still be around in the summer or fall.  
965 We actually respond to these new drifted strains by working  
966 on candidate vaccine viruses, but it is very difficult with  
967 influenza to predict what strains will dominate, whether it  
968 is going to be an H3N2 year or a 1--H1N1 year. And so we  
969 continue to go through the routine seasonal flu work while we  
970 are also developing the candidate vaccine virus--

971 Mr. {Murphy.} Well, let me ask about this pattern. We  
972 have here, I am looking at the mismatch notes, by March there  
973 is about a 10 percent mismatch drift, by May, 17 percent. We  
974 understand by September it was already up to 50 percent. Do  
975 we know in these gaps of April or June or July or August what  
976 those drift rates were? Was there a problem by those times  
977 that was being seen?

978 Dr. {Schuchat.} Yes, we have information for the  
979 summer. It is important to remember that there is very  
980 limited influenza circulating here in the U.S. in the summer,  
981 and it takes off in the fall. That is one of the reasons we

982 do global worldwide surveillance--

983 Mr. {Murphy.} Sure, but right here--

984 Dr. {Schuchat.} --and we have greatly increased the  
985 numbers there.

986 Mr. {Murphy.} But here in September, a decision was  
987 made for the World Health Organization to change this for the  
988 southern hemisphere. And so I am wondering because--big gaps  
989 here, were there discussions between all your agencies that  
990 we ought to be doing something differently or--other than  
991 telling people to have some kind of an antiviral medicine.

992 Dr. {Schuchat.} Thanks. I think it is important--Dr.  
993 Fauci talked about the idea of drift and the idea of shift,  
994 and I think the members remember in 2009 where, in the spring  
995 of 2009, we did decide it was important to go forward with a  
996 monovalent vaccine--

997 Mr. {Murphy.} Right.

998 Dr. {Schuchat.} --against a pandemic. We think of  
999 pandemics as having catastrophic risk because they generally  
1000 are defined by a new strain that the population has no  
1001 protection against at all. It is so differing from--

1002 Mr. {Murphy.} But you could do that fairly quickly  
1003 during that--the issue of the Swine--from 2009. Once it  
1004 reached this level where we are now only 23 percent  
1005 effectiveness, and about 12 percent for senior citizens, a

1006 high-risk group for death, for mortality and morbidity, why  
1007 not move forward at this point with at least a monovalent  
1008 strain for high-risk groups and high-risk geographical areas?

1009 Dr. {Schuchat.} The time between developing a candidate  
1010 vaccine virus, which we started working on in May, and the  
1011 ability to have a lot of doses is about 6 months. So it  
1012 really wouldn't be available--

1013 Mr. {Murphy.} So--but you did it in 12 weeks in 2009.

1014 Dr. {Schuchat.} The large amounts of vaccine were only  
1015 available in November in 2009, after having really started in  
1016 May.

1017 Mr. {Murphy.} But you did it in a much shorter time,  
1018 but not the 6 months. My point is, when you identify  
1019 somebody that is going to have that level of mortality and  
1020 morbidity, and it can be done in a short period of time, were  
1021 your agencies talking with each other and says--clearly, a  
1022 decision was made in September, hey, for the southern  
1023 hemisphere, we need to change that, but for the northern  
1024 hemisphere it says let us keep going with what we have,  
1025 recognizing that it is only effective for 1 out of 5 people  
1026 and 1 out of 10 seniors. It seems to me that you need a  
1027 different decision-making process.

1028 Dr. {Schuchat.} Thanks. I think another point that is  
1029 important to make is the difference between the laboratory

1030 mismatch and the clinical protection. In 2003/'04, we had a  
1031 laboratory mismatch. It turned out that when we measured  
1032 clinical protection, protection was about 50 to 60 percent in  
1033 different populations. So seeing that in the lab in that  
1034 hemagglutinin inhibition testing that there is drift or that  
1035 there is a difference between the strain and the vaccine, and  
1036 the strains that are circulating, doesn't perfectly predict  
1037 how the vaccines will work in practice. So I think it is  
1038 very important to differentiate that decision to make a  
1039 monovalent vaccine against a pandemic where we know there is  
1040 not going to be the widespread protection because people  
1041 haven't seen the strain before, and where it is a race  
1042 against time in terms of the--although it is challenging with  
1043 current technology, the value of trying to make a vaccine is  
1044 worth it.

1045 Mr. {Murphy.} I am way over time. I need to--

1046 Dr. {Schuchat.} By which--okay.

1047 Mr. {Murphy.} --pursue other members.

1048 Recognize Diana DeGette for 5 minutes.

1049 Ms. {DeGette.} Thank you very much, Mr. Chairman.

1050 Well, following up on the chairman's question, Dr.  
1051 Schuchat, would it be fair to say, and this--really yes or no  
1052 would work here, would it be fair to say that the way we are  
1053 going to be able to substantially reduce the time between

1054 when we identify a strain and developing the vaccine will be  
1055 what Dr. Fauci is talking about, which is development of new  
1056 platforms and ways to get the vaccine?

1057 Dr. {Schuchat.} Absolutely.

1058 Ms. {DeGette.} Now, Dr. Fauci, I want to turn to you  
1059 because, over the years, you have come and talked about the  
1060 development of these vaccines. I remember when we had a  
1061 hearing in this committee when we were trying to move from  
1062 the egg to the cell vaccine. And now you say you have the  
1063 cell techniques, but you also say that you are getting ready  
1064 to go into larger clinical trials on these new platforms, is  
1065 that correct?.

1066 Dr. {Fauci.} That is correct, Ms. DeGette. The  
1067 important point is that we really think that anything that  
1068 needs to grow the virus--

1069 Ms. {DeGette.} Right.

1070 Dr. {Fauci.} --and produce it just is a time sync. So  
1071 that is the point that I made on the--

1072 Ms. {DeGette.} Right.

1073 Dr. {Fauci.} --slide.

1074 Ms. {DeGette.} No, and we actually, even those of us  
1075 who only took high school biology, understood that point.

1076 Dr. {Fauci.} Yeah.

1077 Ms. {DeGette.} So--

1078 Dr. {Fauci.} Yeah.

1079 Ms. {DeGette.} --good work again. But what I want to  
1080 know is now that you have done your phase 1 trials, and you  
1081 are trying to move beyond that, what is your time frame for  
1082 that?

1083 Dr. {Fauci.} Well, you know, it is going to really  
1084 depend on, first of all, testing it in a season to show that  
1085 even though you don't specifically have it against this  
1086 particular strain, that it is covering that strain. So when  
1087 you are trying to prove universality, you want to test it in  
1088 a season in which it is a broader response. One of--

1089 Ms. {DeGette.} Right.

1090 Dr. {Fauci.} Yeah. One of--

1091 Ms. {DeGette.} So would that be like next season--

1092 Dr. {Fauci.} Well, we--

1093 Ms. {DeGette.} --do you think?

1094 Dr. {Fauci.} --we actually are going to try now with  
1095 the--in collaboration with BARDA, to make enough of that new  
1096 concept to be able to test it--

1097 Ms. {DeGette.} Test it in this season.

1098 Dr. {Fauci.} --in the following season.

1099 Ms. {DeGette.} Dr. Robinson, you are--

1100 Dr. {Fauci.} Following season.

1101 Ms. {DeGette.} --you are nodding your head, yes. Is--

1102 Dr. {Robinson.} Yeah, the following season.

1103 Ms. {DeGette.} Okay. So what can Congress do to help  
1104 you with that? Do you need additional resources, do you--  
1105 what do you need to be able to start to expedite that  
1106 research?

1107 Dr. {Fauci.} Well, I mean, obviously, you ask a  
1108 scientist if they need resources, the answer is an automatic  
1109 kneejerk--

1110 Ms. {DeGette.} Well--

1111 Dr. {Fauci.} --of course we can do better with more  
1112 resources, but we actually need your continued support to  
1113 keep the focus on the need for this, because when we do these  
1114 tests, remember, it isn't--we don't have control over the  
1115 companies that make the contracts with the various--

1116 Ms. {DeGette.} Right.

1117 Dr. {Fauci.} --health organizations that distribute  
1118 this, but I think the focus that this committee has  
1119 continually put on this has been very helpful to us.

1120 Ms. {DeGette.} Now, in your written testimony, you talk  
1121 about the difference between seasonal flu and pandemic flu.  
1122 Can you briefly explain that to us?

1123 Dr. {Fauci.} So I mentioned in my oral testimony a few  
1124 moments ago that viruses tend to--influenza viruses tend to  
1125 change slightly. We call that a drift.

1126 Ms. {DeGette.} Right.

1127 Dr. {Fauci.} Right.

1128 Ms. {DeGette.} Every season.

1129 Dr. {Fauci.} That is a little bit. Now, if it changes  
1130 slightly, even if you don't get the vaccine match right,  
1131 there is enough background immunity in the community against  
1132 similar viruses that the vast majority of the population are  
1133 not going to have a catastrophic outbreak where people would  
1134 be completely unprotected.

1135 Ms. {DeGette.} Right.

1136 Dr. {Fauci.} When you have an influenza that has what  
1137 we call a shift, not a drift, that means major changes, so  
1138 when you look at the general population, the overwhelming--

1139 Ms. {DeGette.} Right. They don't have that.

1140 Dr. {Fauci.} --majority don't have any background  
1141 protection. So it is almost as if you are totally naïve to  
1142 this new--

1143 Ms. {DeGette.} And that is what happened in--

1144 Dr. {Fauci.} --virus.

1145 Ms. {DeGette.} --2009 and 2010.

1146 Dr. {Fauci.} Indeed. The bad news, it happened in  
1147 2009. The somewhat comforting news that it wasn't a  
1148 particularly varied--

1149 Ms. {DeGette.} Right. Exactly. And that is what we--

1150 Dr. {Fauci.} --virus. So we--

1151 Ms. {DeGette.} --were worried about.

1152 Dr. {Fauci.} --were lucky.

1153 Ms. {DeGette.} So, Dr. Robinson, now, you said in your  
1154 testimony that there remains significant technical challenges  
1155 before a substantially better influenza vaccine is available,  
1156 and I would assume that the biggest concern for both of you  
1157 gentlemen, well, for all four of our witnesses, would be that  
1158 if we don't develop that significantly better vaccine system,  
1159 and we get a virulent pandemic flu, is that right, Dr.  
1160 Robinson?

1161 Dr. {Robinson.} That is right. I mean as Dr. Fauci  
1162 pointed out, we actually have new ways to actually look in  
1163 making these vaccines by looking at a different portion of one  
1164 protein. We normally make the vaccines against the  
1165 hemagglutinin and our immunities to that, the head of that,  
1166 and now we can actually look at the stalk which we are making  
1167 these candidates. We may be able that way to protect against  
1168 many different drifted strains, and serve as a primer for a  
1169 pandemic so that you have one dose of this, so you only need  
1170 one dose of pandemic vaccines instead of maybe two.

1171 Ms. {DeGette.} Yes, and so what we are concerned about,  
1172 or what I am concerned about, what keeps me awake at night,  
1173 is if we don't do enough, both Congress and also our research

1174 institutions, to be able to have that vaccine available if we  
1175 get a virulent pandemic flu. Dr. Fauci, and--

1176 Dr. {Fauci.} So another important point besides the  
1177 fact that all of the issues, the advantages of this universal  
1178 flu vaccine, namely, molecular biology rather than growing--

1179 Ms. {DeGette.} Right.

1180 Dr. {Fauci.} --the critical issue is if you--if we get  
1181 it right, you could actually stockpile it.

1182 Ms. {DeGette.} Right.

1183 Dr. {Fauci.} So we wouldn't have to worry about the  
1184 chart that the chairman put up about it changing and trying  
1185 to keep up with it--

1186 Ms. {DeGette.} Right.

1187 Dr. {Fauci.} --because if you stockpile it, you could  
1188 stockpile it the same way you stockpile polio vaccine,  
1189 measles vaccine, et cetera. That is really the endgame.

1190 Ms. {DeGette.} Thank you. Thank you very much, Mr.  
1191 Chairman.

1192 Mr. {Murphy.} Thank you.

1193 Now recognize Mrs. Blackburn, Vice Chair of the full  
1194 committee, for 5 minutes.

1195 Mrs. {Blackburn.} Thank you, Mr. Chairman. And as I  
1196 said earlier, I want to focus on measles because we are  
1197 hearing so much about this. And bear in mind, I have a

1198 daughter who has two children. They are in kindergarten and  
1199 pre-K, and I can tell you, and I am sure you all and your  
1200 teams, are fully aware that a lot of the mommy blogs are  
1201 focused on this issue right now. And it is a big issue with  
1202 our constituents.

1203 And, Dr. Schuchat, let me come to you first. I just  
1204 want to be sure what we are--what the known knowns are about  
1205 the measles virus. If you would elaborate for just a second.  
1206 We are hearing 102 cases, that out of these only five had a  
1207 vaccination against measles. Do you know what the rate is  
1208 how they are affecting elderly as well as children? If you  
1209 will give us just 1 minute on this.

1210 Dr. {Schuchat.} Yeah, the--so far, there have been 102  
1211 people from 14 states that have developed measles in 2015.  
1212 There are another 11 cases of measles from the end of 2014  
1213 that were linked to the Disneyland outbreak. Not all of the  
1214 102 cases this year are linked with Disneyland, but the  
1215 majority are.

1216 The majority of people in these outbreaks so far have  
1217 not been vaccinated. Only a small number have--are known to  
1218 have been vaccinated. Important to remember that there are  
1219 about 20 million measles cases around the world each year,  
1220 and so measles is literally a plane ride away. When it gets  
1221 into communities like the United States now, in certain

1222 pockets where a lot of people are unimmunized, it has a  
1223 chance to spread. And so that is why California is really,  
1224 you know, working day and night to follow every lead and put  
1225 an end to it there. And that is why the health departments  
1226 in every state are really on alert right now.

1227 Mrs. {Blackburn.} Okay. Let me ask you this. As a  
1228 physician, and a representative of our Nation's public health  
1229 agency, if you are talking to a parent, should they be more  
1230 fearful of the disease, measles, or the measles vaccine?

1231 Dr. {Schuchat.} Every parent wants their child to be  
1232 healthy and safe, and I absolutely respect that. As a  
1233 physician and as a public health expert, I can tell you the  
1234 measles, mumps, rubella, or MMR, vaccine is very effective  
1235 and very safe.

1236 Measles can be serious, and I would hate for a parent to  
1237 think that everything will be fine, and have a bad outcome  
1238 with their child. So I strongly recommend people talk with  
1239 their physicians and get the right information, but  
1240 personally, I would definitely have my child vaccinated.

1241 Mrs. {Blackburn.} Thank you.

1242 Dr. Fauci, same question to you.

1243 Dr. {Fauci.} Same answer from Dr. Schuchat. I--there  
1244 is no doubt, if you do a risk/benefit of the vaccine versus  
1245 the disease, I think it is very, very clear that you have one

1246 of the most highly-effective vaccines against any virus, and  
1247 you have a highly-contagious disease, measles, that can have  
1248 serious complications, so to me it is really a slam dunk what  
1249 the decision would be.

1250 Mrs. {Blackburn.} So if it were you child or  
1251 grandchild, you would say vaccinate?

1252 Dr. {Fauci.} Without a doubt, and I have done that with  
1253 my three children.

1254 Mrs. {Blackburn.} Excellent. Thank you, sir.

1255 I--Dr. Robinson, I am going to let you off the hook  
1256 today. I usually have quite a group of questions for you.  
1257 So--but I--and I do, I have some questions on Tamiflu and on  
1258 the stockpile and the shortage, and--but as one of my  
1259 researchers from Vanderbilt told me this weekend, we don't  
1260 always get the flu right, and had a way of terming how we go  
1261 about looking at this. I am going to, in the interest of  
1262 time, submit these and would love a response from you.

1263 And I yield back.

1264 Mr. {Murphy.} Thank you. Gentlelady yields back.

1265 And now--

1266 {Voice.} Mr.--

1267 {Voice.} Mr. Pallone.

1268 Mr. {Murphy.} Mr. Pallone is recognized. Thank you.

1269 Mr. {Pallone.} Thank you, Mr. Chairman. I wanted to

1270 start out with Dr. Midthun. I am concerned about the low flu  
1271 vaccine rate for children. By November 2014, only 42 percent  
1272 of children between the ages of 6 months and 17 years have  
1273 been vaccinated for the flu, and I think we need to change  
1274 this. And, of course, the measles outbreak raises more  
1275 concerns about childhood vaccination. Yesterday, I--we  
1276 mentioned that Ms. DeGette, Mr. Green and myself called for a  
1277 separate hearing on the outbreak, and the importance of  
1278 vaccination to prevent the spread of measles.

1279 I am sorry, actually, my question is of Dr. Schuchat.  
1280 What can we do to increase childhood vaccination rates, both  
1281 for the flu and for other infectious diseases?

1282 Dr. {Schuchat.} You know, I think that parents'  
1283 decisions to vaccinate their kids are often related to their  
1284 sense of the threat and their sense of the value of the  
1285 intervention. And we are so fortunate in this country that  
1286 our disease rates have been quite low, that many parents  
1287 don't realize these diseases are still out there, and that if  
1288 their children aren't vaccinated, they will come back. So  
1289 with the measles outbreak, I think most parents who weren't  
1290 vaccinating didn't realize measles was still around and could  
1291 be dangerous.

1292 In terms of the value of the intervention, it is  
1293 important for parents to have all the information they need

1294 about the safety, the effectiveness, the risks and benefits.  
1295 It is important to me that parents know that the immunization  
1296 system is deeply committed to transparency, to monitoring  
1297 vaccine safety, to sharing information that--about risks when  
1298 we determine them, and to updating our recommendations  
1299 whenever there is new data. Right now, we know that the  
1300 vaccines we are giving are saving lives and saving money.  
1301 For each dollar we put in, we get about \$10 back for the  
1302 childhood immunization series.

1303         So what we do to try to support and promote immunization  
1304 is a strong public-private partnership between healthcare  
1305 professionals, doctors and nurses, and pharmacists, and  
1306 community groups and consumer groups, to get information  
1307 where it is needed, when it is needed, in many different  
1308 formats. We know that most people trust their doctors and  
1309 nurses more than they trust me or other public figures, and  
1310 so we really try to support the doctors, nurses, pharmacists,  
1311 that are that frontline.

1312         Mr. {Pallone.} Well, thank you. Let me continue with  
1313 you. I know that the flu activity began in early December,  
1314 and continued to increase through the end of 2014. Has the  
1315 flu activity peaked for this year or--and what data do you  
1316 evaluate to make that determination?

1317         Dr. {Schuchat.} We are well along in the season, but it

1318 is difficult to say whether there will be a long tail or not.  
1319 In many areas it is flattening off but not deeply declining  
1320 yet. And sometimes later in the season, we see another  
1321 strain increase. We have had many seasons where one of the  
1322 H1N1 or H3N2 starts off the season, and one of the B strains  
1323 will be quite common later on. So we are not out of the  
1324 woods. It is important for people to be thinking about this.  
1325 And we particularly want people to know that if they develop  
1326 flu-like symptoms, and they are pregnant or they are very  
1327 elderly, or have other immuno-compromising conditions, early  
1328 treatment with antivirals could be very helpful to them. So  
1329 let--they should speak with their clinician.

1330 Mr. {Pallone.} All right, let me go back now. I did  
1331 have a question of Dr. Midthun. The flu vaccine comes in  
1332 different forms. There is the high-dose shot recommended for  
1333 seniors, a quadrivalent nasal spray recommended for young  
1334 children, and a recombinant trivalent, I don't know if I am  
1335 pronouncing it right, recombinant trivalent shot recommended  
1336 for those with egg allergies. How do you communicate to  
1337 different groups about the variety of vaccines, and can the  
1338 greater number of options for vaccines increase the rates?

1339 Dr. {Midthun.} As you point out, there are a number of  
1340 different options now, and what we try to do is really  
1341 communicate clearly the information that we provide on our

1342 Web site in our package inserts as to what groups were  
1343 studied and for which age groups the product is indicated.  
1344 So, for example, the high-dose vaccine you were referring to  
1345 was actually evaluated in individuals 65 years of age and  
1346 older, and was shown to decrease the rate of influenza by 23  
1347 percent, relative to those who got the normal dose vaccine.  
1348 And so--and likewise, quadrivalent vaccines are now available  
1349 for four different manufacturers; three are inactivated and  
1350 one is the live attenuated. They are indicated for somewhat  
1351 different groups across that spectrum, and again, that  
1352 information is put forward.

1353       The recombinant vaccine that you mentioned is--has only  
1354 so far been evaluated and shown to be safe and effective in  
1355 18 years of age and above, and so again, our prescribing  
1356 information will reflect that. But I think I should really  
1357 turn to Dr. Schuchat because that is really the advisory  
1358 committee on immunization practices, which is an advisory  
1359 committee for the CDC that then recommends how these vaccines  
1360 should be used.

1361       Dr. {Schuchat.} And just briefly, we recommend people  
1362 get vaccinated with the vaccine that is available. And so  
1363 while providers and pharmacists get all that information  
1364 about the different types, it is much more important to get a  
1365 vaccine than to worry about which one is there.

1366 Mr. {Pallone.} All right, thank you. Thank you, Mr.  
1367 Chairman.

1368 Mr. {Murphy.} Thank you.

1369 Now recognize the vice chairman of the subcommittee, and  
1370 welcome aboard as vice chairman, Mr. McKinley of West  
1371 Virginia.

1372 Mr. {McKinley.} Thank you, Mr. Chairman. Just a quick  
1373 observation as this--what I have heard and read in your  
1374 testimony and done a little research is, this whole process  
1375 designating which vaccine we are going to come up with in  
1376 September just seems archaic. In fact, it seems more of a  
1377 game of chance and probability. And by virtue of us  
1378 continuing this process, erroneously now with this mismatch,  
1379 we have 50,000 Americans who are going to die this year.  
1380 50,000 Americans. That is more than died in combat in  
1381 Vietnam, over a decade in--of that warfare. And they are  
1382 going to die because of a game of chance and probability.

1383 I am just astounded by that. I wonder what better  
1384 techniques can we use to predict ahead. And that leads me  
1385 then to the second question perhaps, or maybe associated with  
1386 that, is that the high-dose vaccine has been found to be 24  
1387 percent more beneficial to senior citizens, and you have a  
1388 meeting coming up late in February and it is not on the  
1389 agenda as a possibility for September. Could one of you

1390 explain just briefly why that is not on the agenda if it has  
1391 been proven to be helpful for senior citizens?

1392 Dr. {Schuchat.} Yes. Let me answer sort of both parts.  
1393 The high-dose vaccine is one of the licensed vaccines that is  
1394 recommended, and the company that makes it doesn't make  
1395 enough of it for all people 65 and over--

1396 Mr. {McKinley.} Um-hum.

1397 Dr. {Schuchat.} --but they have been increasing the  
1398 production. So it is included in the September and February  
1399 recommendations. The recommendations are really just which  
1400 vaccines to--which virus strains to target, and then there  
1401 are all these different formulations like high-dose.

1402 The other thing I just wanted to comment on about is  
1403 sort of the mismatch. I want to just point out that in the  
1404 past 20 years, this is the fourth time that we have had an  
1405 important mismatch between one of the circulating viruses and  
1406 the vaccine and what dominates. So it is very disturbing  
1407 when we have this and we have excess disease burden, but the  
1408 vast majority of recommended strains have actually been on  
1409 track. Even though, when we have a good match, a well-  
1410 matched vaccine type, we have a lot of morbidity and  
1411 mortality from influenza, and I think it is one of these  
1412 diseases that we as scientists take very seriously, but the  
1413 American public takes a bit for granted. So we wish that we

1414 had more people vaccinated each year, and that we wish that  
1415 people who need to get the antivirals would get them early,  
1416 but we have work to do in terms of the medical community and  
1417 the public--

1418 Mr. {McKinley.} Thank you.

1419 Dr. {Schuchat.} --and in having them take--

1420 Mr. {McKinley.} Thank you, doctor. Is--

1421 Dr. {Schuchat.} --it seriously.

1422 Mr. {McKinley.} I want to build a little bit of  
1423 background for the chairman and his chart. When it was  
1424 discovered first in May, I guess it was, that--or March,  
1425 there was some anomaly showing up. May, 17 percent,  
1426 September, 50 percent. It was obvious there was a problem  
1427 with it. So if I go back to Robinson's testimony, he said  
1428 that they fulfilled the PCAST report recommended improving  
1429 vaccine manufacturing to meet a national goal of making the  
1430 first dose within 12 weeks. Now, yes, the--it would have  
1431 taken to go to a national supply to go 6 months, which again,  
1432 is a real concern about the production, and some of the  
1433 techniques that we can use to reduce that--but if we could  
1434 have produced a vaccine, knowing in September it was 50  
1435 percent, so September, October, November, the 1st of  
1436 December, we could have had a modified drug, even if it is  
1437 limited supply, that we could have tried--whether it is an

1438 antigen or a new virus, or--excuse me, a new vaccine  
1439 entirely, wouldn't we--wouldn't you have recommended let us  
1440 try this and see what--do trials, what the result is. Did we  
1441 solve it. Can we do this in 12 weeks ago and--the next time.  
1442 But--so my question, did you do it? Did you try to do  
1443 anything to modify the vaccine that was wrong?

1444 Dr. {Schuchat.} Um-hum. I want to stress that we were  
1445 not--

1446 Mr. {McKinley.} It is a yes or no, isn't it?

1447 Dr. {Schuchat.} There were many activities taken to  
1448 address the emergence of drifted strain, including preparing  
1449 a candidate vaccine virus--

1450 Mr. {McKinley.} Did you try and modify it?

1451 Dr. {Schuchat.} The issue of protection is both what  
1452 strains are dominant, what efficacy the vaccine has, and how  
1453 many people can get the vaccine. So a highly-effective  
1454 vaccine with very few doses available may not be as good as a  
1455 moderate- or a low-efficacy vaccine and a lot of doses  
1456 available.

1457 Mr. {McKinley.} I will take your answer--

1458 Dr. {Schuchat.} I don't think that--

1459 Mr. {McKinley.} --as a no, that you didn't try and--

1460 Dr. {Schuchat.} No, what I am saying is that we did  
1461 begin to prepare the candidate vaccine virus so that

1462 companies would be able to produce a vaccine against the  
1463 drifted strain. This particular strain has been quite  
1464 challenging to produce vaccines against.

1465 Mr. {McKinley.} Thank you. 50,000 Americans die.

1466 Mr. {Murphy.} Now recognize Ms. Castor for 5 minutes.

1467 Ms. {Castor.} Thank you very much.

1468 Dr. Schuchat, on average, maybe take the last 10 or 20  
1469 years, how many Americans suffer each year from influenza,  
1470 how many are hospitalized, and how many die?

1471 Dr. {Schuchat.} Thank you. Yeah, for the past 5 years  
1472 or so, we have ranged between 19 and 35 million cases of  
1473 influenza illness each year, between 110,000 and almost  
1474 600,000 hospitalizations each year, and 5,300 to 39,000  
1475 deaths attributable to influenza. Those are in the past 5  
1476 years. In that same period, the vaccination efforts we have  
1477 had have been reducing the full burden by about 16 to 17  
1478 percent. You know, we would have more disease, deaths and  
1479 hospitalizations without vaccination, but it is not as high a  
1480 prevented--

1481 Ms. {Castor.} Um-hum.

1482 Dr. {Schuchat.} --fraction as we see for measles, where  
1483 we are preventing 99 percent, you know, of the disease. And  
1484 that is partly because we don't have high coverage.

1485 Ms. {Castor.} How many are vaccinated?

1486 Dr. {Schuchat.} Well, we have gone from 19 percent of  
1487 Americans getting vaccinated against flu, to 46 percent. So  
1488 that is a big improvement, but it is not the majority yet.  
1489 The other factor though besides the coverage is the  
1490 effectiveness, and even in a good year, we are seeing  
1491 vaccines that work about 60 percent efficacy, and so that is  
1492 why we are very committed to the interagency work on  
1493 developing vaccines that could have higher effectiveness,  
1494 particularly in the most vulnerable populations.

1495 Ms. {Castor.} And when it comes to the deaths, what age  
1496 range? We know the elderly are more vulnerable, but what are  
1497 the--

1498 Dr. {Schuchat.} Yeah, you know, the vast majority of  
1499 deaths are in seniors, but unfortunately, we do have children  
1500 die every year. There is--more than 60 children have died so  
1501 far this flu season, and I fear that is not going to be the  
1502 end of it. So we know that statistics say if you are  
1503 elderly, if you have medical immunocompromising conditions,  
1504 if you are under 2, you have more chance of being  
1505 hospitalized or dying from flu, but many parents can tell you  
1506 that their child was perfectly healthy and they actually lost  
1507 a child. So I really want parents and the general public to  
1508 know to take flu seriously.

1509 Ms. {Castor.} And this year, it is a particularly

1510 severe flu season with higher rates of hospitalization and  
1511 mortality. This is especially worrisome for those vulnerable  
1512 populations; children, the elderly, pregnant women, and  
1513 others with weakened immune systems. Dr. Midthun, the  
1514 severity of this year's flu can be partially attributed to  
1515 the fact that it is an H3N2 predominant year. Tell us what  
1516 that means in simple terms. The fact that this is an H3N2  
1517 predominant year. Dr. Midthun.

1518 Dr. {Midthun.} I think oftentimes in H3N2 prevalent  
1519 years, there may be more morbidity and mortality, although I  
1520 think it is very important to remember that all influenza can  
1521 cause morbidity and mortality. H1N1 was responsible for 2  
1522 pandemics, 1918 and the one in 2009. And also B strains can  
1523 be very serious, especially for children, and cause very  
1524 serious outcomes. But Dr. Schuchat may want to add to that.

1525 Dr. {Schuchat.} Yeah. Overall, the H3N2 serious years  
1526 have higher total morbidity and mortality, but as Dr. Midthun  
1527 says, the H1N1 has a predilection for younger people.

1528 Ms. {Castor.} Uh-huh. So you were talking about the  
1529 effectiveness of the current vaccine before this year's flu  
1530 vaccine shows 23 percent effectiveness. I want to hear more  
1531 about how we assess the flu vaccine effectiveness, and better  
1532 understand this. How do we gather information on infections  
1533 and mortality and then test for vaccine effectiveness?

1534 Dr. {Schuchat.} One of the things that the investments  
1535 in influenza have permitted, the resources that CDC has  
1536 gotten over the past several years, is expansion of the  
1537 systems by which we track influenza, and track influenza  
1538 vaccine coverage, and track influenza vaccine effectiveness.  
1539 So we have much better data today than we had several years  
1540 ago. We are able to provide estimates in the middle of the  
1541 year of how many people have gotten vaccinated, as well as  
1542 how well the vaccine is working so far.

1543 We work with state and local health departments in the  
1544 surveillance systems, and we work with academic university  
1545 partners in measurement of influenza vaccine effectiveness,  
1546 essentially, comparing people who have influenza laboratory-  
1547 confirmed disease with others to look back at their  
1548 vaccination history and basically quantify the vaccine  
1549 effectiveness that way. We release our data every week on  
1550 something called FluView. It is on our Web site. And so you  
1551 can essentially look in October 3 and see the first  
1552 information about the drifted strain. So every week as that  
1553 comes out, you can follow what is going on. But in mid-  
1554 January, in fact, we sped up the vaccine effectiveness  
1555 estimates so that the public would know them as quickly as  
1556 possible.

1557 Ms. {Castor.} Well, I know I marched my whole office

1558 down to get the flu vaccine, but I think this is very  
1559 important that people understand what the experts are saying  
1560 today, that this mismatch, parents with children need to be  
1561 especially careful because of the predilection for younger  
1562 folks. But in America, if we only have 46 percent, and that  
1563 is kind of high watermark for flu vaccinations, we can do a  
1564 whole lot better. So thank you very much.

1565 Mr. {Murphy.} Thank you.

1566 And now recognize Dr. Burgess for 5 minutes.

1567 Mr. {Burgess.} Thank you, Mr. Chairman.

1568 And, Dr. Schuchat, let me just pick up for a moment on  
1569 what you were discussing with the vice chair of the  
1570 subcommittee, Mr. McKinley. Now, you had a drifted strain  
1571 that kind of appeared on the scene. The southern hemisphere  
1572 designation is out of phase with what the viral--the vaccine  
1573 release in the northern hemisphere, correct? So you had  
1574 identified the drifted strain when the recommendation was  
1575 made for the inclusion in the vaccine that was released in  
1576 the southern hemisphere, is that correct?

1577 Dr. {Schuchat.} The--yes, that is right.

1578 Mr. {Burgess.} So why not then come forward with a  
1579 recommendation for a booster shot or some additional  
1580 protection for people in the northern hemisphere if we  
1581 already were developing a different vaccine based on a

1582 drifted strain for the southern hemisphere? Your neighbors  
1583 to the north might have been interested in that, don't you  
1584 think?

1585 Dr. {Schuchat.} You know, the manufacturing capacity to  
1586 respond in September to vaccine strain recommendations in  
1587 large number of doses would get us a large number of doses  
1588 probably February or so. So I mean Dr. Robinson might be  
1589 able to comment a little bit more, but the ability for us to  
1590 make a northern hemisphere recommendation for a vaccine in  
1591 September, and have doses in time for the flu season, would  
1592 be very low. And we take that type of step when we are  
1593 worried about a pandemic, and I think the committee is  
1594 raising the question of should we take that type of step when  
1595 it is not a pandemic situation but a drift.

1596 Mr. {Burgess.} We would like you to react with a little  
1597 bit more clarity and be flexible when so many lives are on  
1598 the line, as Mr. McKinley outlined. And I mean, look, we are  
1599 dealing with a, what, a 40 percent uptake of the vaccine as  
1600 it is. If people read the headlines and say only 1 in 5 are  
1601 protected anyway, I would just as soon not get stuck.

1602 Dr. {Schuchat.} Yeah.

1603 Mr. {Burgess.} So I would think you, as an agency, you  
1604 would want to have that flexibility and want to show utility  
1605 for people that we are on top of this, we are working on this

1606 24 hours a day, 7 days a week, 12 months out of the year. We  
1607 are monitoring your health and your safety when it comes to  
1608 the flu virus, and we can't be perfect every time, but when  
1609 we are not, we are going to be there to help you stave off  
1610 the effects. I mean, again, that is what I am hearing as a  
1611 result of this hearing. And as Dr. Fauci acknowledged, we  
1612 have had these hearings before. We had a hearing when we  
1613 only had a trivalent vaccine, and we talked about a  
1614 quadrivalent vaccine. I mean these things, they are  
1615 important, people do pay attention to them. Our vaccine  
1616 rates for influenza are lower than they should be for the  
1617 country.

1618 Dr. {Schuchat.} Um-hum.

1619 Mr. {Burgess.} I have gotten my flu shot every year  
1620 except 2004 when it was politically inadvisable for a Member  
1621 of Congress to receive a flu shot because there was a  
1622 shortage--

1623 Dr. {Schuchat.} Right.

1624 Mr. {Burgess.} --because of the serratia contamination  
1625 that occurred in one of the manufacturing labs. Separate  
1626 story, but every other year I step up and get the vaccine  
1627 because I meet a lot of people every day, I ride on an  
1628 airplane twice a week, this is just a commonsense reaction to  
1629 an--what is an inevitability on the ground.

1630 I want to shift gears for just a moment, and I do feel  
1631 obligated to talk about the measles issue because it has  
1632 achieved so much in the way of headlines, and I am going to  
1633 breach--I am going to violate HIPAA, and I just want to tell  
1634 HHS that I am going to violate HIPAA. I am going to release  
1635 sensitive clinical information about myself. So I never had  
1636 the measles vaccine. I didn't have it because I was too old.  
1637 I mean I was--well, when I was a child in the '50's, it  
1638 hadn't--it wasn't there, it wasn't available. I don't  
1639 remember every scraped knee, every sniffle from my childhood,  
1640 but I remember the measles.

1641 Dr. {Schuchat.} Um-hum.

1642 Mr. {Burgess.} It was bad. I mean you can see--and I  
1643 see in Harrison's here online, hard, shaking chills. I mean  
1644 that--it--yeah, hard, shaking chills doesn't even begin to  
1645 describe it. The chills are so hard they are painful. You  
1646 want to cover up, you want to pull a blanket around yourself,  
1647 but you don't want anything touching your skin. That is  
1648 measles. I mean it is a different disease. And we had  
1649 forgotten about it, quite frankly, because, you know, you  
1650 just never see it, and now we are faced with the prospect  
1651 that we are seeing it. It is important for parents to have  
1652 their children vaccinated.

1653 Dr. {Schuchat.} Um-hum.

1654 Mr. {Burgess.} There are things that can happen to you  
1655 as a consequence of having had the measles. I remember in  
1656 medical school learning about subacute sclerosing  
1657 panencephalitis, and I remember asking at the time why do I  
1658 have to learn about this, no one is going to get it anymore.  
1659 But, in fact, people may get it because it is a consequence  
1660 of having had a measles--an infection with measles. So these  
1661 issues are important.

1662 Now, if I recall correctly, and suddenly somehow this is  
1663 interjected into presidential politics, which is  
1664 inappropriate because, if I recall correctly, since President  
1665 Gerald Ford, there has not been a federal mandate for any  
1666 vaccination. And I will ask that question generally to the  
1667 panel, Dr. Fauci, is--am I correct on that?

1668 {Voice.} Microphone.

1669 Dr. {Fauci.} When President Ford essentially mandated  
1670 through the department that there be massive vaccination for  
1671 the 1976 influenza, the--that famous catastrophic event with  
1672 the Guillain-Barre, but I don't think there has been official  
1673 mandating about--

1674 Mr. {Burgess.} Correct. So these are state-mandated  
1675 vaccines that people have to take before attending public  
1676 schools, and there is a reason for that. It should be a  
1677 state mandate. There is no one asking for a federal mandate.

1678 It doesn't mean that the vaccination is not important. And  
1679 for people who are listening and paying attention today,  
1680 please have your children vaccinated.

1681 Thanks, Mr. Chairman. I will yield back.

1682 Mr. {Murphy.} Thank you.

1683 Now recognize Mr. Green for 5 minutes.

1684 Mr. {Green.} Thank you, Mr. Chairman. Thank our panel  
1685 for being here.

1686 Data from the National Immunization Survey found that  
1687 fewer than half of children and adults are vaccinated by  
1688 November of this current flu season. My numbers said 40.3  
1689 percent, but, doctor, you said 46 percent. Forty-six percent  
1690 of the people and 6 months or older received the flu vaccine.  
1691 These numbers seem similar to what we have seen in the last  
1692 few years.

1693 I wanted to hear why these vaccination rates continue to  
1694 be so low and what we can do to improve it, although I have  
1695 to admit, the recent news that it is only 20 percent--23  
1696 percent effective, and those of us who are much older it may  
1697 only be 12 percent, that would probably tell people not to  
1698 get it. But somehow along the way, we need to do it, and  
1699 encourage much more than 46 percent to be able to get that.  
1700 The data showed that nearly 60 percent of the people had not  
1701 taken advantage of it. Is that accurate?

1702 Dr. {Schuchat.} We--the 46 percent that are vaccinated  
1703 is based on last year's end-of-season, so the 40-some percent  
1704 was the early, you know, by November, how many had gotten  
1705 vaccinated.

1706 You are right that the majority still haven't gotten the  
1707 flu vaccine, and this is something that we think is going to  
1708 take years of work. Part of the issue is whether there is a  
1709 concern about the disease, and part of the issue is whether  
1710 there is confidence in the intervention. And as you know,  
1711 the intervention has different efficacy, different years. So  
1712 it is not a simple message and it is one that we work hard to  
1713 communicate honestly and clearly.

1714 Mr. {Green.} Well, I guess part of the problem is if we  
1715 think it is bad now with the news coverage about the less  
1716 effectiveness, what can we do to make next year that we have,  
1717 one, an effective flu vaccine, I know it is almost like  
1718 throwing darts against the wall, but--and that way we will  
1719 convince more people to get it, because again, the more  
1720 people vaccinated, the more we will defeat it.

1721 Dr. {Schuchat.} The vaccine prediction is most of the  
1722 time good. So out of the last 20 years, this is the fourth  
1723 time where there has been an important mismatch. And in some  
1724 of the previous times where there has been mismatch, there  
1725 has still been much higher efficacy than what we are seeing

1726 this year. This year will be a difficult year to follow in  
1727 terms of our messaging. We do want people to know that  
1728 influenza can be serious, and that the vaccine is still the  
1729 most effective way to reduce your risk, but we also want  
1730 people to know about antivirals, because those are also  
1731 underutilized and could actually reduce the duration of the  
1732 illness, and even reduce the chance of being hospitalized in  
1733 some patients. And so we think it is important to get both  
1734 messages out.

1735         Mr. {Green.} Is there anything that Congress could do  
1736 because when you found out that the effectiveness was so low,  
1737 I know there were some questions earlier from Dr. Burgess  
1738 on--saying, okay, this is--we need a booster for those of us  
1739 who got the vaccine, is there resources available where you  
1740 could do that and make it an issue, saying, you know, it is  
1741 only 23 percent but this booster will get you to 50 percent?

1742         Dr. {Schuchat.} You know, I think the resources that  
1743 have been provided have been incredibly valuable, and there  
1744 is both a short-term and a long-term strategy. You know, the  
1745 short-term strategy, to use available tools better, and to  
1746 make incremental improvements in the production and  
1747 distribution of vaccine, and the long-term strategy that Dr.  
1748 Fauci and Dr. Robinson were talking about with the research  
1749 and investments in universal vaccines. So I think we can't

1750 just do one or the other, we really have to do both, but it  
1751 will be years before there is that really much, much, much  
1752 better flu vaccine. And we are fortunate that we have a lot  
1753 of options now and a much better supply horizon than we have  
1754 had, you know, 5 or 10 years ago. So I think we really need  
1755 to just stick with it and make those incremental  
1756 improvements, and make sure that the public gets the correct  
1757 information, the accurate information, that we are honest  
1758 when he have a year like this where it is quite difficult.  
1759 And unfortunately, the vaccine is only preventing about 23  
1760 percent of what it might be, but that is still significant  
1761 protection.

1762 Mr. {Green.} Well--and again, since the percentage is  
1763 lower for the most vulnerable population of the elderly, that  
1764 is also--we need to encourage the elderly to--even if it is  
1765 only, I don't know what percentage it was, 12 percent,  
1766 because it still gives them that 12 percent. But we would  
1767 sure like to see it up above the efficiency much better.

1768 Dr. {Schuchat.} Yeah. Ironically, the elderly are the  
1769 best at getting vaccinated. It is about 70 percent or so of  
1770 them, but the vaccine works the worst in that population.  
1771 And they really do rely on the rest of the population being  
1772 protected to have more confidence that they will be safe too.  
1773 So it is one of those vaccine-preventable diseases where the

1774 more people that are immunized, the better. And, of course,  
1775 in the future we hope that we will have even more effective  
1776 tools.

1777 Mr. {Green.} I know this has come up before, but--

1778 Mr. {Murphy.} Thank you.

1779 Mr. {Green.} --Ranking Member Pallone and DeGette  
1780 yesterday talked about the measles outbreak in Disneyland,  
1781 and I know that is a concern too that--to do it. And let me  
1782 just follow up, Mr. Chairman, I remember when I was in the  
1783 fifth grade, the whole county, we got a polio vaccine. Was  
1784 that mandated by the Federal Government?

1785 Dr. {Schuchat.} You know, in that era, you didn't need  
1786 to mandate polio vaccines. People were lining up. I think  
1787 the whole country was so thrilled that there was a polio  
1788 vaccine licensed--

1789 Mr. {Green.} Um-hum.

1790 Dr. {Schuchat.} --in 1955 because that was such an  
1791 incredible scourge. The mandates, the school requirements,  
1792 really were shown in the 1980's to massively reduce the risk  
1793 of measles outbreaks in schools, and it was really only when  
1794 states required kindergarten entry to have measles vaccine  
1795 documentation that we started to get a better handle on--

1796 Mr. {Green.} Thank you.

1797 Dr. {Schuchat.} --measles, and then--

1798 Mr. {Green.} Yeah.

1799 Dr. {Schuchat.} --of course, in 2000, we were able to  
1800 eliminate native measles here in the U.S.

1801 Mr. {Murphy.} The gentleman's time has expired. Thank  
1802 you.

1803 Now recognize Mr. Griffith of Virginia for 5 minutes.

1804 Mr. {Griffith.} Thank you, Mr. Chairman.

1805 Let me try to fill in some--or get some blanks filled in  
1806 here. I don't have the answers. The meeting took place with  
1807 who in CDC and FDA and others in February. In March, we know  
1808 that there was a drift that was picked up of about 10  
1809 percent, is that correct?

1810 Dr. {Schuchat.} Actually, it was lower than that.

1811 Mr. {Griffith.} About 7 percent I think I saw in your  
1812 testimony.

1813 Dr. {Schuchat.} It was like 4 percent.

1814 Mr. {Griffith.} Okay. Do we know what April was,  
1815 because we have a few numbers on the chart but we have a lot  
1816 of question marks? And if you don't--

1817 Dr. {Schuchat.} In April--

1818 Mr. {Griffith.} --you can provide it--

1819 Dr. {Schuchat.} --14 viruses were shown that had  
1820 reduced susceptibility to the strain, and that came out--that  
1821 was out of 127, so that would be 11 percent.

1822 Mr. {Griffith.} Okay. And then we have a number from  
1823 May. Then June and July, we don't have another number on  
1824 this chart until September. What were you all seeing in  
1825 June, July and August?

1826 Dr. {Schuchat.} There were 80--in June, July and  
1827 August, there were 88 viruses identified from the whole world  
1828 that had reduced reaction, and so that comes to 36 percent.

1829 Mr. {Griffith.} Okay.

1830 Dr. {Schuchat.} With reduced, you know, that were  
1831 mismatch.

1832 Mr. {Griffith.} And then there is another meeting, and  
1833 there is a different southern hemisphere recommendation made,  
1834 and we don't make the--I think that is five. If you can get  
1835 us the other numbers just so we can kind of track it, that  
1836 would be great. But then--

1837 Dr. {Schuchat.} Absolutely.

1838 Mr. {Griffith.} --my question comes up, and I am happy  
1839 for anybody to answer it, why didn't we have the  
1840 manufacturing capacity for the virus to do turn somewhere in  
1841 this process, I think you said by June we were in the 36--  
1842 June, July, we were in the 36 percent range, recognizing that  
1843 flu season doesn't generally hit in a big way for another  
1844 fair number of months, why does the United States lack that  
1845 manufacturing capacity, and as a subpart of that, if there

1846 was the capability of producing, and I am trying to pronounce  
1847 this correctly, monovalent vaccine, why didn't we do so? And  
1848 if you all could focus on that. Any member of the panel  
1849 please.

1850 Dr. {Schuchat.} Yeah, maybe I can start and let Dr.  
1851 Robinson continue.

1852 I think one thing to recognize in the summer is that we  
1853 were looking at increasing proportions of H3N2 that were not  
1854 well matched the vaccine, but we still had the other 2 or 3  
1855 different strains that were in the vaccine. So the concept  
1856 of producing a monovalent vaccine, you--we might have been  
1857 asking the American public to take a monovalent vaccine plus  
1858 the tri or quadrivalent seasonal vaccine. As we have been  
1859 hearing, the American public isn't all that keen to get one  
1860 flu vaccine a year. Would they really be lining up to get 2?  
1861 But there are, of course, major limitations in the  
1862 manufacturing capacity to make 2 different products for the  
1863 same season. So I will let Dr. Robinson answer that.

1864 Mr. {Griffith.} Dr. Robinson?

1865 Dr. {Robinson.} Thank you. During the manufacturing  
1866 season, they are producing three or four vaccine strains all  
1867 the way to June, maybe even July if it is a tough year for  
1868 them. At that time--and most of those are egg-based. At  
1869 that time, they within the summer are putting those together,

1870 we call them blending and putting together, to go forward  
1871 with the vaccine that was released in September to go out on  
1872 the shelves.

1873           The ability to have what was called a competent vaccine  
1874 that could be very quickly--that is certainly true, it can be  
1875 maybe faster than some of the egg-based vaccines, but the  
1876 capacity that we have right now with the licensed vaccine,  
1877 the only one recombinant-based vaccine, is very, very small.  
1878 It would have made a--only been able to produce maybe  
1879 hundreds of thousands of--

1880           Mr. {Griffith.} Okay. Let me--

1881           Dr. {Robinson.} --doses.

1882           Mr. {Griffith.} Let me ask the why on that. Is it  
1883 because there is not a profit--

1884           Dr. {Robinson.} No, no.

1885           Mr. {Griffith.} --to be made?

1886           Dr. {Robinson.} One instance, it is a new vaccine--

1887           Mr. {Griffith.} Okay.

1888           Dr. {Robinson.} --and, two, they--since it is a new  
1889 vaccine, they are just scaling up to the market. They--this  
1890 is an incumbent market, very competitive, and they were  
1891 licensed in 2013. We are actually supporting their efforts  
1892 in building a much larger facility to produce maybe tens of  
1893 millions of doses, and so that they actually can going

1894 forward be able to produce, say, 50 million doses in 4 months  
1895 of a monovalent vaccine for a pandemic or, maybe in this  
1896 case, another influenza vaccine.

1897 Mr. {Griffith.} So you anticipate that our capacity  
1898 will be greater in the next couple of years than it is today  
1899 to react?

1900 Dr. {Robinson.} Indeed, it will be, because we will  
1901 actually have the cell-based influenza vaccine facility down  
1902 in North Carolina that has a large capacity, and we will be  
1903 able to have that product on the market. But again, they are  
1904 limited in that they are making seasonal flu vaccine at the  
1905 same time that we may have wanted to do that.

1906 The other thing is that these manufacturers also produce  
1907 vaccines for the southern hemisphere. So when they came off  
1908 of making the vaccine for the northern hemisphere, then they  
1909 started back to actually making the vaccine for the southern  
1910 hemisphere. So we would have had to make a decision and tell  
1911 them in September, stop doing that and go forward with the  
1912 new vaccine. And we know that that is a difficult midcourse  
1913 shift.

1914 Mr. {Griffith.} But if we--

1915 Dr. {Robinson.} The future will be--

1916 Mr. {Griffith.} But we could have done that even in,  
1917 say, July when we knew we were at 36 percent that had

1918 drifted?

1919 Dr. {Robinson.} It would have been very, very  
1920 difficult, sir.

1921 Mr. {Griffith.} Okay. All right. I appreciate it. I  
1922 see my time is up and yield back.

1923 Mr. {Murphy.} All right, I want to clarify something.  
1924 So you said 36 percent, June, July, and we have a 50 percent  
1925 cutoff. So some time in September the 50 percent number was  
1926 significant enough to say, okay, we need to do something  
1927 different in the southern hemisphere. What is the magic  
1928 number where you say we need to make a change here?

1929 Dr. {Schuchat.} Actually, it wasn't that there was  
1930 something different, it is that every September the strains  
1931 are reviewed worldwide. All--

1932 Mr. {Murphy.} Why not--

1933 Dr. {Schuchat.} --of them.

1934 Mr. {Murphy.} Why not August? Why--I don't--what I am  
1935 concerned here is, we want to break through, if there is some  
1936 bureaucratic hurdles, this committee wants to help--

1937 Dr. {Schuchat.} Thank--yes.

1938 Mr. {Murphy.} --but if you say, well, we don't look at  
1939 this until--we don't really meet and discuss this until  
1940 September, that is not a lot of solace for what Mr. McKinley  
1941 was raising for the hundreds of thousands of seniors and--who

1942 are going to be sick. What--what is--what do we do?

1943 Dr. {Schuchat.} Right. In September every year, the  
1944 groups convene to review all the data for the southern  
1945 hemisphere production, and that is because it takes that long  
1946 to get vaccine that will be ready by that time. It is not--

1947 Mr. {Murphy.} I am not--

1948 Dr. {Schuchat.} --because we are not looking all the  
1949 way between.

1950 Mr. {Murphy.} Yeah, but you have said--you have already  
1951 said you can get a vaccine ready in 12 weeks when you need a  
1952 monovalent strain when there was a pandemic.

1953 Dr. {Schuchat.} Not--

1954 Mr. {Murphy.} Wasn't that done in 2009, you did  
1955 something quickly--

1956 Dr. {Schuchat.} No.

1957 Mr. {Murphy.} --Dr. Robinson?

1958 Dr. {Robinson.} Okay, go ahead.

1959 Dr. {Midthun.} No--

1960 Mr. {Murphy.} I want to be clear.

1961 Dr. {Midthun.} --I think in 2009 the virus emerged in  
1962 April. In May it was recognized that it was causing  
1963 significant disease, and at that time a decision was made  
1964 across the HHS that a monovalent vaccine would be pursued.  
1965 And so all stops were pulled out to do that, but in point of

1966 fact, the first vaccine was not available from--for that H1N1  
1967 monovalent until the end of October, and the bulk of vaccine  
1968 was not available until late December, into January. So just  
1969 point taken that the manufacturing process itself takes many  
1970 months, and although we--

1971 Mr. {Murphy.} To get to the critical number. I know it  
1972 is Mr. Tonko's turn, but we are talking about just to start  
1973 to give it to some seniors and high-risk group.

1974 Mr. Tonko, you are recognized for 5 minutes.

1975 Mr. {Tonko.} Thank you, Mr. Chair. And welcome to the  
1976 panel.

1977 There has been much discussion here today about parents  
1978 and the advice they get about having their children  
1979 vaccinated or not vaccinated. I would like to ask it from  
1980 yet another perspective. Yesterday, a United States senator  
1981 asserted that routine vaccinations could cause, and I will  
1982 quote, ``walking-talking normal children to wind up with  
1983 profound mental disorders.''

1984 And so my request of the panel is a simple yes-or-no  
1985 response. Is there any shred of credible evidence that shows  
1986 that this, in fact, is the case? Dr. Schuchat?

1987 Dr. {Schuchat.} Not the vaccines we are using today.

1988 Mr. {Tonko.} Dr. Midthun?

1989 Dr. {Midthun.} No, not for the vaccines we are causing--

1990 -using today, although I think it is important to note that  
1991 any vaccine can have some safety issues associated with it,  
1992 but typically, they are very rare, and that is why we also  
1993 have the Vaccine Injury Compensation Program.

1994 Mr. {Tonko.} Dr. Robinson?

1995 Dr. {Robinson.} I am in agreement with Dr. Schuchat and  
1996 Dr. Midthun.

1997 Mr. {Tonko.} Dr. Fauci?

1998 Dr. {Fauci.} Agree.

1999 Mr. {Tonko.} Pardon me?

2000 Dr. {Fauci.} Agree with my colleagues.

2001 Mr. {Tonko.} Thank you for clarifying.

2002 In addition to promoting vaccination, Dr. Schuchat, how  
2003 else does the CDC work to prevent spread of the flu? For  
2004 example, does the CDC recommend symptomatic individuals to  
2005 stay home from work?

2006 Dr. {Schuchat.} Yeah, we have a multipronged approach  
2007 to prevention. The best protection is to get vaccinated. We  
2008 also recommend sensible measures like washing your hands,  
2009 covering your cough, staying home when you are sick, staying  
2010 away from other people when you are sick. And then, of  
2011 course, if you are ill, and particularly those with  
2012 underlying conditions or the elderly, we think prompt  
2013 antivirals can be important, and so talk to your clinician

2014 about that.

2015 Mr. {Tonko.} Are there any data showing how many flu  
2016 transmissions occur in the workplace when symptomatic  
2017 individuals do come to work?

2018 Dr. {Schuchat.} I don't have that date, but it--there  
2019 have been analyses showing the value of vaccination to reduce  
2020 workplace absenteeism and to improve productivity.

2021 Mr. {Tonko.} Um-hum.

2022 Dr. {Schuchat.} So we think it is a good thing for  
2023 health, and it is also a good thing for the workplace to be  
2024 protected against flu. To stay home for when you are sick  
2025 for a variety of conditions is good counsel.

2026 Mr. {Tonko.} I do know that in speaking with my  
2027 constituents, there are a number of working moms and dads who  
2028 can't afford to take time off of work because it would mean  
2029 they are not paid, and so they attempt to come to work even  
2030 though they really shouldn't. In your opinion, would paid  
2031 leave policies help to prevent the transmission of the flu  
2032 and other illnesses by encouraging more workers to stay home  
2033 when they are indeed sick?

2034 Dr. {Schuchat.} We think the easier it is for people to  
2035 do the right thing, the better.

2036 Mr. {Tonko.} Okay, thank you.

2037 Dr. Midthun, the FDA has licensed a number of new

2038 vaccines since the year 2009. How have these new vaccines  
2039 contributed to preparedness efforts in the last several  
2040 years?

2041 Dr. {Midthun.} Thank you for that question. I think  
2042 what they have done, especially with regard to the cell-  
2043 culture-based vaccine and the recombinant protein vaccine, is  
2044 they offer an alternative manufacturing platform relative to  
2045 the egg-based manufacturing that was the basis for the  
2046 vaccines that had been approved up until that time. And it  
2047 is always important to have a diversified way in which you  
2048 can manufacture vaccines. It also widens the platform  
2049 available in the event of a pandemic because, typically, the  
2050 pandemic vaccines are made on the same manufacturing  
2051 platforms that the seasonal vaccines are made on, and so it  
2052 really provides greater diversity and more resilience.

2053 Mr. {Tonko.} And, doctor, in your testimony you talked  
2054 about work to speed up the manufacturing process for existing  
2055 vaccines. Can you tell us more about that work?

2056 Dr. {Midthun.} Yes. It is actually a very strong  
2057 collaboration between BARDA, CDC, NIH and ourselves, and it  
2058 looks at a number of different aspects. One aspect is to  
2059 look at the potency testing that is done for vaccines. Right  
2060 now, that relies on reagents that are made by immunizing  
2061 sheep, you develop antiserum, this usually is a process that

2062 can take up to 2 months. And so, obviously, having potency  
2063 assays that are much more rapid would really decrease the  
2064 time that it takes to do this, to make these reagents. And  
2065 so there are some approaches using more modern platforms, and  
2066 in conjunction with some of our colleagues, there actually  
2067 are some tests that are being planned that will be embarked  
2068 upon later this year to compare some of these newer assays to  
2069 the standard assay that is used right now, the radial  
2070 immunodiffusion test, to see how these compare to each other  
2071 in actual testing of vaccine samples that the manufacturers  
2072 are providing to us. And some of the manufacturers have  
2073 actually expressed interest in also participating in the  
2074 testing to see what the feasibility is. So that is one  
2075 aspect that we are working on.

2076 Another one that has been very important, and that the  
2077 CDC and others have really done a lot of work on, but we have  
2078 also contributed to, is to try to identify high-growth  
2079 viruses that will lead to good yield when you grow the virus  
2080 in the eggs or in the cell culture. As you recall, Dr. Fauci  
2081 was referring to the fact that that can often be a wait-  
2082 limiting step. And so trying to develop viruses that you  
2083 know will yield high growth when these new strains emerge  
2084 could really facilitate and take time off that process.

2085 And then also there was the sterility testing, and the

2086 FDA actually changed its regulations in 2012 to allow for  
2087 more flexibility in sterility testing. Up until that time,  
2088 it was very prescriptive and this 14-day test by USP had to  
2089 be used, but now manufacturers can come in with novel  
2090 testing, and we actually know that some, you know, testing  
2091 that has been described in the literature could actually be  
2092 accomplished in 5, 6 days potentially.

2093 Mr. {Tonko.} Thank you.

2094 Mr. {Murphy.} Thank you.

2095 Mr. {Tonko.} I yield back, Mr. Chairman.

2096 Mr. {Murphy.} Thank you.

2097 Now recognize a new member of the subcommittee, Dr.  
2098 Bucshon, who is a cardiothoracic surgeon by training, and is  
2099 here from Indiana. Welcome to the subcommittee, and you are  
2100 recognized for 5 minutes.

2101 Mr. {Bucshon.} Thank you, Mr. Chairman. First of all,  
2102 I would like to associate myself with the comments of our--  
2103 unanimous comments of our expert panel in recommending that  
2104 parents get their child--children immunized to prevent  
2105 childhood diseases. All my children are immunized.

2106 Based on the testimony we have heard today, it seems  
2107 like we could have had a monovalent vaccine available by  
2108 maybe December, and if that is true, do you lack--Dr.  
2109 Schuchat, do you lack the authority to make that happen in a-

2110 -in that way, or whomever is--what--because through the  
2111 testimony, we have asked--I think a lot of members have asked  
2112 what can we do to help, but for us, for Congress to help, we  
2113 have to have a specific thing to help with. So is there new  
2114 authority or any other authority that would be helpful to  
2115 make this happen?

2116 Dr. {Schuchat.} I don't believe so. The key issues is  
2117 a risk assessment and trying to predict the most likely  
2118 course of events, but I believe there are authorities if the  
2119 decision is made to go ahead with the monovalent, whether for  
2120 pandemic or for drift.

2121 Mr. {Bucshon.} Okay. As a healthcare provider, I know  
2122 that, you know, liability is a significant issue in our  
2123 American healthcare system, and not only physician  
2124 malpractice, but product liability is a substantial issue, I  
2125 know, that has an effect on the healthcare industry. Anyone  
2126 can comment on this. Do product liability issues affect our  
2127 ability to act in a more nimble way when it comes to  
2128 vaccines, because you do have private companies that product  
2129 these. And so let us start with that and then I will  
2130 spearhead off from there.

2131 Dr. {Schuchat.} The Vaccine Injury Compensation Program  
2132 exists so that product liability won't be a factor, so that  
2133 we can make sure that we have vaccines made but the people

2134 who are injured by vaccines are compensated. And so that  
2135 is--the funding from that comes from an excised tax on the--  
2136 on every vaccine dose that is sold, so that we know that  
2137 vaccines are very safe, but there are sometimes rare,  
2138 important complications, and the Injury Compensation Program  
2139 exists for those families who have been injured.

2140 Mr. {Bucshon.} Okay. Thanks for clarifying that, but--  
2141 and I think that is important to understand.

2142 Dr. Midthun, from the FDA's standpoint, is there--are--  
2143 is there--how do I want to say this, a risk averse, you know,  
2144 regulatory process? It seems like at the FDA, you know, over  
2145 a number of years--but for a variety of reasons have--I think  
2146 been, in my view, sometimes overly cautious with new products  
2147 or changing quickly. Do you see that as an issue, you know,  
2148 and that comes into the liability issue again, is there  
2149 resistance or reluctance to quickly move based on the concern  
2150 about these type of things?

2151 Dr. {Midthun.} No, I don't see that. I think in the  
2152 influenza domain, we, every year, are primed to approve the  
2153 new vaccine strains that are recommended for inclusion of the  
2154 vaccine those years. I think also our record of having  
2155 approved since 2003--I think in 2003 we had three licensed  
2156 influenza vaccines. Today we have 16 licensed influenza  
2157 vaccines, including our cell-based, recombinant-based,

2158 quadrivalent, high-doses, and also I should point out that  
2159 many of those we actually approved using accelerated approval  
2160 which actually allows us to approve something based on the  
2161 new response that is likely to predict clinical benefit. And  
2162 so we have used accelerated approval regulations to approve  
2163 any of those and get them to market more quickly. So I think  
2164 we--and also I should point out we approved the novel  
2165 adjuvanted H5N1 vaccine in 2013. So I think that we really  
2166 looked very carefully, and balanced the benefits and the  
2167 risks, and are really very flexible.

2168 Mr. {Bucshon.} Great. That is good to hear.

2169 There is a recent CDC study that looked at clinician  
2170 practices on patients that come to the emergency room with--  
2171 and the date is striking, only 16 percent of patients with  
2172 laboratory-confirmed influenza were prescribed antiviral  
2173 drugs.

2174 So the first question I have, do they work? Do the  
2175 antiviral drugs work?

2176 Dr. {Schuchat.} Yeah, last week there was a new meta-  
2177 analysis of all the published and unpublished randomized  
2178 control trial data on Oseltamivir, and it shed new light on  
2179 the benefits as well as potential risks that--there is--

2180 Mr. {Bucshon.} So they--

2181 Dr. {Schuchat.} --benefit for the work.

2182 Mr. {Bucshon.} Short answer, they do work, because I am  
2183 running out of time.

2184 Dr. {Schuchat.} Yes.

2185 Mr. {Bucshon.} Because surprisingly, 30 percent of the  
2186 patients with laboratory-confirmed influenza were--30 percent  
2187 were prescribed one of three common antibiotics, which are  
2188 for bacteria, not viruses. Is there anything that we can do  
2189 to better, you know, as a physician, better make the, you  
2190 know, change that practice? Maybe Dr. Fauci can answer that.

2191 Dr. {Fauci.} Yeah, that is another whole issue of  
2192 antimicrobial resistance which we have even discussed before  
2193 this committee. So certainly, over the last year, there has  
2194 been the extraordinary effort on the part of the Congress and  
2195 the Administration in--from everything from executive orders  
2196 to 5-year plans to counter the kinds of practices that lead  
2197 to antimicrobial resistance, and one of the most common, as I  
2198 am sure you are aware, sir, is that someone comes in with a  
2199 viral infection and they get an antibiotic. That is very,  
2200 very common, unfortunately.

2201 Mr. {Bucshon.} I yield back, Mr. Chairman.

2202 Mr. {Murphy.} Thank you.

2203 Now recognize a new member to the committee, Ms. Yvette  
2204 Clarke, who represents--Ms. Schakowsky is next? I am sorry,  
2205 I thought it was--Clarke was next.

2206 {Voice.} Okay.

2207 Mr. {Murphy.} No, by sitting down we--all right. I had  
2208 it down by the person sitting here at the time of the gavel,  
2209 so I am sorry. We can go with Schakowsky or whatever you  
2210 say.

2211 Ms. {Schakowsky.} I was here earlier.

2212 Mr. {Murphy.} All right, thank you.

2213 Ms. {Schakowsky.} Thank you, Mr. Chairman.

2214 So if the--the vaccine that we are using now has been  
2215 viewed as 23 percent effective, and usually in the past it  
2216 has been 50 to 60 percent effectiveness, are we seeing--is  
2217 that--maybe it is Dr. Schuchat, are seeing a commensurate  
2218 increase in the incidents of flu?

2219 Dr. {Schuchat.} Yes. When we compare this season with  
2220 2 years ago, the 2012/'13 season, the last big H3N2 season,  
2221 we have--much of the pattern is similar, but our  
2222 hospitalizations in the elderly are much higher at the same  
2223 time this year. So we will get, you know, the end-of-season  
2224 statistics, but it has been a very bad year for the elderly.

2225 Ms. {Schakowsky.} I see. So the lab tests predicted 23  
2226 percent--

2227 Dr. {Schuchat.} Um-hum.

2228 Ms. {Schakowsky.} --but you are seeing it actually out  
2229 in the country, that it is also much higher?

2230 Dr. {Schuchat.} Right. Yeah, we are seeing, you know,  
2231 both the lab mismatch and then our vaccine effectiveness low  
2232 estimate, and then the incidents of the hospitalizations is  
2233 high.

2234 Ms. {Schakowsky.} Okay. With the passage of the  
2235 Affordable Care Act in 2010, we took important steps on  
2236 preventive medical coverage for free, and since the law went  
2237 into effect, approximately 76 million Americans have received  
2238 no-cost coverage for preventive services. So I am wondering  
2239 if we are seeing that there actually was an impediment to  
2240 getting these preventive services, vaccines, because of the  
2241 cost, and now without the cost, that more people are making  
2242 that available to themselves.

2243 Dr. {Schuchat.} For influenza vaccine, I think it is  
2244 too soon for us to see, but we do know that there are  
2245 important disparities in influenza vaccination coverage, and  
2246 that insured people have been more likely to be vaccinated  
2247 than uninsured. So I think that over the years ahead, we may  
2248 start to see some progress there.

2249 Ms. {Schakowsky.} So we do think, although we don't  
2250 have the new data--

2251 Dr. {Schuchat.} Um-hum.

2252 Ms. {Schakowsky.} --that cost has been a barrier to--in  
2253 the past--

2254 Dr. {Schuchat.} That is right. We--

2255 Ms. {Schakowsky.} --is that what you think?

2256 Dr. {Schuchat.} And we know even for the workplace, for  
2257 instance, when workplaces will offer flu vaccine for free for  
2258 workers or, you know, particularly for healthcare workers,  
2259 the uptake is better than when it is out-of-pocket, off-site,  
2260 need-to-see vaccine.

2261 Ms. {Schakowsky.} I think it is great that we are  
2262 having this hearing today because this whole question of  
2263 vaccines, as many of my colleagues have mentioned, has really  
2264 been in the news, and it is disturbing that a number of high-  
2265 profile political figures have weighed in on this in a  
2266 negative way, I would say, that this is, you know, parents  
2267 should make the decision, and I have seen some children that  
2268 have been deeply affected by this--by vaccines in a negative  
2269 way. What I am wondering is what is the public health  
2270 outreach effort to make sure that--you heard my colleague,  
2271 Marsha Blackburn, talking about the mom blogs. I mean there  
2272 is a lot that is going on, not only on television, and I am  
2273 glad you were on, Dr. Fauci, and that is very important that  
2274 we get the message out in every medium, but I am just  
2275 wondering if we are also just looking at how people are  
2276 communicating with each other in the social media and getting  
2277 the facts out.

2278 Dr. {Schuchat.} Yeah, we spend quite a bit of time and  
2279 attention monitoring the social media as well as the general  
2280 media, and we work closely with--at the national level, but  
2281 also at the state and local level on communication, both  
2282 direct to consumer as well as through clinicians and other  
2283 trusted partners, because we think getting information that  
2284 speaks to you close to where you are is really important in  
2285 your health behaviors.

2286 There--I would just like to say that the vast majority  
2287 of parents vaccinate their kids against most of the  
2288 recommended diseases on time, and yet there are some minor  
2289 voices that get a lot of attention.

2290 Ms. {Schakowsky.} Exactly. I think maybe we need to  
2291 make sure we communicate with all political voices as well  
2292 that are out there to make sure that we are communicating the  
2293 science, the facts, that suggest that all parents should  
2294 vaccinate their children.

2295 So I yield back.

2296 Mr. {Murphy.} Who is next?

2297 {Voice.} Mr. Flores.

2298 Mr. {Murphy.} All right, now we recognize Mr. Flores  
2299 from Texas, who is also new to this committee. Third term in  
2300 Congress, and we welcome him to this subcommittee.

2301 Mr. {Flores.} Thank you, Mr. Chairman. I also want to

2302 thank the panel, particularly for your positive comments  
2303 regarding the benefits of having children vaccinated for  
2304 measles. I have an extended family member who has not done  
2305 that for her children yet, and it just baffles me why she  
2306 can't do that. And so I hope she is hearing this today, that  
2307 she heard your comments, and that she will do so.

2308 I want to talk about the weakness in the strain  
2309 selection process, and talk about the opportunities to  
2310 mitigate that weakness. And I want to focus my questions to  
2311 you, Dr. Robinson, because you--BARDA is a tool, I think,  
2312 that we have to do this.

2313 And so my first question is this. Are--is BARDA funding  
2314 any projects or initiatives to develop two things; one,  
2315 better technologies--testing technologies, or two, better  
2316 approaches for making the vaccine candidates?

2317 Dr. {Robinson.} So the answer is yes on both--let me  
2318 just--in my testimony, I identified that we were supporting  
2319 the development of evolutionary biology methods that would  
2320 actually help the existing methods inform what strains are  
2321 out there. There are only so many ways a virus can mutate.

2322 Mr. {Flores.} Right.

2323 Dr. {Robinson.} And we know that actually--you can do  
2324 the experiments to show which ones would predominate, and  
2325 that may actually inform of which ones we may see the next

2326 season. And certainly, the underpinning of that the NIH has  
2327 funded over the years, and so we are moving forward primarily  
2328 for our pandemic purposes, but certainly could be used in  
2329 seasonal. So that is one way towards the selection, and then  
2330 informing new vaccine designs.

2331 Mr. {Flores.} Okay.

2332 Dr. {Robinson.} Secondly, with the technologies, we  
2333 have supported with our colleagues here from NIH, CDC and  
2334 FDA, ways--new technologies to make these vaccines, whether  
2335 it be cell-based or recombinant. And working with the NIH,  
2336 we are looking at universal flu vaccine candidates with a  
2337 number which Dr. Fauci enumerated of going forward. It is  
2338 not because those haven't--technologies haven't been tried  
2339 before, but as he explained, there is a limitation in how the  
2340 body actually sees these viral proteins. And so there are  
2341 some new ways now that we can do that, we couldn't do before.

2342 Mr. {Flores.} And in terms of looking at BARDA's  
2343 priorities, where would you say that this--getting these  
2344 better technologies for the strain selection process is in  
2345 your sort of list of all the things you have to do on your  
2346 wish list.

2347 Dr. {Robinson.} Yeah. Well--

2348 Mr. {Flores.} Is it in the top third, or the middle or  
2349 the bottom or--

2350 Dr. {Robinson.} No, it is at the top.

2351 Mr. {Flores.} Okay.

2352 Dr. {Robinson.} Yeah.

2353 Mr. {Flores.} Great. Sounds like we should keep it  
2354 there and--from what I am hearing today.

2355 The third question is how can we expedite the  
2356 development and deployment of better technologies, say, use  
2357 of genetic sequencing, to detect virus change, which you have  
2358 talked about, to ensure that the U.S. has a vaccine that can  
2359 be matched to a drifted H3N2 strain?

2360 Dr. {Robinson.} Certainly, one of the ways that we  
2361 actually have employed with biosynthetic technology work with  
2362 the Craig Venter Institute and then one of the manufacturers.  
2363 We did that in 2013 with H7N9 to actually come up--what we  
2364 didn't need the traditional way of having the virus actually  
2365 sent from one laboratory to another. We actually had the  
2366 nucleotide sequences available, then made--using that, and  
2367 actually made the virus seed strains and went forward with  
2368 H7N9. Regardless it is an egg-based or cell-based or  
2369 recombinant, we can do that.

2370 Mr. {Flores.} Okay.

2371 Dr. {Robinson.} And we are moving forward with those  
2372 efforts also.

2373 I just want to say one other thing that Dr. Midthun had

2374 talked about, and that is high production yield seed strains.  
2375 Why is that important? It means that the virus doesn't have  
2376 to be passaged to eggs or cells or medium many times because,  
2377 very early on, we can actually have high production seed  
2378 strains, and that is why the manufacturers keep passaging the  
2379 virus to get high production. If we had that immediately,  
2380 then the virus that actually is in the vaccine is going to be  
2381 very similar to the circulating virus.

2382 Mr. {Flores.} Um-hum.

2383 Dr. {Robinson.} Much more so.

2384 Mr. {Flores.} Okay. And then the last question I have  
2385 has to do, you know, I have always been fascinated with the  
2386 initiatives to try to develop the universal flu vaccine, and  
2387 I appreciate what Dr. Fauci talked about today, and educating  
2388 the committee and subcommittee on how to do that.

2389 What role does BARDA play in the development, deployment  
2390 and stockpiling of a universal flu vaccine?

2391 Dr. {Robinson.} So certainly hand in hand with the NIH,  
2392 we are moving forward with the development, not only for  
2393 seasonal, as I had pointed out, for pandemic purposes. It  
2394 may serve as a primer for future pandemic vaccines. Again,  
2395 you may only need one dose of the pandemic vaccine as opposed  
2396 to two which you normally would need. And so we can  
2397 stockpile that vaccine or actually have it as part of our

2398 commercial products that are out there every year.

2399 Mr. {Flores.} Okay. Thank you for your responses. As  
2400 you know, it is a--this is important to me because you have a  
2401 facility in my district that I think is doing some great  
2402 work.

2403 Mr. Chairman, I yield back.

2404 Mr. {Murphy.} Thank you.

2405 And now recognize Ms. Clarke of New York, the Brooklyn  
2406 area, as a new member of the subcommittee. Welcome. You are  
2407 recognized for 5 minutes.

2408 Ms. {Clarke.} Thank you very much, Mr. Chairman.

2409 Being the low one on the totem pole, oftentimes, it  
2410 comes with the territory.

2411 Let me welcome our panelists as well, and pick up on  
2412 some of the line of questioning that my colleague, Mr. Tonko,  
2413 raised with respect to research.

2414 So, Dr. Fauci, your testimony discussed the potential  
2415 for a universal flu vaccine that could provide protection  
2416 against numerous strains of the flu over several seasons.  
2417 What can you tell us about the research on this vaccine?

2418 Dr. {Fauci.} Okay. So the research on this vaccine, as  
2419 I had mentioned, really starts off with the fundamental basic  
2420 observation that a part of the protein that is the target of  
2421 the vaccines that we have developed over decades is one that,

2422 unfortunately, has a component of it that tends to change  
2423 from season to season. We refer to that as a drift. Big  
2424 change is the shift. The part that doesn't change is the  
2425 part that we have just recently recognized on the thin stem  
2426 part of the protein that we now know that if you show it to  
2427 the immune system in a certain way, and you can only do that  
2428 by molecular biological techniques because, generally, when  
2429 you show the immune system the whole virus, the part that you  
2430 really wanted to make an immune response is crowded out and  
2431 covered by the larger part. So now you are essentially  
2432 teasing it out and showing the immune system just the part  
2433 that you want to make a response again. And we have done  
2434 that. We have done it with a number of different platforms,  
2435 and we have shown now in a small animal, in a ferret, and now  
2436 even in a human, that, A, it is feasible, B, it is safe, and  
2437 C, it does induce the kind of response that you would predict  
2438 would have a much broader effect.

2439         So that is the real first solid step. We have to  
2440 perfect that, and then we have to show in a broad study that  
2441 it actually does protect against multiple strains.

2442         Ms. {Clarke.} That sounds very promising, Dr. Fauci.

2443         Dr. Robinson, you mentioned in your testimony a new  
2444 initiative to support development of new flu vaccine  
2445 candidates that offer broader, longer-lasting immunity. Can

2446 you tell us more about this initiative?

2447 Dr. {Robinson.} Certainly. We are working with Dr.  
2448 Fauci with many of the candidates that he has talked about,  
2449 and in addition, there are other ways in which we can broaden  
2450 the immunity. Some might be with adjuvants, and other  
2451 designs of the vaccines going forward, and not only for  
2452 seasonal but for pandemic purposes.

2453 Ms. {Clarke.} So it sounds like we are moving into the  
2454 21st century.

2455 Dr. {Robinson.} Yes.

2456 Ms. {Clarke.} Very well. Very well. I would like to  
2457 shift a bit to the idea of strains, the strain selection  
2458 process, Dr. Midthun. Can you outline the role of the FDA's  
2459 Vaccines and Related Biological Products Advisory Committee  
2460 in the strain selection process, and when does this process  
2461 actually begin?

2462 Dr. {Midthun.} The process is actually year-round. I--  
2463 as, you know, CDC and other WHO collaborating centers for  
2464 influenza are monitoring influenza strains year-round to be  
2465 looking for trends, changes, emerging situations, so that is  
2466 going on all the time. Then you have--

2467 Ms. {Clarke.} How does the advisory committee arrive at  
2468 its recommendations on the selection of a strain?

2469 Dr. {Midthun.} Okay. So what happens in usually

2470 February or early March, when the Vaccines Advisory Committee  
2471 meets, is that we have experts come and present the data on  
2472 the influenza strains that have been circulating over the  
2473 last--really the last year, and those strains are evaluated  
2474 to see which appear to be prevalent, and really based on  
2475 those data a decision is made about which vaccine strains  
2476 should be included in the vaccine manufacturing. And then  
2477 once that recommendation is made, of course, the  
2478 manufacturers then use that information to start  
2479 manufacturing their vaccines. But I think a very important  
2480 point to note is that, typically, manufacturers actually  
2481 start manufacturing the vaccine before the advisory committee  
2482 is even held. They usually start in January. Why? Because  
2483 they are aware of the data also. As I mentioned, this is an  
2484 ongoing process year-round, and so they will usually  
2485 anticipate what they think will be the strain that is not  
2486 going to change. They do this at risk, but the point is  
2487 that--

2488 Ms. {Clarke.} That is what I was going to ask--

2489 Dr. {Midthun.} --it is a process--

2490 Ms. {Clarke.} --has there ever been an incident where  
2491 perhaps the advisory committee did not necessarily agree and  
2492 the manufacturer is already proceeding?

2493 Dr. {Midthun.} Yes, that can happen. I mean you would

2494 have to ask individual manufacturers--

2495 Ms. {Clarke.} Yes.

2496 Dr. {Midthun.} --but I suspect that that has definitely  
2497 happened, although, you know, typically, I think they will go  
2498 with something that they think, based on the data, is  
2499 unlikely to change. But it really is a process where we make  
2500 the recommendation in February, but clearly, there is a lot  
2501 of work that precedes that and there is a lot of work that  
2502 continues after that to actually have vaccine available. And  
2503 usually vaccine becomes available in July, August, that time  
2504 frame, and then it is continued to be released really  
2505 throughout end of October. So you can see it is a process  
2506 that, even though you do a recommendation in February, and  
2507 much work starts before that even, it really does take many,  
2508 many months to actually have vaccine available for the  
2509 influenza season--

2510 Mr. {Murphy.} Thank you.

2511 Dr. {Midthun.} --which, you know, typically can begin,  
2512 you know, October, November, although sometimes not until  
2513 later.

2514 Mr. {Murphy.} Thank you.

2515 Ms. {Clarke.} Thank you.

2516 Mr. {Murphy.} Thank you.

2517 Now recognize another new member for the committee,

2518 Susan Brooks of Indiana, who has a second term of Congress,  
2519 previously she was in the Homeland Security Committee and was  
2520 a U.S. Attorney. We look forward to you being a part of this  
2521 committee. You are recognized for 5 minutes.

2522 Mrs. {Brooks.} Thank you, Mr. Chairman. I do want to  
2523 thank all of the witnesses for your work with respect to the  
2524 public health and safety of our citizens. On Homeland  
2525 Security, I chaired the subcommittee on emergency  
2526 preparedness response and communications, and this is  
2527 something that we know everyone is passionate about. I  
2528 think, obviously, when we have an epidemic the way we have  
2529 right now, the public pays a lot more attention to it, but I  
2530 think the public also expects us to get it right. And the  
2531 public is expecting us to, you know, leave no stone unturned,  
2532 and to continue to ask the questions and figure out how can  
2533 we do it better, how can we do it faster, what mistakes, you  
2534 know, have we learned from in the past and, you know, how do  
2535 we--what do we do to keep our country safe.

2536 This year is a much higher death toll, as you have said.  
2537 In Indiana, there were 72 deaths statewide. The year before,  
2538 70. We have already had 108 deaths in Indiana, and it is  
2539 just the end of January, and the flu season, as I understand  
2540 it, goes often in through May, so we have a lot that we are  
2541 very, very concerned about. I spoke with the head of our

2542 Marion County, which is Indianapolis' Public Health  
2543 Department, and she has indicated that the flu has gotten so  
2544 severe in Indianapolis that she is barring anyone under the  
2545 age of 18 from visiting hospitals. So if you are 15 years  
2546 old and your mom is in the hospital, you can't visit your  
2547 mom. If you--and so we have reached, just to let you know,  
2548 as I am sure you know, and you are very focused on this, but  
2549 these types of precautions are obviously being taken for the  
2550 safety of the patients, but we also know, as we have heard,  
2551 vulnerable, you know, whether they are children or seniors,  
2552 are so vulnerable. But yet one of the things she also shared  
2553 with me, and she was explaining the ag. culture technology  
2554 that we use, and it takes a long time, but yet she shared the  
2555 new cell mediator technology that you have mentioned in  
2556 production is faster, but yet it is not widely used. And so  
2557 I would like to explore why.

2558         You mentioned a cell-based facility in North Carolina.  
2559 Can we please talk a bit more about if these technologies are  
2560 out there, why are they not being, you know, more widely  
2561 used? And I don't know if, Dr. Schuchat, you want to start,  
2562 and, Dr. Robinson.

2563         Dr. {Schuchat.} Yeah, I will just make an overview  
2564 comment that production of flu vaccine has been increasing  
2565 over the past decade, with more, you know, factories in the

2566 U.S., more companies, more products, but we also have to work  
2567 on demand, and the more vaccine we use every year, the more  
2568 the companies will make. They don't make lots of vaccine at  
2569 a risk. And so it is a, you know, a cycle that is  
2570 interdependent. But Dr. Robinson can talk about the cell-  
2571 based plant and some of the other manufacturing efforts.

2572 Mrs. {Brooks.} And is that correct, that a cell-based  
2573 technology would allow vaccines to be produced faster? Is  
2574 that correct or is that not correct?

2575 Dr. {Fauci.} Not significantly faster. The cell-based  
2576 is more consistent, whereas eggs, you know, it depends on  
2577 supply of eggs, whereas you can keep growing up cells. I  
2578 think that is a common misconception that there is a game-  
2579 changing difference in the amount of time it takes. And the  
2580 answer to that, and I am sure Robin will verify that, isn't  
2581 the case. You both have to grow the virus, that is the  
2582 problem, as opposed to in a recombinant DNA or molecular  
2583 technology, be able to make it more quickly. So even though  
2584 we welcomed the transition, and hope we even do more from egg  
2585 to cell, the answer for the time frame itself is not going to  
2586 be solved by cell-based technology.

2587 Mrs. {Brooks.} What is the answer to increase the time-  
2588 -to shorten the time, rather, of production?

2589 Dr. {Fauci.} And that is what I just said when I was

2590 talking about changing from a need to grow the virus, to the  
2591 ability to do it from a molecular way where you actually  
2592 develop a vaccine by recombinant DNA technology, which  
2593 doesn't require your having to grow the virus. That is  
2594 really the major transformation from one platform to another.

2595 Mrs. {Brooks.} Dr. Robinson, how do we--

2596 Dr. {Robinson.} No, I agree with them. I mean that is  
2597 where we see the biggest savings in time is with recombinant  
2598 vaccines, but they are new and they are just with very  
2599 limited capacity, they will grow in time. With the cell-  
2600 based vaccines, we may even be able to have--shave a couple  
2601 of weeks off than what we have with the standard egg-based  
2602 vaccines at this time.

2603 The other issue is that it is a new product, and this is  
2604 the--a very competitive industry, and they are trying to get  
2605 their market share at this time. And as they improve and--to  
2606 be equal to be equal to or better, then they will actually  
2607 become more commonplace in the overall vaccine supply.

2608 Mrs. {Brooks.} Can--so are you saying that there is  
2609 just one manufacturer that is manufacturing in that manner?

2610 Dr. {Robinson.} That is cell-based in the U.S., there  
2611 is only one licensed manufacturer.

2612 Mrs. {Brooks.} Is there any issuing--is there any issue  
2613 in the licensing process?

2614 Dr. {Midthun.} No, there is no issue of the licensing  
2615 process. We have approved on cell-based manufacturer and one  
2616 recombinant-based manufacturer. We basically work with  
2617 anyone who wants to come in and make a product, and we are  
2618 there to facilitate that process, but it really is up to, you  
2619 know, the sponsor to come in and say we would like to do  
2620 this. Certainly, you know, BARDA has done much to support  
2621 some of these new technologies, and certainly, again, we are  
2622 grateful for the support you have given in that regard.

2623 Mrs. {Brooks.} Okay.

2624 Mr. {Murphy.} Thank you.

2625 Mrs. {Brooks.} Thank you.

2626 Mr. {Murphy.} We now recognize another new member of  
2627 the committee, Markwayne Mullin of Oklahoma. We welcome you,  
2628 and you are recognized for 5 minutes.

2629 Mr. {Mullin.} Thank you, Mr. Chairman.

2630 Dr. Robinson, my state of Oklahoma has been hit  
2631 particularly hard this year. According to Walgreens,  
2632 Oklahoma City is the number one place for prescriptions to be  
2633 issued out for Tamiflu. Tulsa is number five. I think we  
2634 have had somewhere like 50 deaths, and in the neighborhood of  
2635 1,300 individuals being hospitalized. My family was hit real  
2636 hard this year. Out of my five kids, four got it. My fourth  
2637 daughter, who is 6, received actually two different strains

2638 of the flu. My wife and all my family missed the swearing in  
2639 because of the flu. And now it is kind of ironic that I am  
2640 sitting up here talking about this.

2641 I--just some follow-up questions. My understanding is  
2642 part of the challenge of being able to respond to the mix-  
2643 match vaccine is the burden of regulations, but underneath  
2644 declaration of maybe an emergency, those regulatory burdens  
2645 change. Is that correct?

2646 Dr. {Robinson.} Certainly, if a public health emergency  
2647 is declared then we can move forward, but there are  
2648 regulatory issues, I think Dr. Midthun may want to testify--

2649 Mr. {Mullin.} No, I just wanted a yes or no on it. If-  
2650 -there is--if it is declared an emergency, those regulatory  
2651 burdens change quite a bit, right? Okay.

2652 In 2009, the President declared a public emergency  
2653 during the swine blue--flu, or the HN--or H1N1 crisis. That  
2654 is correct, right?

2655 Dr. {Robinson.} Correct.

2656 Mr. {Mullin.} How many cases of swine flu had been  
2657 confirmed, not deaths but had been confirmed in the U.S.,  
2658 when the President declared that public emergency?

2659 Dr. {Robinson.} I think Dr. Schuchat can answer that.

2660 Dr. {Schuchat.} I don't have the numbers, but there was  
2661 a--

2662 Mr. {Mullin.} It was 20.

2663 Dr. {Schuchat.} --an enormous change in the  
2664 epidemiology--

2665 Mr. {Mullin.} There--we do have the number, there was  
2666 20 of them that was in that--

2667 Dr. {Schuchat.} Well, but instead of flu coming down,  
2668 it was going up after the season--

2669 Mr. {Mullin.} Right.

2670 Dr. {Schuchat.} --with a completely different strain.

2671 Mr. {Mullin.} But there was--

2672 Dr. {Schuchat.} So--

2673 Mr. {Mullin.} But there was an emergency declared with  
2674 only 20 confirmed cases in the U.S. There has already been  
2675 50 deaths in just my state of Oklahoma.

2676 Dr. {Schuchat.} Um-hum.

2677 Mr. {Mullin.} So I am trying to make a comparison here.

2678 I believe the flu season goes through May in the  
2679 northern hemisphere, is that correct? Right?

2680 Dr. {Schuchat.} It can extend to May. It can end  
2681 earlier.

2682 Mr. {Mullin.} Okay, what exactly is the definition of  
2683 public health emergency? Dr. Robinson, do you want to take  
2684 that? What is the criteria of us meeting a public emergency?

2685 Dr. {Schuchat.} Yes, the--a public health emergency is

2686 not a black-and-white definition.

2687 Mr. {Mullin.} So there is no set of specific criteria  
2688 that we can look at, like the number of deaths or  
2689 hospitalization to determine what is in the public's best  
2690 interest as far as a health emergency?

2691 Dr. {Schuchat.} Yeah, the issue with a pandemic is that  
2692 the potential impact is exceptionally greater than the normal  
2693 range. It--

2694 Mr. {Mullin.} So it doesn't matter how many deaths we  
2695 have, it is just 100 percent of--

2696 Dr. {Schuchat.} One would be--

2697 Mr. {Mullin.} --CDC to make that--

2698 Dr. {Schuchat.} One would be declaring that much in  
2699 advance of seeing the deaths, because of the time needed to  
2700 take steps to intervene.

2701 Mr. {Mullin.} Would it help if Congress or you guys  
2702 could come up with maybe some criteria that we could look at  
2703 that could maybe trigger it, rather than just waiting for the  
2704 next crisis to happen, or, honestly, a public outcry?

2705 Dr. {Schuchat.} I think we could probably provide the  
2706 language about a public health emergency. What I was trying  
2707 to say was that it is not the same for each condition, for  
2708 each disease or--

2709 Mr. {Mullin.} I understand there is some type of

2710 flexibility and, you know, there has got to be a little bit  
2711 of more understanding of what we are dealing with, but it  
2712 seems odd that there is no criteria at all for us to  
2713 understand it--

2714 Dr. {Schuchat.} Yeah, I--

2715 Mr. {Mullin.} --when something like the swine flu, that  
2716 just had 20 cases in the country, was declared an emergency  
2717 by the President, and yet we have a pandemic going on right  
2718 now with the flu, and we could have maybe changed some of  
2719 this with the regulatory burdens going through if we would  
2720 have declared it an emergency faster, where maybe we could  
2721 have got help to individuals.

2722 Dr. {Schuchat.} In 2009, a new strain emerged from  
2723 animals that had genetic re-assortment that has--was  
2724 completely unique to humans. And so what we are dealing with  
2725 with the drift is slight changes, a very different scenario.  
2726 But what you indicate is correct that the ultimate burden of  
2727 disease from a drifted H3N2 strain may end up being greater  
2728 than a completely new to humans re-assortment like the H1N1--

2729 Mr. {Mullin.} So--

2730 Dr. {Schuchat.} --swine-origin pathogen in 2009.

2731 Mr. {Mullin.} Could you maybe help us maybe draw some  
2732 type of criteria that needs to be laid out so the next time  
2733 this happens, we could have something to compare it to?

2734 Dr. {Schuchat.} We would be happy to provide follow-up  
2735 on the public health emergency and how that is defined.

2736 Sure.

2737 Mr. {Mullin.} Thank you. I yield back.

2738 Mr. {Murphy.} Thank you. Gentleman yields back.

2739 Now recognize another new member of our committee and  
2740 subcommittee, Chris Collins of New York, a second term in  
2741 Congress. Welcome aboard, and you are recognized for 5  
2742 minutes.

2743 Mr. {Collins.} Thank you, Mr. Chairman.

2744 I will be as quick as I can to get the information  
2745 really directed more at Dr. Fauci and Dr. Schuchat.

2746 And I appreciate your issue of the jump on swine flu,  
2747 the same thing we were worried about with the bird flu, that  
2748 didn't happen. That is the good news of RNA viruses, they  
2749 don't jump off to--but if they do, it can be devastating. So  
2750 my question is really on the universal vaccine discussion.  
2751 And I don't think it has been made clear here. We have DNA  
2752 viruses and we have RNA viruses. And when we talked about  
2753 the vaccine for HPV, the vaccine for herpes, smallpox,  
2754 chickenpox, those are all DNA vaccines. And it is relatively  
2755 straightforward to get a vaccine for a DNA-based virus. Then  
2756 you have your RNA viruses; HIV, Ebola, West Nile, SARS,  
2757 influenza. They mutate a lot, that is what they do, but they

2758 don't jump species much.

2759           So my question is this, since we are talking about an  
2760 RNA virus, so you can't compare influenza with HPV, you can't  
2761 compare influenza with herpes, they are--and I don't think  
2762 that was made clear, but now that we are talking about an  
2763 RNA-based virus, I guess my question is this, because they  
2764 mutate, drift so often, that is the insidious nature of RNA  
2765 viruses, which is why the answer to a lot of the questions  
2766 coming here is more because they do mutate, that is the basis  
2767 of that virus. So how is it that since measles is an RNA  
2768 virus, polio is an RNA virus, rubella is an RNA virus, and so  
2769 is mumps, so you have mumps, measles, rubella and polio on  
2770 the one hand, RNA, and we have vaccines for them, what is the  
2771 difference in the reason we don't have vaccines for things  
2772 like influenza?

2773           Dr. {Fauci.} You have asked a very complicated  
2774 question, and I can tell you that there is not a one-to-one  
2775 relationship of whether you can or cannot get a vaccine,  
2776 whether it is an RNA or a DNA vaccine. And also, RNA  
2777 vaccines--RNA viruses do jump species. I mean the--

2778           Mr. {Collins.} Rarely.

2779           Dr. {Fauci.} Yeah--well, HIV, influenza, I mean there  
2780 is the fowl virus that jumps, HIV, the chimp virus that  
2781 jumps, so--

2782 Mr. {Collins.} Yeah, but much less--

2783 Dr. {Fauci.} Yeah.

2784 Mr. {Collins.} --likely than a DNA virus.

2785 Dr. {Fauci.} But the things that go into whether or  
2786 not--your point is very well taken, that if you have in  
2787 general, and--

2788 Mr. {Collins.} Um-hum.

2789 Dr. {Fauci.} --you have to be really careful when you  
2790 pick this one or the other one, in general, a virus that has  
2791 a proofreading mechanism, which RNA viruses have--

2792 Mr. {Collins.} Right.

2793 Dr. {Fauci.} --they don't correct their mistakes when  
2794 they mutate, allows it to do what influenza does--

2795 Mr. {Collins.} Right. Right.

2796 Dr. {Fauci.} --drift. It allows it to do what HIV  
2797 does. If you give it one drug, it will mutate to be  
2798 resistant unless you give it--

2799 Mr. {Collins.} Sure.

2800 Dr. {Fauci.} --three drugs.

2801 Mr. {Collins.} Sure.

2802 Dr. {Fauci.} You are perfectly correct on that.

2803 However, it really isn't specifically that. These are easy  
2804 to make one against, and these are difficult. It just  
2805 doesn't work that way because there are a lot of other things

2806 that go into whether or not you are going to have a  
2807 successful vaccine. But the fundamental principles that you  
2808 mentioned are correct.

2809 Mr. {Collins.} So how did we end up with one for  
2810 measles, polio, and why has it been so God awful, if not  
2811 impossible, to get one for HIV or influenza? Is there any--

2812 Dr. {Fauci.} Well, the body makes a very good immune  
2813 response against measles, even if--when it is a serious  
2814 disease. Ultimately, the body will completely clear measles  
2815 in the--

2816 Mr. {Collins.} Right.

2817 Dr. {Fauci.} --overwhelming majority of people. So we  
2818 already know the body has the capability of inducing an  
2819 effective immune response, therefore, you follow what the  
2820 body does and you induce the same response that natural  
2821 infection does. With HIV, the body does not make an adequate  
2822 immune response against HIV, so there is no proof of--

2823 Mr. {Collins.} Yeah, but now, HIV, that is where the  
2824 immune system doesn't even see the viral particles.

2825 Dr. {Fauci.} Well--

2826 Mr. {Collins.} Now, that is different than influenza.

2827 Dr. {Fauci.} Well, I am sorry, sir, it does see it, it  
2828 just doesn't make a good response.

2829 Mr. {Collins.} It doesn't react to it.

2830 Dr. {Fauci.} It doesn't make a good response--

2831 Mr. {Collins.} Right.

2832 Dr. {Fauci.} --against it.

2833 Mr. {Collins.} Right, but that is what is unique about  
2834 HIV.

2835 Dr. {Fauci.} Exactly. You need the body's ability to  
2836 do it naturally to mimic it. That is what vaccines are all  
2837 about; mimicking natural infection without--

2838 Mr. {Collins.} Sure.

2839 Dr. {Fauci.} --hurting the host.

2840 Mr. {Collins.} So one real quick question for Dr.

2841 Schuchat. They use adjuvanted--adjuvant-based vaccines in  
2842 Europe. We don't do it here. The question on the  
2843 monocrobial, if we did that with an adjuvant, we could use--  
2844 extend that production, we could produce much less, extend  
2845 it, because you were saying production is the big issue. If  
2846 it was adjuvant-based, you wouldn't need as much. Should we  
2847 be looking at that as a natural part of the monocrobial?

2848 Dr. {Schuchat.} You know, I think that adjuvanted  
2849 influenza vaccines hold a lot of promise, and I know that the  
2850 FDA has licensed one so far in the U.S. In terms of  
2851 extending the supply and also--

2852 Mr. {Collins.} Right.

2853 Dr. {Schuchat.} --and also potentially expanding the

2854 immune response. As you heard from some of the measles  
2855 discussions, here in the U.S. our population has a lot of  
2856 questions about vaccines and about their safety, and they  
2857 have, even in 2009 when we were doing community engagement  
2858 around H1N1 vaccination, we had lots of questions about  
2859 whether there would be adjuvants in those vaccines or not.  
2860 In Europe, they use adjuvanted--

2861 Mr. {Collins.} Right.

2862 Dr. {Schuchat.} --H1N1 vaccines and we didn't. Our  
2863 public really needs to come along with us in the scientific  
2864 endeavor, and so I think that is an area where the FDA is  
2865 really critical in reviewing the safety data.

2866 Mr. {Collins.} Yeah. Thank you very much.

2867 Yield back, Mr. Chairman.

2868 Mr. {Murphy.} Thank you, Mr. Collins.

2869 And now as a tradition of this committee, if another  
2870 member of the committee wishes to be part of this, we will  
2871 welcome back a former member of the subcommittee for this  
2872 special visit, Mrs. Ellmers of North Carolina. You are  
2873 recognized for 5 minutes.

2874 Mrs. {Ellmers.} Thank you, Mr. Chairman, and thank you  
2875 to our ranking member also, for allowing me to be part of  
2876 this important subcommittee hearing on this very timely  
2877 issue. And to our panel, thank you for being here today.

2878           And I just want to point out a couple of things. One,  
2879 in October, looking at this issue and knowing the importance  
2880 of it moving forward, especially when it comes to vaccine  
2881 production, I had the honor of hosting a roundtable  
2882 discussion in the District of the--in the research triangle.  
2883 Dr. Midthun and Dr. Robinson, thank you again for  
2884 participating in that very important discussion. We learned  
2885 a lot from that. As we all know, Dr.--or, excuse me,  
2886 Chairman Upton is leading the 21st Century Cures Initiative,  
2887 and the vaccine space fits right in there. And I am working  
2888 on very important legislation right now to actually bolster  
2889 vaccine production and bring vaccines to market. As we know,  
2890 it is very, very important. And I have also the honor of  
2891 having the facility in Holly Springs, North Carolina, which  
2892 has been referred to already, which will be addressing the  
2893 issue of seasonal and pandemic vaccine production, using the  
2894 cell culture technology. Very important to my district. And  
2895 I also want to point out, and I think this is something that  
2896 we need to look at into the future when we are trying to  
2897 solve these problems. This was a public-private partnership  
2898 between Novartis, HHS and BARDA. So, again, thank you all  
2899 for your input today. This is a very, very difficult  
2900 situation, but I believe that we can get out of it and we can  
2901 move forward, and we can identify ways that we can identify

2902 improve upon this process.

2903           Dr. Schuchat, I have a question for you. In the  
2904 legislation that I am working on right now, my Bill, we  
2905 create mechanisms to help increase the communication and  
2906 sharing between the CDC and industry, and, you know, ways  
2907 that we can get that information out to impact public health.  
2908 In your opinion, how can the CDC work more closely in  
2909 partnership with industry to reduce the risk and uncertainty  
2910 of investing in the novel vaccines?

2911           Dr. {Schuchat.} We appreciate the chance to work  
2912 closely with industry as they are doing their early  
2913 development and research.

2914           Mrs. {Ellmers.} Um-hum.

2915           Dr. {Schuchat.} We welcome companies to come meet with  
2916 us to share their ideas, and we--

2917           Mrs. {Ellmers.} Um-hum.

2918           Dr. {Schuchat.} --share all of the information--

2919           Mrs. {Ellmers.} Um-hum.

2920           Dr. {Schuchat.} --we have in terms of the public health  
2921 burden--

2922           Mrs. {Ellmers.} Um-hum.

2923           Dr. {Schuchat.} --need and likely interest in terms of  
2924 public or providers.

2925           Mrs. {Ellmers.} Um-hum.

2926 Dr. {Schuchat.} So we do that regularly, and we welcome  
2927 the opportunity to do it systematically.

2928 Mrs. {Ellmers.} Dr. Midthun, again, thank you for being  
2929 here, and again, thank you for being a participant in the  
2930 roundtable discussion that I had back in the District in  
2931 October. As we are looking at vaccine manufacturers to more  
2932 readily export vaccines from the U.S. and make them available  
2933 to people around the world, again, the legislation that we  
2934 are working on right now helps to expedite the licensure  
2935 process. In addition to expediting export licenses, what  
2936 else can the FDA do to help speed up production and approval  
2937 on delivery of flu vaccine availability?

2938 Dr. {Midthun.} No, I think we currently use all the  
2939 expedited pathways that are available. So we can use  
2940 accelerated approval, which we--

2941 Mrs. {Ellmers.} Um-hum.

2942 Dr. {Midthun.} --have done for numerous influenza  
2943 vaccines.

2944 Mrs. {Ellmers.} Um-hum.

2945 Dr. {Midthun.} We also did recently for the 2  
2946 meningococcal B vaccines that we approved; one in October and  
2947 one just last month. We also used the breakthrough  
2948 designation which basically means that there is a very  
2949 concerted interactive approach early on and throughout the

2950 process with industry to really accelerate the development of  
2951 products. So we use all of these tools, and they are very  
2952 important. They, of course, do rely on having certain  
2953 science.

2954 Mrs. {Ellmers.} Um-hum.

2955 Dr. {Midthun.} So, for example, to use--

2956 Mrs. {Ellmers.} Sure.

2957 Dr. {Midthun.} --accelerated approval, you typically  
2958 rely on what we call a surrogate endpoint. Usually in the  
2959 case of a vaccine it would be some immune response. But you  
2960 need to have information that actually indicates that this  
2961 immune response is--

2962 Mrs. {Ellmers.} Um-hum.

2963 Dr. {Midthun.} --is, you know, you know, really likely  
2964 to predict clinical benefits. So there is also a scientific  
2965 piece that is very, very important that others, for example--

2966 Mrs. {Ellmers.} Um-hum.

2967 Dr. {Midthun.} --in industry, NIH and other partners,  
2968 need to work on--

2969 Mrs. {Ellmers.} Um-hum.

2970 Dr. {Midthun.} --to make that kind of--

2971 Mrs. {Ellmers.} Um-hum.

2972 Dr. {Midthun.} --process available, but we work very  
2973 closely, obviously, with our sponsors to facilitate whatever

2974 their development plans are.

2975           Mrs. {Ellmers.} Thank you. And one last comment that I  
2976 would like to make, Mr. Chairman, if you would indulge me.  
2977 One of the concerns that was raised by Mr. Tonko from New  
2978 York, having to do with the issues that our families are  
2979 dealing with, with sick children and, you know, having to  
2980 take time off of work, I would advocate for my good friend,  
2981 Martha Roby from Alabama, she has a wonderful Bill, Working  
2982 Families Flexibility Act, that actually addresses this issue  
2983 and allows our workforce to be able to take part in the  
2984 availability and ability to use overtime and bank it so that  
2985 in the event that pediatric appointments need to be made, or  
2986 any of these things, families can make those choices. So I  
2987 would advocate to the co-sponsorship of that Bill. It is a  
2988 very good Bill, and it addresses the very issues that we are  
2989 talking about today.

2990           Mr. {Murphy.} Thank you.

2991           Mrs. {Ellmers.} So thank you, Mr. Chairman, and I--

2992           Mr. {Murphy.} Thank you.

2993           Mrs. {Ellmers.} --yield back.

2994           Mr. {Murphy.} And I want to thank the panelists. Look,  
2995 I think we are all frustrated, we need to be speeding up this  
2996 process and the science, and if there are other legislative  
2997 things we need to do, please let us know. I don't--this is

2998 the day after Groundhog Day, and I don't want to be here with  
2999 another Groundhog Day a couple of years from now running into  
3000 the same problems, with the same issues, and having the same  
3001 crisis with so many Americans getting sick and dying for  
3002 whatever this is. So I ask--

3003 Ms. {DeGette.} Would the gentleman yield for one  
3004 second?

3005 Mr. {Murphy.} Yes.

3006 Ms. {DeGette.} I completely agree with the Chairman,  
3007 but I will say I want to commend this panel and others at the  
3008 CDC and NIH because, having been on this committee now for 18  
3009 years, we really have made advances from when we first  
3010 started with those early hearings on egg-based technologies.  
3011 We just need to accelerate that. So anything we can do to  
3012 help, we are here to help. Thank you.

3013 Mr. {Murphy.} Appreciate that. I ask unanimous consent  
3014 that Members' written opening statements be introduced into  
3015 the record, and without objection, the documents will be  
3016 entered in the record.

3017 [The information follows:]

3018 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
3019           Mr. {Murphy.} In conclusion, thank you again to the  
3020 witnesses, and Members that participated in today's hearing.  
3021 I remind Members they have 10 business days to submit  
3022 questions for the record, and I ask that all witnesses agree  
3023 to respond promptly to those questions.

3024           And with that, this committee is adjourned. Thank you.

3025           [Whereupon, at 12:34 p.m., the Subcommittee was  
3026 adjourned.]