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4 ``REVIEW OF THE PROPOSED GENERIC DRUG AND BIOSIMILARS USER
5 FEES AND FURTHER EXAMINATION OF DRUG SHORTAGES''
6 THURSDAY, FEBRUARY 9, 2012
7 House of Representatives,
8 Subcommittee on Health
9 Committee on Energy and Commerce
10 Washington, D.C.

11 The subcommittee met, pursuant to call, at 10:00 a.m.,
12 in Room 2123 of the Rayburn House Office Building, Hon. Joe
13 Pitts [Chairman of the Subcommittee] presiding.

14 Members present: Representatives Pitts, Burgess,
15 Shimkus, Murphy, Gingrey, Latta, Lance, Cassidy, Pallone,
16 Dingell, Towns, Engel, Capps, DeGette, and Waxman (ex
17 officio).

18 Staff present: Clay Alspach, Counsel, Health; Michael

19 Beckerman, Deputy Staff Director; Nancy Dunlap, Health
20 Fellow; Paul Edattel, Professional Staff Member, Health;
21 Debbie Keller, Press Secretary; Ryan Long, Chief Counsel,
22 Health; Carly McWilliams, Legislative Clerk; John O'Shea,
23 Professional Staff Member, Health; Chris Sarley, Policy
24 Coordinator, Environment and Economy; Heidi Stirrup, Health
25 Policy Coordinator; Phil Barnett, Democratic Staff Director;
26 Alli Corr, Democratic Policy Analyst; Eric Flamm, FDA
27 Detailee; Karen Nelson, Democratic Deputy Committee Staff
28 Director for Health; Rachel Sher, Democratic Senior Counsel;
29 and Elizabeth Letter, Assistant Press Secretary.

|
30 Mr. {Pitts.} The subcommittee will come to order. The
31 chair recognizes himself for 5 minutes for an opening
32 statement.

33 Today, we will discuss two new user fee authorizations,
34 one for generics and one for biosimilars, and also examine
35 the worsening drug shortage problem facing our country.
36 Under the terms of the Generic Drug User Fee agreement that
37 industry and FDA have negotiated, industry will pay
38 approximately \$1.5 billion over the next 5 years in exchange
39 for more efficient and predictable review of generic drug
40 applications and increased inspections of drug facilities.

41 Currently, there are approximately 3,000 generic drug
42 applications sitting in a backlog at FDA. One of the goals
43 of the agreement is to eliminate this backlog within 5 years,
44 speeding generic drugs to the patients who need them without
45 sacrificing quality or safety. Another goal of the agreement
46 is to have FDA inspect all drug facilities at an increased
47 frequency and to bring parity between inspections of foreign
48 and domestic facilities.

49 Industry and FDA have also negotiated a second user fee
50 agreement for biosimilars--those products approved under the
51 abbreviated approval pathway for biological products shown to
52 be highly similar to an FDA-licensed biological product.

53 This subcommittee has spent a great deal of time in the last
54 few years trying to achieve a pathway to approval for
55 biosimilars. This agreement authorizes four types of fees:
56 application, product, establishment, and biosimilars product
57 development, to make this a reality.

58 Finally, every day we are hearing from providers in our
59 districts about increased difficulties in acquiring the drugs
60 necessary to treat their patients. As this subcommittee
61 looks to develop a package of ways to alleviate drug
62 shortages, I look forward to hearing from our witnesses and
63 learning their views on the matter.

64 Again, thank you to all of our witnesses on both panels
65 and I will yield the balance of my time to Mr. Murphy from
66 Pennsylvania for an opening statement.

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

68 ***** COMMITTEE INSERT *****

69 Mr. {Murphy.} Thank you, Mr. Chairman.

70 Brand name and generic medicines are simultaneously
71 necessary and essential components of quality and cost-
72 effective healthcare, but approximately 78 percent of
73 prescriptions dispensed in the United States in 2010 were
74 filled with generic drugs. It is estimated that over the
75 last 10 years, the use of generic medications has saved our
76 healthcare system nearly \$1 trillion. However, in recent
77 years, the backlog of generic drug applications at the Food
78 and Drug Administration has dramatically increased. Today,
79 there are over 2,500 applications awaiting review with an
80 average review time of almost 31 months. At the same time,
81 events like the 2007 contamination of heparin manufactured in
82 China have raised serious concerns about the security of the
83 U.S. pharmaceutical supply chain.

84 Today, 40 percent of all drugs sold in the U.S. are
85 manufactured overseas and as much as 80 percent of the active
86 pharmaceutical ingredients--called API--in those drugs come
87 from foreign sources. According to the Government
88 Accountability Office, FDA inspects U.S. pharmaceutical
89 factories every 2 to 3 years but inspects overseas facilities
90 on average only once every 9 years.

91 In the face of these challenges, the FDA and the generic

92 pharmaceutical industry have come together with other
93 stakeholders to negotiate a historic 5-year agreement that
94 will bring less expensive therapies to market faster. Less
95 expensive drugs mean better access to care for patients; that
96 means fewer costly complications from untreated chronic
97 diseases, fewer hospitalizations. Industry has agreed to do
98 their part by paying \$1.5 billion in user fees to FDA over 5
99 years and in return FDA has pledged to review 90 percent of
100 new applications within 10 months by year 5 of the agreement.
101 The FDA has also agreed to work to address supply chain
102 safety concerns while ensuring level playing fields for
103 domestic and foreign manufacturers by achieving parity
104 between domestic and foreign facility inspections.

105 Yesterday, I introduced the Generic Drug and Biosimilar
106 User Fee Act of 2012 based on this agreement with
107 Representatives Pallone, Pitts, and Waxman. I look forward
108 to working with my colleagues on this committee as we review
109 to enact this critical piece of legislation.

110 Finally, let me thank and commend Representative Dingell
111 for his many years of leadership and work on the issue of
112 drug safety. When we enact this legislation, it will be to a
113 large extent because of his dedication and long-term efforts.

114 And with that, I yield back.

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

116 ***** COMMITTEE INSERT *****

|
117 Mr. {Pitts.} The chair thanks the gentleman and now
118 yields to the ranking member of the full committee, Mr.
119 Waxman, for 5 minutes for an opening statement.

120 Mr. {Waxman.} Thank you very much, Mr. Chairman.

121 Today, we begin the process of establishing two
122 critically important programs at FDA that will help speed
123 low-cost generic drugs and biosimilars to the market.
124 Because these are new user fee programs that will now join
125 the other long-existing programs, just yesterday,
126 Representative Murphy, Pallone, Pitts, and I introduced the
127 Generic Drug and Biosimilars User Fee Act which will give FDA
128 the authority and resources it needs to review generic
129 applications in a timely and effective manner. I am proud
130 that we were able to work together in such a strong
131 bipartisan fashion on this legislation. It reflects our
132 shared commitment to ensuring that American patients have
133 access to these life-saving medicines early and at a price
134 they can afford.

135 I also want to comment FDA and the biotech and generic
136 drug industries for the hard work they put into negotiating
137 these thoughtful and thorough proposals. These programs are
138 long overdue. We have had a long history of success with the
139 other user fee programs for brand name drugs and medical

140 devices. In contrast, for some time now, FDA's generic drug
141 review program has been starved for resources, which resulted
142 in a dramatic backlog of applications. That, of course, has
143 meant fewer generic drugs on the market and consequently
144 higher medication prices for American patients. At long
145 last, this legislation will help us turn this untenable
146 situation around.

147 Likewise, FDA will also now have the resources it needs
148 to review applications for biosimilar drugs. By most
149 accounts, biotech drugs are the most promising medicines on
150 the horizon. This law will permit FDA to fully implement the
151 newly established biosimilars pathway and we will all begin
152 to see its benefits.

153 On a different note, I am encouraged that the
154 subcommittee is taking another look at the very dire
155 situation surrounding drug shortages. This is the kind of
156 issue that can and should be tackled on a bipartisan basis.
157 It is a complex and multifaceted problem but I feel confident
158 that we will work together to find workable solutions.

159 Thank you for holding this hearing today and I look
160 forward to the testimony of our witnesses. I yield back my
161 time.

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

163 ***** COMMITTEE INSERT *****

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164 Mr. {Pitts.} The chair thanks the gentleman and at this
165 point recognizes the vice chairman of the Health
166 Subcommittee, Dr. Burgess, for 5 minutes for an opening
167 statement.

168 Dr. {Burgess.} Thank you, Mr. Chairman, for the
169 recognition.

170 Dr. Woodcock, welcome to our committee. Certainly, you
171 have always been very receptive to our questions and we
172 appreciate the efforts that you provided to me and my staff
173 on our visit to the FDA a few months ago.

174 We are discussing two of the pending user fee agreements
175 before the committee, but also today, I think many of us are
176 interested in the issue of the drug shortages. When doctors
177 lack the essential tools, they are extremely restricted as to
178 what they can do for patients. It is a complex issue. You
179 have stated that before. Your agency has stated that before.
180 But make no mistake; the FDA has a role in helping us find a
181 solution.

182 In calendar year 2010, over 240 drugs were identified as
183 being in short supply or unavailable and more than 400
184 generic equivalents were backordered. Many generic lines
185 operate at margins that are so tight that when production
186 becomes difficult, they can't afford to make the changes to

187 revamp their machinery and make those compounds available.
188 In an ideal free market, competitors would then move in and
189 assume this market share, but now we are in a situation where
190 some competitors cannot afford to ramp up to meet the
191 resulting demand. We have to ask ourselves is this the
192 result of hyper-competition? And if so, is that ultimately a
193 good thing? So is approval of multiple competitors in a
194 limited space leading to market forces that actually end up
195 driving patients back to branded products at higher prices
196 and increased spending? Is that good in the long run?

197 And inevitably, we have to face the over 3,000 number of
198 backlogs of generic applications and I am very interested in
199 tracking the goals in this user fee agreement in regard to
200 the one-time fee the industry has agreed to in order to clear
201 that backlog.

202 Finally, we have to look at the issue of bioequivalence
203 and when the Food and Drug Administration chooses to exercise
204 the flexibility they have in the approval process. In some
205 instances, I believe this authority has been used
206 questionably. In others, I question why it hasn't been used
207 at all. On January 6, in response to a request for
208 flexibility on bioequivalent studies for a substitute for
209 Doxil, a chemotherapeutic agent used in treating gynecologic
210 cancer, Mr. Conner, the Director of Bioequivalence of the

211 Office of Generic Drugs wrote, ``the Food and Drug
212 Administration may take steps to expedite regulatory reviews.
213 However, the Agency has determined that it is necessary that
214 bioequivalence or bioavailability study in patients be
215 conducted.''

216 Now, I don't have any other information on the quality
217 of this submission, but I do know this: Doxil is gone now to
218 treat patients. The line is shut down. Any stockpile that
219 was there went to treat the ill, and that is appropriate, but
220 how do you conduct a bioequivalent study if you don't have
221 the product against which to test. When you are doing a
222 randomized clinical trial, it requires that you have the
223 product to test. You can't do that, and yet the Food and
224 Drug Administration just simply wants to say, well, you have
225 got to do the bioequivalence study. They are not telling us
226 what we should do in this event where we have no product left
227 against which to test. These are tools on which physicians
228 rely every day, and what do we do when they are not there?

229 Here are some other observations: ``A 51-year-old
230 patient with platinum-resistant ovarian cancer had already
231 been treated with another chemotherapeutic agent. She has
232 few choices for therapy and would likely die before the drug
233 shortage is corrected. I have three promising clinical
234 trials which are now on hold because of shortages. Please

235 help us.' ' Another quote: ``I cannot obtain Doxil for
236 patients stabilized on therapy. I have switched to alternate
237 drugs with more side effects.' ' Another quote: ``We have
238 encountered regimen changes, difficulties with patient
239 insurance approval, and an increase in hospitalization due to
240 side effects of older regimens.' ' I have 35 such
241 testimonials as part of a survey conducted by the Society of
242 Gynecologic Oncology and the FDA letter, and I would ask that
243 those be submitted for the record.

244 Look, no physician wants to tell a patient that they
245 cannot receive the care they need because there is no
246 treatment but because the product is simply not available and
247 we won't provide alternatives is no solution at all.

248 I will be glad to yield the remaining time to anyone
249 one on my side who would request it. If not, I yield back to
250 the chairman.

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

252 ***** COMMITTEE INSERT *****

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253 Mr. {Pitts.} Without objection, those will be entered
254 into the record.

255 [The information follows:]

256 ***** COMMITTEE INSERT *****

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257 Mr. {Pitts.} And the chair now recognizes the ranking
258 member of the Subcommittee on Health, Mr. Pallone, for 5
259 minutes for opening statement.

260 Mr. {Pallone.} Thank you, Chairman Pitts.

261 This hearing is the second in a series of important
262 hearings that this subcommittee will hold in relation to the
263 FDA User Fee Agreements, and I welcome everyone for joining
264 us. And as I noted last week, I am encouraged by the
265 bipartisan nature of these efforts, and I look forward to
266 working with my colleagues.

267 Today's topics will cover two brand new user fee
268 programs that the subcommittee will authorize. The first is
269 a Generic Drug User Fee Agreement, also known as GDUFA. That
270 will create a program at the FDA in order to help expedite
271 review of their applications similar to the way brand name
272 drug manufacturers pay user fees. Primarily, the agreement
273 will help address the significant backlog of generic
274 applications currently at the FDA. Unfortunately, over the
275 last several years, this backlog has continued to grow at an
276 alarming rate. In fact, the median time for a generic drug
277 approval has doubled to 32 months, and that means all these
278 generic drug products are kept off the market and out of the
279 hands of consumers, which is a waste and simply too long.

280 Generic drugs, as we know, have proven to help lower
281 healthcare costs. In the last decade alone, generic drugs
282 have provided more than \$824 billion in savings to the
283 Nation's healthcare system. Clearly, bringing generic drugs
284 to market faster should be a priority, and luckily, the
285 generic industry was able to recognize that we must provide
286 the Office of Generic Drugs with adequate resources to do
287 their job effectively. As much as I advocate for increased
288 government funding for the FDA, that simply has become too
289 difficult a battle to overcome, and so I appreciate the
290 industry's ability to work with the FDA and move forward on a
291 strong agreement and I commend your efforts.

292 The second user fee program is the Biosimilars User Fee
293 Agreement, also known as BsUFA, which is the product of the
294 Biologics Price Competition Innovation Act, the law that
295 created a pathway for biogeneric medicine onto the
296 marketplace. This agreement came together through a
297 collection of brand and generic companies and FDA. Now, I
298 know it is difficult for many to comment on the strength and
299 robustness of the agreement because of the law's infancy, but
300 it is a step forward in providing FDA the necessary resources
301 to bring promising medicines to patients at a lower cost and
302 I am supportive of its passage. I think that both Mr. Waxman
303 and Mr. Murphy mentioned that last night, the two of us, as

304 well as Chairman Pitts--the four of us I should say--
305 introduced a standalone measure that covers both these
306 agreements and shows that they have bipartisan support and
307 that we are going to move forward with them.

308 Another issue under discussion today is the current drug
309 shortage of vital medications that are impacting clinicians,
310 hospitals, and patients who have depended upon these
311 medications for years. It is alarming the drugs that have
312 been around for so long would suddenly be the most difficult
313 to keep hospitals, pharmacies, and doctors' offices supplied
314 with. I strongly believe this committee has the
315 responsibility to address this sudden increase in drug
316 shortages. We had a hearing last September that brought
317 light to some important inadequacies of the system and I know
318 there is a strong bipartisan appetite to work out a solution
319 and I hope that we can get there. It is not a simple task
320 but there are strong ideas that we have to consider and flesh
321 out.

322 Lastly, Ms. DeGette has a bill that focuses on industry
323 reporting as a worthy objective. I am also aware the generic
324 industry has a proposal that we will be discussing today
325 about a voluntary self-regulatory system. While I welcome
326 their advocacy on addressing the problem, self-regulation
327 always raises some critical questions. So I look forward to

328 hearing more about that and I trust the FDA and our other
329 witnesses can give specific insight into some of these
330 proposals.

331 I wanted now to yield what time I have left to the
332 chairman emeritus, Mr. Dingell.

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

334 ***** COMMITTEE INSERT *****

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335 Mr. {Dingell.} Mr. Chairman, as I have brought to the
336 committee's attention in the past, drug supply chain safety
337 is critical to the issue of health and safety to the American
338 people. This hearing is going to reinforce how imperative it
339 is to provide FDA with appropriate authorities and resources
340 to secure our medicines. This committee has a long
341 bipartisan history of working on this issue and looking into
342 drug safety. It is now time for us to act. Our friends in
343 the Senate have put together a bipartisan working group on
344 this matter and we in the House should follow suit. Time is
345 short. If we don't work together in good faith on this
346 issue, we will not be finding a solution and the situation
347 will continue deteriorating with death and hurt occurring
348 throughout the American population by reason of our failure
349 to address the difficulty. The American public deserves a
350 solution.

351 As we proceed today, I am asking my colleagues to join
352 me in working on this vital issue and to demonstrate to the
353 American people that the Congress does indeed work for them
354 and that we follow on the steps that we took in the last
355 Congress to see to it that we made foods much safer than they
356 were by following on and addressing now questions relative to
357 the safety of pharmaceuticals, appliances, and devices, and

358 ultimately, cosmetics.

359 And I thank you, Mr. Chairman.

360 [The prepared statement of Mr. Dingell follows:]

361 ***** COMMITTEE INSERT *****

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362 Mr. {Pitts.} The chair thanks the gentleman. That
363 concludes the opening statements for the members. We are now
364 voting on the floor. So we have two votes. We will take a
365 recess until the end of the second vote at which time we will
366 reconvene.

367 The subcommittee stands in recess.

368 [Recess.]

369 Mr. {Pitts.} The subcommittee will come to order.

370 Our first panel will have just one witness, Dr. Janet
371 Woodcock, the Director of the Center for Drug Evaluation and
372 Research at FDA. We are happy to have you with us today, Dr.
373 Woodcock, and your written testimony will be made part of the
374 record and you are recognized for 5 minutes to summarize.

|
375 ^STATEMENT OF JANET WOODCOCK, M.D., DIRECTOR, CENTER FOR DRUG
376 EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION;
377 ACCOMPANIED BY THERESA MULLIN, DIRECTOR, OFFICE OF PLANNING
378 AND INFORMATICS, CENTER FOR DRUGS; PETER BECKERMAN, SENIOR
379 ADVISOR, OFFICE OF POLICY, FOOD AND DRUG ADMINISTRATION; AND
380 VALERIE JENSEN, ASSOCIATE DIRECTOR, CENTER FOR DRUG
381 EVALUATION AND RESEARCH, DRUG SHORTAGE PROGRAM, FOOD AND DRUG
382 ADMINISTRATION

383 } Dr. {Woodcock.} Thank you very much and good morning.

384 Mr. Chairman and members of the subcommittee, I would
385 really like to thank you for the opportunity to testify about
386 three important issues: the United States Generic Drug
387 Program and user fees that would support it, the new
388 Biosimilars Program and proposed user fee, and the ongoing
389 crisis of shortage of essential drugs in the United States.

390 I am joined today by Dr. Theresa Mullin on my right, who
391 is the director of the Office of Planning and Informatics at
392 the Center for Drugs. Dr. Mullin was the lead negotiator on
393 Prescription Drug User Fee Program and on the Biosimilars
394 Program. And to my left is Mr. Peter Beckerman, who is the
395 senior advisor for policy in the Office of Policy at FDA.
396 And he was one of the lead negotiators on the Generic Drug

397 User Fee Program.

398 Since enacted by Congress in 1984, the current generic
399 drug program has been a stunning success by most accounts.
400 Today, over 3/4 of prescriptions dispensed are for high
401 quality, affordable generics, as the members have said,
402 saving Americans billions of dollars literally. But this
403 program has been the victim of its unprecedented success.
404 Applications to the program have skyrocketed and the program
405 has not been able to keep up. Times to approval have
406 lengthened and are prolonged, and over 2,000 applications are
407 in a so-called backlog at the Office of Generic Drugs.

408 At the same time, globalization of the industry has
409 challenged FDA to assure the same level of inspectional
410 coverage that is carried out domestically for the foreign
411 facilities. The new user fee program proposed to Congress
412 addresses both these problems head on. The program would
413 bring timelines and predictability to the review process,
414 eliminate the backlogs. It would also provide a level
415 playing field for inspections to ensure that the same quality
416 standards are maintained wherever in the world the generic
417 drug is made. These changes will ensure that U.S. consumers
418 continue to have access to safe, effective, high quality, and
419 affordable generic drugs.

420 The proposed Biosimilar User Fee Program is intended to

421 support a new emerging industry. Biologics drugs developed
422 over the past 20 years have provided new and effective
423 treatment options for patients with serious diseases such as
424 rheumatoid arthritis and cancer, but the generic drug program
425 that existed did not apply to and was not really appropriate
426 for these complex biological molecules. In 2007, Congress
427 created a new pathway for biosimilar biologics and instructed
428 FDA to develop a user fee proposal, which we have done. This
429 program is intended to support an emerging industry and I
430 will be very pleased to be able to discuss it.

431 I would like to thank the members--Mr. Murphy and Mr.
432 Pitts and the additional members--for introducing
433 legislation. We are really happy to hear that there is
434 bipartisan support and we look forward to working with you.

435 I am also pleased to announce that, later today, FDA
436 will introduce three draft guidances for industry on
437 biosimilars. These contain technical information that will
438 help the industry as they develop these new products for the
439 U.S. market.

440 The third topic, drug shortages, is a very important
441 issue. Millions of Americans rely on medicines to support or
442 sustain their health as we heard from Dr. Burgess. The
443 recent shortages of sterile injectable drugs, many of which
444 are essential in cancer treatment or in seriously ill

445 patients, have brought a spotlight on this problem. The
446 causes of drug shortage are multi-factorial, but in this
447 case, a perfect storm came together to create the current
448 situation of shortages. FDA does everything possible to both
449 prevent and ameliorate shortages, including stimulating the
450 production of other manufacturers, allowing risk mitigation
451 strategies for products that have manufacturing difficulties,
452 moving up the queue of applications so we could get
453 additional products onto the market to alleviate shortages,
454 and even arranging for temporary importation of similar
455 products from other countries. For the current shortages,
456 this has not been enough and hospitals and clinicians are
457 facing and have been facing significant shortages.

458 We look forward with working with you to ensure that
459 Americans have continued uninterrupted access to effective,
460 safe, high quality, and affordable drugs to sustain their
461 health. Thank you very much.

462 [The prepared statement of Dr. Woodcock follows:]

463 ***** INSERT 1 *****

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464 Mr. {Pitts.} The chair thanks the gentlelady and now
465 begins the questioning and I will recognize myself for 5
466 minutes for that purpose.

467 Dr. Woodcock, how many applications are in the generic
468 backlog at FDA?

469 Dr. {Woodcock.} We count what you might consider a
470 backlog to have about 2,000 applications.

471 Mr. {Pitts.} Two thousand.

472 Dr. {Woodcock.} That includes some drugs that couldn't
473 be approved now because the patents haven't expired on the
474 innovators. You can send in your application beforehand and
475 then you have to wait. But there are many in that backlog
476 that could be approved if we had time to get to them or had
477 the inspectional resources to do the inspection.

478 Mr. {Pitts.} And how will the Generic Drug User
479 Agreement help clear out this backlog?

480 Dr. {Woodcock.} The agreement has several parts and one
481 is specifically directed at the backlog. What we have
482 recommended to Congress is that there be a one-time backlog
483 fee paid at the start of the program of \$50 million. That
484 would go toward us beginning to work on the backlog. One of
485 the goals of the program that we would be held to is clearing
486 up the backlog by the end of the 5-year user fee program. So

487 by that time, we would be in steady state--applications in
488 the door, applications out the door with predictability in
489 that process and timelines. So we would expect with the
490 backlog fee and our commitments and timelines that the
491 backlog would be eliminated.

492 Mr. {Pitts.} Can you be a little more specific on what
493 kind of generic drug applications are in this backlog and how
494 will clearing this backlog save patients in our healthcare
495 system money?

496 Dr. {Woodcock.} Most of the drugs in the backlog are
497 additional copies of a drug where there is already a generic
498 because we expedite the first generic out the door to try and
499 get patients that initial savings so that additional copies
500 of a generic have been shown to further lower the cost of the
501 drug, the price due to competition. So this is important for
502 lower cost drugs and also to have a robust supply. I think
503 we are learning and we know from the shortage situation it is
504 important to have multiple manufacturers of important drugs.

505 Mr. {Pitts.} Now, in your testimony you talk about
506 FDA's efforts to expedite review of manufacturer submissions
507 to help alleviate drug shortages, and currently, it takes FDA
508 31 months to review these submissions. Can you give us more
509 background on what expedite means? On average, how long does
510 it take to expedite those submissions that can help alleviate

511 drug shortages?

512 Dr. {Woodcock.} I can't give you an exact number but we
513 have a queue, and so everything is waiting and usually
514 generic drugs are reviewed first in and they are reviewed
515 first. So if you are the third in, you are reviewed third
516 and so forth for fairness purposes. What we do if there is a
517 shortage drug where that application might help ameliorate
518 the shortage, we pull it out of the queue and review it as
519 quickly as possible. So much of that 30 months can be gone.
520 If the application is good, we can review that rapidly and
521 get that drug on the market. So we have very few drugs
522 waiting in the queue that actually would address shortages.
523 We have identified any of those drugs and we have expedited
524 review of the applications.

525 Mr. {Pitts.} Now, how will the Biosimilars User Fee
526 Program provide predictability and consistency regarding the
527 review of biosimilars applications, and how will the
528 Biosimilars User Fee Program help this burgeoning industry?

529 Dr. {Woodcock.} The Biosimilars User Fee Program will
530 provide predictability of timelines and review and process to
531 this industry similar to what the Prescription Drug User Fee
532 does for innovator products. To some extent, the biosimilars
533 program was modeled on the GDUFA program. However, it has a
534 development piece in it to recognize the emerging nature of

535 this industry and that development piece, they pay fees and
536 they get a series of development meetings so we can give them
537 extensive advice on how to develop their products. And then
538 when the final application comes in, there are timelines and
539 goals associated with those timelines. So FDA, in exchange
540 for having this user fee program, will be expected to meet
541 those timeliness goals on review.

542 Mr. {Pitts.} All right, thank you.

543 My time has expired. I will recognize the ranking
544 member of the subcommittee, Mr. Pallone, for 5 minutes for
545 questions.

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

547 Dr. Woodcock, we have heard these statistics about the
548 drug production overseas that 40 percent of drugs and 80
549 percent of the active pharmaceutical ingredients come from
550 abroad. That is my concern. As you know, Mr. Dingell, Ms.
551 DeGette, myself, and Mr. Waxman have introduced the Drug
552 Safety Enhancement Act that gives the FDA authorities and
553 resource to address the problem of these ingredients and
554 drugs from overseas. You mention in your testimony the
555 challenge represented by foreign inspections, but my
556 understanding is that current law requires FDA to inspect
557 domestic drug facilities every 2 years but is silent with
558 respect to foreign facilities. That seems to be an uneven

559 playing field obviously, and I know resources are always
560 going to be an issue, but I still think that the bifurcation
561 doesn't make sense.

562 You know, so assuming you have unlimited resources,
563 which of course is absurd, but assuming you have unlimited
564 resources, do you agree that inspecting foreign and domestic
565 facilities at the same frequency would make sense?

566 Dr. {Woodcock.} Yes, I believe that what we need to do
567 is a risk-based approach, and some facilities in the United
568 States and some facilities overseas may need very close FDA
569 supervision because of the problems they are having. Other
570 facilities may be on a different schedule based on the risks
571 that they pose but I don't believe--

572 Mr. {Pallone.} They are not based on whether they are
573 domestic versus overseas?

574 Dr. {Woodcock.} That is exactly right.

575 Mr. {Pallone.} Now, would you need new authority to
576 permit you to do that, which, you know, to make sure that it
577 is not different foreign versus domestic and to do the risk
578 assessment? Would you need new authority for that?

579 Dr. {Woodcock.} We primarily lack the resources to
580 perform this inspectional program and one of the principal
581 goals of the new Generic Drug User Fee Program is to level
582 that playing field of inspection. And one of the proposals

583 there is that we conduct risk-based surveillance inspections
584 around the world and achieve parity or a level playing field
585 on--

586 Mr. {Pallone.} So it is more a question of the
587 resources than new authority then?

588 Dr. {Woodcock.} Yes, I believe that. Of course the law
589 sort of sends a message that you are supposed to do the
590 domestic every 2 years and is silent on the foreign, but from
591 what we are doing, we are trying to ensure the quality of
592 drugs for our patients, and where the drug is produced should
593 not be taken into account.

594 Mr. {Pallone.} Thank you. Now, would it be helpful to
595 have additional resources to conduct more foreign inspections
596 of brand facilities? I mean this isn't confined to just
597 generic, correct?

598 Dr. {Woodcock.} We need to inspect all facilities
599 producing drugs of any kind, including over-the-counter drugs
600 and so on at the appropriate intensity for the risk that they
601 bear.

602 Mr. {Pallone.} Okay. Now, what about the
603 responsibility of U.S. companies? You know, for example, you
604 know, we have the heparin situation illustrated the
605 importance of raising expectations of pharmaceutical
606 companies to be familiar with their own suppliers, you know,

607 coming from abroad. Do you think that U.S. companies should
608 have to be able to ensure that the products they sell meet
609 U.S. requirements even though those ingredients are coming
610 from abroad? Are there any new authorities that would help
611 the FDA in making sure that companies meet those
612 responsibilities?

613 Dr. {Woodcock.} Yes. As we have said repeatedly, we
614 feel that our authorities at the border in particular are
615 somewhat limited and there are additional authorities that
616 have been discussed that would aid in keeping foreign
617 products that don't meet our standards out of this country.

618 Mr. {Pallone.} All right, let me just ask--I have a
619 minute left--with regard to BsUFA and the BsUFA negotiations.
620 Both you and the FDA Commissioner Hamburg gave assurances to
621 the generic industry that the Biosimilar User Fee Program
622 would receive 20 million in funding. Now, I understand we
623 are talking about, you know, money that would be shifted
624 around within the Agency. What steps are being taken to make
625 sure that that happens?

626 Dr. {Woodcock.} Well, we have made a commitment. Dr.
627 Mullin, who is here, we have been just discussing our time
628 reporting and other tracking mechanisms. We keep very close
629 track of how we spend both our BA money and our user fee
630 money.

631 Mr. {Pallone.} But is this something that you are going
632 to move around within the Agency, is it going to be in the
633 budget, or is it a new \$20 million that we have to come up
634 with? I assumed it was within the Agency. That is what I am
635 trying to find out.

636 Dr. {Woodcock.} Of course we would appreciate, you
637 know, having resources to conduct this program. However, we
638 do have \$1.8 million right now in appropriated dollars for
639 the biosimilars program and we would make up the money. If
640 we don't receive appropriated money, we would use BA funds
641 that are existing within the Center for Drugs.

642 Mr. {Pallone.} All right. Thank you so much.

643 Mr. {Pitts.} The chair thanks the gentleman and
644 recognizes the gentleman from Pennsylvania, Dr. Murphy, for 5
645 minutes for questions.

646 Mr. {Murphy.} Thank you, Mr. Chairman, and thank you,
647 doctor, for being here, appreciate your candid and informed
648 comments on this.

649 Let me start off by asking--I want to make sure I
650 understand FDA rules with regard to these medications. The
651 Federal Food and Drug Cosmetic Act assumes that a drug is
652 adulterated unless the methods used for manufacture of drug
653 products conform to good manufacturing practice. Am I right
654 that it works under that assumption?

655 Dr. {Woodcock.} That is correct.

656 Mr. {Murphy.} Can you explain the role and importance
657 of these good manufacturing practices in terms of helping to
658 ensure the safety and integrity of FDA-approved products?
659 Can you explain how that works?

660 Dr. {Woodcock.} Certainly. When drugs are produced in
661 mass production in a factory, all right, there are many
662 procedures. The modern term would be quality management,
663 okay, to make sure that each time the drug is produced
664 adequately and of adequate quality and that no errors have
665 occurred. And it would be amazing if you go in a factor as
666 we do all the time to see how many times something can go
667 wrong. And so you must check and you must observe and you
668 must test and you must improve and do all that. And those
669 are embodied in regulations called the current good
670 manufacturing practices regulations. And we also have
671 international agreements on a lot of this, how it should
672 look, that we have worked out through the International
673 Conference on Harmonization.

674 Mr. {Murphy.} So the assumption is unless you have
675 actually seen what they do and given your seal of approval to
676 that, we are assuming it has not met that standard. Is that
677 a fair statement?

678 Dr. {Woodcock.} Well, we have set standards for what

679 the quality management should be like, and also we review the
680 drug, make sure the testing and so forth will control the
681 drug adequately, but until we go in there, we don't know if
682 they are actually following those procedures. And they may
683 follow them at one time and then later slip from that and get
684 into problems and not produce a quality drug.

685 Mr. {Murphy.} Hence the importance of inspecting plants
686 on a regular or a tighter basis and you sometimes do a
687 surprise visit and they occur in a short period and show up
688 again.

689 I know we have had hearings in the past where there is
690 no such thing as a surprise visit to a foreign country and
691 they know you are coming--

692 Dr. {Woodcock.} That is correct.

693 Mr. {Murphy.} --and when you are going. So do these
694 practices differ in the United States versus other countries
695 then in terms of how medications are manufactured?

696 Dr. {Woodcock.} You mean by the manufacturers
697 themselves?

698 Mr. {Murphy.} Yes, by the manufacturers themselves.

699 Dr. {Woodcock.} Well, there is a wide range of capacity
700 and functionality in different countries, all right. In the
701 United States there has been a long history of FDA
702 inspections and understanding of what the standards are.

703 Nevertheless, I will point out over the past year or so we
704 have had multiple recalls and some of the drug shortage
705 problems are due to U.S. manufacturers who are not being able
706 to manufacture their product. So it requires vigilance and
707 continued attention to be able to manufacture these products
708 right. That said, in other parts of the world, it is much
709 more uneven. They may have extremely modern factories and be
710 right on top of their game, and there may be many factories
711 that may be substandard in many areas.

712 Mr. {Murphy.} So given all that, what is preventing the
713 FDA from updating good manufacturing practices right now that
714 require companies to verify their suppliers are complying?
715 And associated with that, do you think the bills before us
716 here sufficiently address your concerns, and either way, will
717 you be able to offer the recommendations or cleaning up these
718 bills if you feel that is necessary?

719 Dr. {Woodcock.} Yeah, well, we would be happy to work
720 with you. I believe that the user fee bills are not about
721 policy or regulation. They are about providing extra
722 resources to perform activities. The regulations or law
723 around drug safety and quality have not been really modified
724 for a long time and are probably not totally congruent with
725 modern understanding. So there has been discussion by this
726 committee and others about are there additional standards

727 that could be put into place that bolster and bring these up
728 to modern understanding of what is needed.

729 For example, I am always surprised and I am sure most
730 Americans would be to hear that we can't really--there is a
731 presumption that anything that is being imported to our
732 country, a drug, is okay. And we have to prove that there is
733 something wrong with it rather than the opposite. Most other
734 countries that is not the case.

735 Mr. {Murphy.} I want to make sure I hear what you are
736 saying. You are saying you have to prove something is wrong
737 with the imported drug? So what you told me before is with
738 companies here there, there is an assumption that it is
739 adulterated unless they can prove they have gone through
740 inspection. But you are saying when a foreign drug comes
741 over, the assumption is everything is fine unless you prove
742 otherwise?

743 Dr. {Woodcock.} Yes, that--

744 Mr. {Murphy.} It is two different standards.

745 Dr. {Woodcock.} Now, I am not a lawyer, all right, but
746 that is how I understand the legal framework is set up. So
747 we have to look at that and prove some way that it is not
748 adequate for entry into the United States.

749 Mr. {Murphy.} I appreciate it. I think that would come
750 as a shock to most Americans to understand that that is how

751 things are going. Thank you so much.

752 Dr. {Woodcock.} And I would tell you that is not the
753 case in other countries where they can hold things at the
754 border if they even feel that they may not meet the
755 standards.

756 Mr. {Murphy.} Thank you.

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

758 Mr. {Pitts.} The chair thanks the gentleman and
759 recognizes the gentleman from Michigan, Mr. Dingell, for 5
760 minutes for questions.

761 Mr. {Dingell.} Mr. Chairman, I thank you for your
762 courtesy.

763 Welcome, Dr. Woodcock. I am sponsor of H.R. 1483, which
764 I hope this committee will give some strong consideration to.
765 My questions today are going to require only yes or no
766 answers due to the fact that I have so many. Starting, over
767 70 percent of prescriptions filled today are for generic
768 drugs. Considering the fact that 40 percent of all drugs
769 come from overseas and 80 percent of pharmaceutical
770 ingredients are also from overseas, it is critical that we be
771 able to protect American consumers by ensuring the safety of
772 the drug supply chain. In order to do this, FDA must clearly
773 have the proper authorities in place.

774 Dr. Woodcock, yes or no if you please. Does the Federal

775 Food and Drug Cosmetic Act require FDA to complete GMP
776 inspections of domestic drug manufacturers every 2 years?
777 Yes or no?

778 Dr. {Woodcock.} Yes.

779 Mr. {Dingell.} Does the Federal Food Drug and Cosmetic
780 Act require FDA to complete GMP inspections of foreign drug
781 manufacturers on a comparable basis? Yes or no?

782 Dr. {Woodcock.} No.

783 Mr. {Dingell.} Would you have the resources to do it if
784 they did?

785 Dr. {Woodcock.} Not currently.

786 Mr. {Dingell.} Is it accurate to say that current law
787 is silent on the frequency with which FDA must inspect
788 foreign facilities? Yes or no?

789 Dr. {Woodcock.} Yes.

790 Mr. {Dingell.} Does FDA generally meet the biannual
791 inspection requirement for domestic drug facilities
792 currently? Yes or no?

793 Dr. {Woodcock.} Yes.

794 Mr. {Dingell.} Is it true that FDA does not inspect
795 foreign facilities at the same frequency as domestic
796 facilities? Yes or no?

797 Dr. {Woodcock.} Yes.

798 Mr. {Dingell.} Is it true that a lack of financial and

799 personnel resources are contributing to factors not for
800 inspecting foreign drug facilities more frequently? Yes or
801 no?

802 Dr. {Woodcock.} I am sorry. Could you repeat that a
803 little more slowly?

804 Mr. {Dingell.} I will give it again. Is it true that a
805 lack of financial and personnel resources are contributing
806 factors to not inspecting foreign drug facilities more
807 frequently? Yes or no?

808 Dr. {Woodcock.} Yes.

809 Mr. {Dingell.} Do you agree that conducting inspections
810 of domestic and foreign drug facilities at comparable
811 frequency is as important to ensuring a level playing field
812 for drug manufacturers? Yes or no?

813 Dr. {Woodcock.} Yes.

814 Mr. {Dingell.} Sometime the playing field gets slanted
815 against United States manufacturers because of our inability
816 to inspect foreign manufacturers and suppliers of different
817 kinds, isn't that so?

818 Dr. {Woodcock.} Yes.

819 Mr. {Dingell.} Can our goal be achieved by using risk-
820 based inspection systems? Yes or no?

821 Dr. {Woodcock.} Yes.

822 Mr. {Dingell.} Yes or no?

823 Dr. {Woodcock.} Yes.

824 Mr. {Dingell.} Do you agree that a risk-based
825 inspection schedule for domestic and foreign drug facilities
826 based, for example, on the compliance history, time since
827 last inspection, volume and type of product would allow FDA
828 to better target their resources? Yes or no?

829 Dr. {Woodcock.} Yes.

830 Mr. {Dingell.} Do you agree that conducting comparable
831 inspections of domestic and foreign facilities is important
832 to public health? Yes or no?

833 Dr. {Woodcock.} Yes.

834 Mr. {Dingell.} Do you agree that FDA needs adequate
835 resources, both financial and personnel, to conduct
836 comparable inspections of domestic and foreign drug
837 manufacturers? Yes or no?

838 Dr. {Woodcock.} Yes.

839 Mr. {Dingell.} Does the Prescription Drug User Fee
840 Agreement currently provide resources for preapproval
841 inspection? Yes or no?

842 Dr. {Woodcock.} Yes.

843 Mr. {Dingell.} Does the Prescription Drug User Fee
844 Agreement currently provide resources for any inspections
845 beyond preapproval inspection? Yes or no?

846 Dr. {Woodcock.} No.

847 Mr. {Dingell.} As you know, the Generic Drug User Fee
848 Agreement provides additional resources for FDA to conduct
849 GMP inspections of both domestic and foreign drug facilities.
850 Now, does FDA need similar resources for inspections of
851 facilities manufacturing innovator drugs? Yes or no?

852 Dr. {Woodcock.} Yes, we need similar resources.

853 Mr. {Dingell.} Now, one obstacle for ensuring
854 comparable inspections of domestic and foreign facilities is
855 a lack of complete and accurate information that FDA has on
856 generic drug manufacturing establishments. Will the Generic
857 Drug User Fee Act help FDA to identify all domestic and
858 foreign drug and active pharmaceutical ingredient facilities
859 involved in the making of generic drugs through registration?
860 Yes or no?

861 Dr. {Woodcock.} Yes, as proposed.

862 Mr. {Dingell.} And I am assuming that that is a very
863 badly needed authority at Food and Drug. Is that yes or no?

864 Dr. {Woodcock.} Absolutely.

865 Mr. {Dingell.} Mr. Chairman, I have completed my
866 business and with 9 seconds to spare. I yield back the
867 balance of my time.

868 Dr. {Burgess.} [Presiding] The chair thanks the
869 gentleman for his gracious--

870 Mr. {Dingell.} Mr. Chairman, I ask unanimous consent

871 that the record will include an analysis of H.R. 1483, the
872 Drug Safety Enforcement Act of 2011, of which I am a sponsor.
873 Thank you, Mr. Chairman.

874 Dr. {Burgess.} Without objection, so ordered.

875 [The information follows:]

876 ***** COMMITTEE INSERT *****

|
877 Dr. {Burgess.} I now recognize myself for 5 minutes for
878 questions.

879 And again, Dr. Woodcock, welcome to our humble little
880 hearing room here at the Energy and Commerce Committee. We
881 welcome you back. Let me ask you a couple of questions that
882 deal with the issue of conflicts and the exclusion of people
883 from the FDA advisory panels because of conflicts of
884 interest. Have there been instances where experts have been
885 disqualified from serving on advisory committees because they
886 served as an investigator for the product under
887 consideration?

888 Dr. {Woodcock.} Yes.

889 Dr. {Burgess.} Have there ever been instances where
890 someone is disqualified because they have been in a clinical
891 trial as an investigator for an unrelated product?

892 Dr. {Woodcock.} Yes.

893 Dr. {Burgess.} So I think I have an accurate quote from
894 you where you say it is difficult finding highly experienced
895 people who do not have conflicts?

896 Dr. {Woodcock.} That is correct.

897 Dr. {Burgess.} And we have delays in the panels because
898 of this policy. And in fact your commissioner, Margaret
899 Hamburg, Dr. Hamburg has said some meetings require expertise

900 that is limited to a handful of experts who can often have
901 conflicts of interest. So tell us what the real world
902 consequences of this are. Most of us have never been in an
903 FDA advisory panel meeting so what are the implications of
904 having people that have to exclude themselves or be excluded
905 because they either have knowledge of the product under
906 consideration or they have been involved in an unrelated
907 investigation?

908 Dr. {Woodcock.} We are asking the committee for advice
909 on very complicated scientific questions. Our scientists are
910 very well versed on the topic and will have gone over all the
911 information in the application and any related literature.
912 So they really want people at the table who can help them
913 grapple with these complex questions and they would really
914 like experts, trialists or disease experts who can shed
915 additional light on the problem they are trying to deal with.

916 Dr. {Burgess.} Just as someone from the outside, is the
917 converse of that universe also true that the people who are
918 involved may not have the knowledge set or skills to make
919 some of the decisions they are required to make and in some
920 cases maybe even lack the basic fund of knowledge to deal
921 with the clinical question at hand?

922 Dr. {Woodcock.} Yes.

923 Dr. {Burgess.} Thank you for that succinct and concise

924 answer. Let me ask you this since you have given me the
925 benefit of some time. I have been in a ping pong match for
926 the past couple of weeks, couple of months, since the first
927 of January when the EPA banned the sale of over-the-counter
928 asthma inhalers. I am an asthma patient myself and I will
929 just tell you all across this country people are going to be
930 going to the CVS pharmacy at midnight because they have had
931 an asthma attack and they are out of all of their other
932 options and they are used to being able to buy for \$16
933 Primatene inhaler and now they cannot. And we as Members of
934 Congress are going to start hearing about that. It is not
935 going to happen all at once but it is slowly going to start
936 rolling out into the American landscape such that by the time
937 of the August recess, I suspect there will be a number of
938 people who show up in each Member's town halls complaining
939 about this policy.

940 Now, we have heard from the EPA and the EPA says it is
941 your fault, and Commissioner Hamburg said no, it is the EPA.
942 Can you help us? Primatene has been on the market for a long
943 time and the only thing that has changed is the propellant,
944 CFC changed to HFA. I would argue that HFA is not as
945 efficient a dispersant as CFC but that being aside, there
946 really is no difference in the active pharmaceutical
947 ingredient in the over-the-counter inhaler Primatene, but for

948 whatever reason, it is held up somewhere. Can you help us
949 get that done?

950 Dr. {Woodcock.} The switching of all the asthma
951 inhalers was triggered by the Montreal Protocol that was
952 agreed to by the United States to eliminate CFCs to help with
953 the problem of the ozone layer. And FDA has gone through a
954 very long process to inform the manufacturers, work with the
955 community, prepare them, and then execute the switches. For
956 the prescription albuterol inhalers, which are really a
957 preferred standard of care, as you know, for asthma--

958 Dr. {Burgess.} Yeah, but I always don't plan ahead.

959 Dr. {Woodcock.} Right.

960 Dr. {Burgess.} You know, I am the world's worst asthma
961 patient and I will forget--

962 Dr. {Woodcock.} Right.

963 Dr. {Burgess.} --and then something happens that
964 triggers an attack at two o'clock in the morning and now the
965 only option is to go to the emergency room and get a
966 treatment and that is \$1,500.

967 Dr. {Woodcock.} I understand.

968 Dr. {Burgess.} It was \$16, \$16.00 before, and this is
969 what we have visited upon people. I do want to enlist your
970 aid in getting this problem solved. I have asked the EPA to
971 allow the sale of existing Primatene inhalers with CFC until

972 those markets are exhausted, but we really do have to--that
973 is why we have an approval rating of 8 percent because people
974 look at this and say well, this is a simple problem. The
975 stuff was for sale before, it has got a different propellant,
976 sell it again. Or did you really think that asthma patients
977 were blowing a hole in the ozone layer. I don't think so and
978 you will never convince me otherwise. But my time has
979 expired and I am going to yield to--who am I going to yield
980 to? No one on your side. I will yield to Dr. Gingrey. Oh,
981 I beg your pardon. Okay, Dr. Gingrey, you are recognized for
982 5 minutes for questions, sir.

983 Ms. {DeGette.} I just want to welcome Dr. Woodcock.

984 Dr. {Woodcock.} Thank you.

985 Ms. {DeGette.} Thanks.

986 Dr. {Gingrey.} Mr. Chairman, thank you.

987 Dr. Woodcock, much has been made over the past months
988 and years about drug and medical production moving overseas
989 to countries like China and many reasons for this migration
990 have been put forward. In a study that ran in Health
991 Affairs--this is November 2011--entitled ``Evolving Brand
992 Name and Generic Drug Competition'' may warrant a revision of
993 the Hatch-Waxman Act. The authors state that ``the Hatch-
994 Waxman Act in 1984 raises questions about whether the Act's
995 intended balance of incentives for cost savings and continued

996 innovation has been achieved. Generic drug usage and
997 challenges to brand name drugs' patents have increased
998 markedly, resulting in greatly increased cost savings but
999 also potentially reduced incentives for innovators, new drug
1000 application, brand name. Congress should review whether
1001 Hatch-Waxman is achieving its intended purpose of balancing
1002 incentives of generics and innovation. It also should
1003 consider whether the law should be amended so that some of
1004 its provisions are brought more in line with recently enacted
1005 legislation governing approval of so-called biosimilars.''

1006 Dr. Woodcock, do you believe that Congress should review
1007 the current Hatch-Waxman paradigm to ensure that the intended
1008 balance of incentives for cost savings and innovation
1009 continues to have been achieved?

1010 Dr. {Woodcock.} I would say that deciding on those
1011 tradeoffs between innovation and cost saving for the American
1012 public is one of the jobs of Congress, and FDA will execute
1013 the provisions as they are laid out by the Congress. It is
1014 clear that there have been tremendous cost savings as many of
1015 the Members have indicated from the generics program. We
1016 also know that the innovator industry is struggling right
1017 now, and that again is multi-factorial and would have to be
1018 the subject of a different discussion. But the innovator
1019 industry overall is in a crisis.

1020 Despite that, they have put forth many innovative drugs
1021 which we have been able to approve over the past year. We
1022 approved 30 new entities last year, many of them very
1023 innovative drugs. So whether that is the correct balance I
1024 think is a very complicated economic issue that I am not able
1025 to opine on, and it involves many societal tradeoffs to
1026 decide--

1027 Dr. {Gingrey.} Well, I thank you and I know you can't
1028 state exactly, but your answer certainly suggests that you
1029 have some concerns that maybe the balance that we are trying
1030 to achieve is not there. Is that a fair statement or--

1031 Dr. {Woodcock.} I think many of us are concerned about
1032 the health of the innovator industry which is what brings new
1033 products and treatments and cures to people who lack
1034 therapies right now. However, whether or not Hatch-Waxman is
1035 the way to deal with that is beyond my purview.

1036 Dr. {Gingrey.} Yeah. Thank you, Dr. Woodcock. I want
1037 to commend the FDA on its concern for U.S. patients in light
1038 of our current drug shortage crisis. As you know, this is an
1039 issue that is important to this committee and this Congress
1040 and I want to commend my colleague, Representative DeGette,
1041 for her leadership in this area. As a medical provider, I
1042 believe that proper notification can play a critical role in
1043 ensuring patients get the best care possible, especially

1044 those with life-threatening conditions such as cancer. In
1045 your testimony, you state that ``although many of the root
1046 causes of drug shortages are beyond our control, we are
1047 committed to addressing this important issue and look forward
1048 to working with the subcommittee on this issue. Tell me, Dr.
1049 Woodcock, what are the root causes of drug shortages and
1050 which ones are beyond our control?

1051 Dr. {Woodcock.} Well, I would refer you to the
1052 excellent document that was written at HHS, the assistant
1053 secretary for Planning Evaluation I believe at HHS that
1054 discussed this because many of them are economic issues.
1055 What we saw with the sterile injectables, which are the drugs
1056 that are in great shortage right now was a surge in capacity
1057 over the past 10 years but with a very limited number of
1058 manufacturers, most of whom are in the United States. And
1059 with that capacity surge, they took on a large inventory of
1060 sterile injectables that they were producing, each of these
1061 manufacturers, and then when they developed problems in their
1062 manufacturing ability where they were getting particulates or
1063 endotoxin or other potential bacterial contamination, so
1064 forth, which I will add these things are hard to avoid and
1065 they take a lot of diligence to keep sterile manufacturing,
1066 you know, at a high quality level. But when they encountered
1067 these problems, then we lapsed into a shortage situation with

1068 a few alternatives or maybe no alternatives.

1069 Dr. {Gingrey.} I see my time has expired and as I yield
1070 back, would you be sure and get that report to me? I would
1071 appreciate it.

1072 Dr. {Woodcock.} Happy to do so.

1073 Dr. {Gingrey.} Thank you. Mr. Chairman, I yield back.

1074 Dr. {Burgess.} I thank the gentleman for yielding. The
1075 chair now recognizes Mr. Towns of New York for 5 minutes for
1076 the purpose of questioning the witness.

1077 Mr. {Towns.} Thank you very much, Mr. Chairman. Thank
1078 you for having this hearing.

1079 Dr. Woodcock, I am concerned about the larger backlog of
1080 generic drug applications. What can be done about that?

1081 Dr. {Woodcock.} Well, I am concerned about it, too, and
1082 the proposal that we have given to Congress for the Generic
1083 Drug User Fee Program has a specific provision to eliminate
1084 the backlog over the first course of that program.

1085 Mr. {Towns.} Right. Is there cooperation across the
1086 board, you know, in terms of the pharmaceutical companies and
1087 all that? Everybody is on board with this agreement?

1088 Dr. {Woodcock.} Yes, I think it is in everyone's best
1089 interest to eliminate this backlog and to have a predictable
1090 and efficient generic drug process.

1091 Mr. {Towns.} Right. Once this goes into place, what

1092 will the turnaround time be approximately?

1093 Dr. {Woodcock.} The goal time for any generic drug
1094 application is a first review, a complete response within 10
1095 months of the submission of the application.

1096 Mr. {Towns.} All right.

1097 Dr. {Woodcock.} So the goal would be every generic drug
1098 applicant would get an answer back in 10 months and we would
1099 then look at how many of those could get right on the market
1100 or what were the problems that would keep them going into
1101 another cycle.

1102 Mr. {Towns.} Right. Mr. Chairman, I am going to do
1103 something we don't do around here. I am going to yield back.

1104 Dr. {Burgess.} The chair recognizes the gentleman's
1105 generosity and recognizes the gentleman from Ohio, Mr. Latta,
1106 for 5 minutes for questions.

1107 Mr. {Latta.} I thank the chairman.

1108 And Dr. Woodcock, thanks very much for being with us
1109 today. I would like to kind of go back to what Dr. Gingrey
1110 was talking about at the very end in regards to drug
1111 shortages, and I have been working with several other members
1112 in the past few months on this issue. And first of all, you
1113 said in your opening statement that, especially on drug
1114 shortages, that we had a perfect storm. Could you describe
1115 what that perfect storm is or was?

1116 Dr. {Woodcock.} Well, it was the enhanced utilization
1117 of the older sterile injectable drugs, okay, so the demand
1118 went up for them. At the same time, new sterile injectable
1119 drugs went generic, and so then firms took those on as well
1120 so then the demand on their lines--they have a limited number
1121 of manufacturing lines that can make sterile injectables, all
1122 right, because it is very hard to do that. So the demand
1123 went up, both for the existing drugs and the new generic
1124 drugs that were sterile injectables. At the same time, it
1125 takes a while to expand the capacity and bring up new
1126 facilities. So that did not happen.

1127 And then manufacturing problems occurred within many of
1128 those lines, thus making them have perhaps to shut down the
1129 line and precipitate a sudden shortage. The other
1130 manufacturers who might take up the slack were also having
1131 capacity problems of their own and/or having manufacturing
1132 problems. So all these factors came together to create
1133 really an unprecedented amount of shortages that we are
1134 trying to deal with and shortages of drugs that Americans
1135 cannot do without.

1136 Mr. {Latta.} Let me ask, then, over the past year, what
1137 have you all done to alleviate that problem?

1138 Dr. {Woodcock.} In 2011, 175 drug shortages were
1139 alleviated by our actions. Now, 86 of those I think were

1140 from one firm where we were able to do interventions, but we
1141 have multiple interventions as I describe but we can
1142 alleviate those. Nevertheless, there are several hundred
1143 shortages that are ongoing.

1144 Mr. {Latta.} Are there additional items that you can do
1145 then?

1146 Dr. {Woodcock.} Pardon me?

1147 Mr. {Latta.} Are there additional items that you could
1148 work on to help on that issue?

1149 Dr. {Woodcock.} Yes. Well, since the executive order
1150 by the President that asked firms to notify us of any kind of
1151 shortage and we have also put in a database that we are
1152 tracking these very carefully. We have added staff to the
1153 drug shortage program that we have at FDA. But we do feel
1154 that if there were legislation that requested companies or
1155 required companies to notify us, that would help us in
1156 perhaps averting more shortages.

1157 Mr. {Latta.} And also is there a disease area where
1158 there are more significant drug shortages than others?

1159 Dr. {Woodcock.} Right now, we are hearing from the
1160 cancer community and that is because many of the cancer drugs
1161 are injectables. But the injectable drug shortage affects
1162 many other kinds of disease areas and over the years,
1163 historically, you couldn't predict where the shortages would

1164 arise. They have been in all sorts of disease areas.

1165 Mr. {Latta.} And also, will the generic drug user fee
1166 help with the drug shortage issue do you believe?

1167 Dr. {Woodcock.} I believe that having a robust industry
1168 that has predictable timelines for its applications and can
1169 get applications through and also having an inspectional
1170 force that we can get out there quickly and do the
1171 inspections in the appropriate time will help with shortages
1172 because one of the things we need for shortages is we need
1173 more than one manufacturer that is able to make that drug.
1174 So if something happens at one plant, then there is somebody
1175 else who can ramp up production.

1176 Mr. {Latta.} Okay. And some of the committee hearings
1177 and the press have suggested the key characteristic of the
1178 drugs in shortage older physician-administered drugs
1179 underscore failure in the older generic market and that
1180 incentives in this market are critical in solving the crisis.
1181 Do you agree with that assessment?

1182 Dr. {Woodcock.} I am sorry. Could you repeat that?

1183 Mr. {Latta.} Yeah. There has been in some of the
1184 committee hearings and also out in the press have suggested
1185 that the key characteristics of drugs in shortage older
1186 physician-administered drugs underscore a failure in the
1187 older generic market and that incentives in this market are

1188 critical to solving that crisis. And do you agree with that
1189 assessment?

1190 Dr. {Woodcock.} I am not qualified to make a judgment
1191 on that being a physician and not an economist. The HHS
1192 report felt that it was a multiple number of factors and it
1193 wasn't simply an incentives problem. Theresa, do you have--

1194 Ms. {Mullin.} Yeah, I think that that report would
1195 probably the best description of all the kinds of factors. A
1196 number of them are economic and factors that are not within
1197 our ability to control and there may be other ways to address
1198 those but we have limited ability to address those factors.

1199 Mr. {Latta.} Okay.

1200 Ms. {Mullin.} No ability in some cases.

1201 Mr. {Latta.} Thank you very much.

1202 Mr. Chairman, I see my time has expired and I yield
1203 back.

1204 Mr. {Pitts.} The chair thanks the gentleman and
1205 recognizes the gentlelady from California, Mrs. Capps, for 5
1206 minutes for questions.

1207 Mrs. {Capps.} Thank you, chairman, for recognizing me.

1208 And Dr. Woodcock, thank you for your testimony today. I
1209 am actually going to just make a statement to add onto the
1210 list of reasons why the topic at hand, the drug shortages, is
1211 a very real issue. I would ask a question following but it

1212 has already been asked and you supplied the answer that I
1213 know you would answer to me. But it is such a prevalent
1214 problem plaguing manufacturers, hospitals, doctors, and
1215 patients alike. So this is a story of one of my constituents
1216 who reached out to our office. She is a pharmacy buyer at a
1217 nonprofit organization in my district which works with cancer
1218 patients. So right now, her organization is not able to
1219 purchase life-saving critical care drugs, and for some of
1220 them, they have been waiting more than 4 months. I know this
1221 isn't the new story to you either, but it is one more story.
1222 And the only route available for this organization because
1223 they are nonprofit is to get these drugs from the black
1224 market who is essentially auctioning them off, often charging
1225 three times more than what they ought to cost. As a
1226 nonprofit, you can imagine they never are successful in their
1227 bids, and instead, the treatments for their patients they are
1228 representing are delayed. This is hard to believe in this
1229 country at this moment.

1230 So let me turn to something a little different--

1231 Dr. {Woodcock.} May I say something?

1232 Mrs. {Capps.} Of course, please.

1233 Dr. {Woodcock.} We are accepting reports from outside
1234 parties where they have encountered excessive pricing
1235 behavior and other behaviors that we can refer to the

1236 Department of Justice.

1237 Mrs. {Capps.} I appreciate that and actually will take
1238 that back to this constituent and to others who will let our
1239 district offices know when they hear these stories there is a
1240 path that can be followed. You don't just have to say I am
1241 so sorry. We can say, well, there is a path and there could
1242 be some recompense that is made in that area.

1243 Another mechanism for helping to address drug shortages
1244 is notifying of the FDA of impending shortages. I know that
1245 in the next panel, you are going to hear testimony discussing
1246 the Accelerated Recovery Initiative that the industry is
1247 putting forward to help address and prevent shortage,
1248 anticipating that might come up in their discussion. What do
1249 you think of this proposal, and in particular, do you think
1250 it should be implemented, in what ways would it obviate the
1251 need for legislation, and how is this going to help us so we
1252 can focus on things that would make a difference for you and
1253 that they are going to come up with a solution?

1254 Dr. {Woodcock.} Yeah, we haven't had the opportunity to
1255 examine the proposal in detail and we look forward to working
1256 with the industry on the proposal as well as with Congress.

1257 Mrs. {Capps.} Okay. So you are going to be listening
1258 carefully to the next panel as well.

1259 And then finally, with the rest of my time, we have

1260 heard a lot of discussion today about the increasingly
1261 globalized drug supply chain and the challenges it opposes.
1262 I want to ask you about a couple of problems I have heard
1263 about in particular. First, I understand the FDA has had
1264 problems conducting or completing inspections of facilities
1265 overseas or abroad. Would you be willing to describe some of
1266 these problems such as if a foreign manufacturer doesn't
1267 allow you in to inspect its plant or unduly delays you for an
1268 inspection, what recourse do you now have and what additional
1269 authority would be helpful?

1270 Dr. {Woodcock.} Mr. Beckerman will address that.

1271 Mrs. {Capps.} Yes.

1272 Mr. {Beckerman.} Sure. Currently, FDA has to show that
1273 a drug appears to be adulterated or misbranded to keep it out
1274 of the country, and if FDA inspectors are delayed, limited,
1275 or denied in the inspection, there is no immediate recourse
1276 that the Agency can take. And so having an explicit
1277 authority to allow us to exclude a drug if our inspectors
1278 have been impeded would be extremely helpful.

1279 Mrs. {Capps.} So these companies know very well that if
1280 they delay or deny that nothing is going to happen anyway?

1281 Mr. {Beckerman.} There are very different incentives
1282 depending on the type of inspections being done. Firms have
1283 an obvious incentive to let FDA investigators in for a

1284 preapproval inspection because that is a condition precedent
1285 to getting their drug on the market. Once a drug is on the
1286 market, that incentive no longer exists and it would be
1287 helpful for FDA to have a tool.

1288 Mrs. {Capps.} So having a tool would be useful to you
1289 to note?

1290 Mr. {Beckerman.} That is right.

1291 Mrs. {Capps.} I also understand that information
1292 sharing with foreign regulatory partners has posed some
1293 challenges. Could you describe a couple of these challenges--
1294 --there are a few more seconds left--and also the role of
1295 importers in the supply chain that has become a more
1296 prominent one in recent years?

1297 Mr. {Beckerman.} On the information sharing question,
1298 in particular the Food, Drug, and Cosmetic Act has a
1299 provision that prevents FDA from sharing what is called trade
1300 secret information, and this is not typically the sort of
1301 thing that we think about as, you know, the secret formula
1302 for Coke, but it is information related to the manufacturing
1303 process. It is critical to be able to share that information
1304 with regulatory partners if we want to take advantage of
1305 their regulatory reach and be as efficient as possible. So
1306 addressing the inability to share, that sort of information
1307 would be very helpful.

1308 Mrs. {Capps.} Would that require legislation?

1309 Mr. {Beckerman.} It would.

1310 Mrs. {Capps.} Okay. Thank you very much. I yield
1311 back.

1312 Mr. {Pitts.} The chair thanks the gentlelady and
1313 recognizes the gentleman from Louisiana, Dr. Cassidy, for 5
1314 minutes for questions.

1315 Dr. {Cassidy.} Thank you, Dr. Woodcock. I am always
1316 impressed at how well you answer questions.

1317 The grey market--I am speaking of course about drug
1318 shortages--what is the volume of drug on the--5-FU is in a
1319 shortage, do we have a sense of how much the grey market will
1320 arise to fill that need?

1321 Dr. {Woodcock.} Well, I would ask Captain Valerie
1322 Jensen, who is our head of drug shortages. Do you have any
1323 insight into that?

1324 Ms. {Jensen.} Yes. I am Val Jensen, Associate Director
1325 of Drug Shortage Program, and we don't think there is a large
1326 supply in the grey market from what we understand about the
1327 grey market. FDA doesn't receive a lot of information about
1328 the grey market, but we do know that from what we hear, it is
1329 a very small volume that is in the grey market right now.

1330 Dr. {Cassidy.} Now, but I am concerned in this report
1331 of HHS, they speak about if there is early notification of

1332 shortages, there may be hoarding. That almost seems like you
1333 are throwing gasoline upon the potential of a grey market.
1334 Would you agree with that?

1335 Ms. {Jensen.} We would agree with that.

1336 Dr. {Cassidy.} And so it is good to have early
1337 notification or not?

1338 Ms. {Jensen.} So if we received the early notification,
1339 what we do with that is try to work with the company,
1340 whatever company is having the problem on addressing that
1341 issue as soon as possible. Hopefully, we can prevent the
1342 shortage before it even occurs. That is our goal.

1343 Dr. {Cassidy.} Now, I am also concerned, and I don't
1344 know this; I am just asking--do some people make it a
1345 practice to hoard in anticipation and therefore step in? It
1346 clearly would be a nice way to make some money. You
1347 mentioned there could be a referral to DOJ, but this is kind
1348 of a late development. Have people done that in the past?
1349 Have we looked at the ordering patterns of companies? Do
1350 they order here, then they suddenly order there sort of
1351 thing?

1352 Ms. {Jensen.} FDA doesn't normally get that type of
1353 information, the ordering information.

1354 Dr. {Cassidy.} Would that be HRSA?

1355 Ms. {Jensen.} The manufacturers would know what is

1356 being ordered. When there is a potential shortage, sometimes
1357 companies do--

1358 Dr. {Cassidy.} But let me ask because I think here last
1359 time--and people have mentioned they don't know the source of
1360 drugs on the grey market--it seems logical to look at wait,
1361 who is ordering? Is there a difference in ordering pattern
1362 relative to a particular entity's patient base? Does that
1363 make sense? Now, that just occurs to me and frankly I have
1364 looked at that, and when you look at that, you think that is
1365 kind of interesting, small little hospital ordering a lot of
1366 drugs. Now, has anybody pursued that more than just kind of
1367 looking at it?

1368 Ms. {Jensen.} It is just not data that FDA has access
1369 to as far as hospital ordering patterns.

1370 Dr. {Cassidy.} I could give it to you. I mean I just
1371 made a phone call and got it and it actually just kind of
1372 raises questions frankly.

1373 Dr. {Woodcock.} Right. Well, I think those are the
1374 types of things that law enforcement might be interested in.
1375 Also, I would say if we have early notification process, we
1376 would not plan to make it public unless we had failed to
1377 avert the shortage and the shortage was imminent.

1378 Dr. {Cassidy.} And again, as you were describing the
1379 means by which you averted shortage, there seems to be

1380 somewhat of an ad hoc basis to it. You got a call, you
1381 rushed in, you started making it. In my life I have learned
1382 that it is better to have a system as opposed to an ad hoc.
1383 Now, do you systemize that or is it still somewhat ad hoc?

1384 Dr. {Woodcock.} I think we have systematized it to the
1385 extent it is possible. The problem is that the manufacturers
1386 cannot predict when they are going to run into shortage.
1387 Many of these shortages are precipitated by manufacturing
1388 failures. They make the drug, they are going along making
1389 the drug, everything is fine, and then they discover
1390 particulates, they have mixed up the drug--

1391 Dr. {Cassidy.} Presumably there is quality control that
1392 on a regular basis they are going to pull up and say, okay,
1393 every 6 weeks we are going to, you know, run a sample and
1394 make sure it doesn't have sporacide or something in it.

1395 Dr. {Woodcock.} Well, it is much more than that
1396 actually. There is a very tight system of controls. You
1397 were talking about the good manufacturing processes call for
1398 very tight controls--

1399 Dr. {Cassidy.} I only have 53 seconds. By the way,
1400 just to go back, if you don't have access to the ordering
1401 pattern of the hospitals, who does have that data?

1402 Ms. {Jensen.} Yeah, I think we would have to look into
1403 that.

1404 Dr. {Cassidy.} Could you let me know that? I would be
1405 really interested in that.

1406 Let me ask one more thing. Going back, Mr. Dingell had
1407 a line of questions about whether or not you need more
1408 resources. I think it was our previous conversation you
1409 mentioned that union contracts would limit the ability to
1410 send people overseas. Dr. Hamburg was here and she really
1411 kind of rope-a-doped me on that, so let me just ask a yes or
1412 no. Do you have the ability under your union contract to
1413 send somebody overseas to inspect a plant if they otherwise
1414 object? Yes or no?

1415 Dr. {Woodcock.} I don't know the answer to that. I
1416 don't supervise the field staff. And I imagine it depends on
1417 the circumstances. So I can get back to you but I can't
1418 answer that straight out.

1419 Dr. {Cassidy.} Does anybody on the panel know that?
1420 Okay, if you could, I would appreciate that.

1421 Dr. {Woodcock.} Certainly.

1422 Dr. {Cassidy.} Thank you. I yield back.

1423 Mr. {Pitts.} The chair thanks the gentleman. That
1424 concludes the members of the subcommittee questioning.

1425 Without objection, we will go to the members of the full
1426 committee. Ms. DeGette of Colorado is recognized for 5
1427 minutes for questions.

1428 Ms. {DeGette.} Thank you, Mr. Chairman.

1429 I just want to ask a follow-up question about the drug
1430 shortages and I appreciate my colleagues on both sides of the
1431 aisle working with me on this issue because it is something
1432 that sort of hit and escalated, and we are all hearing about
1433 it from our hospitals. And, you know, we are all concerned
1434 about the stories we hear, particularly with these generic
1435 injectables, about the shortages that hospitals are having.
1436 A lot of them are pediatric cancer patients and other
1437 patients like that. But I am hearing from my pharmacist at
1438 the hospital that this is now expanding to many other drugs.
1439 They told me that they have a drug shortage a day at some of
1440 these hospitals, some place where they are trying to make
1441 these value judgments about what they treat the patients
1442 with. And so I also am concerned about the hoarding issues
1443 and the other issues, but I guess I would ask you, any of the
1444 witnesses, to talk about under the current voluntary program
1445 that you have, do you see a lot of problem with hoarding
1446 right now?

1447 Ms. {Jensen.} We do receive reports from pharmacists,
1448 mostly faxes and emails that they have received from grey
1449 marketers, from companies advertising these drugs at very
1450 high prices, and we do forward all of those reports to the
1451 Department of Justice.

1452 Ms. {DeGette.} And have you seen a large incidence of
1453 that?

1454 Ms. {Jensen.} We have--

1455 Ms. {DeGette.} Okay.

1456 Ms. {Jensen.} --over the past--

1457 Ms. {DeGette.} And do you think there are some ways we
1458 can write legislation so we don't experience a lot of
1459 hoarding if we make a mandatory reporting program?

1460 Ms. {Jensen.} So with notifications of mandatory
1461 reporting, we would not post a shortage until we know that
1462 shortage is going to occur, absolutely going to occur, or has
1463 already occurred. We would want to hold off because our goal
1464 is to try to prevent all shortages. If we can do that
1465 through working with the manufacturers, through working with
1466 alternate manufacturers to ramp up, as well as sometimes
1467 having to temporarily import product, that is what we are
1468 doing.

1469 Ms. {DeGette.} So your process would be if you got
1470 notification of a shortage to contact the manufacturers to
1471 see if it could be resolved internally--

1472 Ms. {Jensen.} Absolutely.

1473 Ms. {DeGette.} It is a little bit of a waiting game,
1474 isn't it, because if you don't notify the hospitals and the
1475 physicians quickly enough, then having any kind of a

1476 notification system is pointless, right?

1477 Ms. {Jensen.} Right.

1478 Ms. {DeGette.} So you are going to have to figure out
1479 how to do that.

1480 Ms. {Jensen.} We need a good way to get information out
1481 when we know there is going to be a shortage, get it out as
1482 quickly as possible so that hospitals can make decisions.

1483 Ms. {DeGette.} And what would happen if you did have a
1484 system where you could get that notification out? What would
1485 the hospitals then do with that information?

1486 Ms. {Jensen.} Well, they could plan accordingly.
1487 Sometimes treatments can be reserved for certain types of
1488 patients where there is an alternative for other patients.
1489 They can use those alternatives. Sometimes it helps
1490 hospitals make those decisions.

1491 Ms. {DeGette.} Okay. Dr. Woodcock, in your written
1492 testimony, you had said that the FDA sent a letter to the
1493 pharmaceutical manufacturers reminding them of their current
1494 legal obligations to report certain discontinuances to the
1495 Agency and urging them to voluntarily notify the FDA of all
1496 potential disruptions of the prescription drug supply to the
1497 U.S. market even when disclosure is not currently required by
1498 law. After you did that, you said that there has been a
1499 significant increase in the number of potential shortages

1500 reported to the FDA. So my question is, is it your sense
1501 that manufacturers were not complying with current law before
1502 they got that letter?

1503 Dr. {Woodcock.} Our sense is I think that manufacturers
1504 were complying with current law, but the current law only has
1505 a limited universe of things that have to be reported. And
1506 we asked for voluntary reporting of a much wider universe.

1507 Ms. {DeGette.} So as I understand it, the Agency cannot
1508 expand the reporting, cannot require more reporting without
1509 authorization from Congress, is that right?

1510 Dr. {Woodcock.} Not more mandatory reporting.

1511 Ms. {DeGette.} Without authorization from Congress,
1512 right? Okay. Thank you very much.

1513 Thank you, Mr. Chairman. I yield back.

1514 Mr. {Pitts.} The chair thanks the gentlelady. The
1515 chair recognizes the gentleman from Illinois, Mr. Shimkus,
1516 for 5 minutes for questions.

1517 Mr. {Shimkus.} Yeah, I am sorry, Dr. Woodcock. I know
1518 you have been here for a while. I had to go speak on Yucca
1519 Mountain, so I had my different jobs I have to do.

1520 So I just really wanted to focus on Generic User Fee Act
1521 issues and the proposal to develop better science for new
1522 bioequivalent methods for locally acting drugs. So how do we
1523 know what the promises are? So what types of metrics do you

1524 think there will be for Congress and the American people to
1525 judge whether we are getting our best return on investment
1526 with this?

1527 Dr. {Woodcock.} Well, similar with the user fee
1528 program, you know, there are interim goals throughout this
1529 Generic Drug User Fee Program that have been devised, and we
1530 will report on those goals and you will know exactly what our
1531 performance is against the goals. So there are many metrics
1532 that are put into place for performance of the program. We
1533 intend to meet those metrics, but right from the beginning,
1534 we will have to do things in the first year, and we can
1535 report on those actions.

1536 Mr. {Shimkus.} Yeah, and I appreciate that. I think
1537 Congress would like to see I think the folks who are working
1538 with you collaboratively would like to make sure that is
1539 transparent, there is predictability. A lot of our concern
1540 is the length of time without it. So I mean there is just
1541 hope that in paying for an expedited, clear, safe system,
1542 that we are going to get what is going to be paid for.

1543 Dr. {Woodcock.} Well, I hope you can feel some
1544 confidence because of our track record of the Prescription
1545 Drug User Fee Program where we have exceeded or met our goals
1546 up through almost the entire program.

1547 Mr. {Shimkus.} And I mentioned this numerous times in

1548 various hearings and I applaud it; I think focusing on the
1549 risk-based approach in the recent reports is right on. I
1550 mean if good actors are good actors and they have been good
1551 actors, they continue to be good actors, then there may be a
1552 time to revisit but annually may--we can make that
1553 determination. Obviously, when we are not inspecting, we
1554 would much rather have inspections of facilities we haven't
1555 even visited versus continually re-inspecting the good
1556 actors. So I find that a positive and I look forward to
1557 that.

1558 Utilizing prediction information from companies, foreign
1559 governments, and third parties could help us, obviously, to
1560 do this risk-based system. Can you describe the importance
1561 of the risk-based approach in ensuring the safety of imported
1562 drugs?

1563 Dr. {Woodcock.} Certainly. What we know about
1564 facilities is that if they are having problems, they may not
1565 correct them and the problems may get worse. So we go into a
1566 plant initially, we discover problems, if we don't go and
1567 return and verify that they are on an improvement trajectory,
1568 we may be seeing a situation where the production methods may
1569 be deteriorating. And so it is very important for us to go
1570 sort of where the money is, where the risk is and to be able
1571 to follow up on those facilities that are subpar, all right,

1572 and also to follow up more closely on those facilities that
1573 are producing riskier products such as the sterile
1574 injectables to make sure they are continuing to meet their
1575 obligations.

1576 Mr. {Shimkus.} And I appreciate that. And my last
1577 question is how can we leverage the third party actors or
1578 foreign governments? Help me talk through how do we get a
1579 little more buy-in or can get them to understand the
1580 importance of what we are trying to do.

1581 Dr. {Woodcock.} The foreign governments?

1582 Mr. {Shimkus.} Right, or other third party entities
1583 that may be involved.

1584 Dr. {Woodcock.} Other third parties, um-hum. As Mr.
1585 Beckerman said, we would like to have better ability to
1586 exchange information with foreign countries who have
1587 inspectorates. Many countries now are developing
1588 pharmaceutical inspectorates. They go to the factories; they
1589 have information. We do get heads up from them when there
1590 are problems, but we would like to have a much better global
1591 safety net so that all the regulators are working together
1592 and any other inspectorates that might be out there, third
1593 party inspectorates. So we share information and we make
1594 sure around the world that that safety net exists.

1595 Mr. {Shimkus.} Yeah, historically, I think we have all

1596 believed that FDA has been really the gold standard. I think
1597 the EU is because of their timeliness is getting into a
1598 competitive arena with us. We would like to continue the
1599 gold standard and maybe push those values but also a timely
1600 process so we don't lose that leverage.

1601 Thank you, Mr. Chairman, and I yield back.

1602 Thank you, Dr. Woodcock.

1603 Mr. {Pitts.} The chair thanks the gentleman. And that
1604 concludes panel one. Do we have another one? I am sorry. I
1605 didn't see you.

1606 The chair recognizes the gentleman from New York for 5
1607 minutes for questions.

1608 Mr. {Engel.} Thank you, Mr. Chairman. It is hard to
1609 see on the side, I know. Thank you.

1610 Dr. Woodcock, several of the witnesses in the second
1611 panel in their written testimony mention that the user fees
1612 included in GDUFA and BsUFA are meant to be in addition to a
1613 solid base of annually appropriated funds for the FDA. So I
1614 was pleased to see that for the fiscal year 2012 the FDA
1615 received a 50 million increase in funding over fiscal year
1616 2011 funding levels. But this was a hard-fought victory
1617 given that the first proposal was a 285 million cut in FDA
1618 funding. So could you elaborate on why it is so important
1619 that the FDA be adequately funded and how cuts to the FDA

1620 could impact the Center for Drug Evaluation and researchers'
1621 ability to meet the review time frames and inspection
1622 standards outlined in the GDUFA and BsUFA user fee
1623 agreements?

1624 Dr. {Woodcock.} Yes. All of the user fee programs
1625 assume that there is an appropriated base funding that we
1626 build on and that is augmented by the user fees. As I think
1627 the discussion on drug shortage has illustrated, FDA has many
1628 other jobs, and the drug program has many other jobs other
1629 than simply review. And for the health and safety of our
1630 population, we need to do all those activities well and we do
1631 need resources to do them. So the Generic Drug User Fee
1632 Program that is being proposed is built upon a platform of
1633 appropriated dollars and is additive. The Prescription Drug
1634 User Fee Program has always had a trigger and is of
1635 appropriated funds and the fees are additive that allow us to
1636 meet the goals and accomplish all that ambitious program.
1637 And similarly, for biosimilars it will be built on an
1638 appropriated base.

1639 Mr. {Engel.} Well, thank you. You mentioned the drug
1640 shortages. The largest employer in my district is Montefiore
1641 Medical Center in Bronx, New York. They are, as you know, a
1642 premier academic medical center with centers of excellence in
1643 cancer care, cardiovascular services, pediatrics,

1644 transplantation, and neurosciences, and my constituents have
1645 really come to rely on them. All three of my children were
1646 born there and they are really, really a treasure. When I
1647 asked them about the impact of drug shortages on Montefiore,
1648 they estimated to me that members of their staff, including
1649 pharmacists and physicians, spent more than 110 hours a week
1650 addressing issues directly related to drug shortages. So
1651 clearly this issue, dealing with this, requires a significant
1652 amount of people power and labor costs in order to track down
1653 medications. Can you describe the steps the FDA is taking to
1654 assist our hospitals like Montefiore in staying on top of
1655 current and anticipated drug shortages?

1656 Dr. {Woodcock.} Certainly. We sent a letter out to all
1657 manufacturers reminding them of their statutory obligations
1658 and asking them to voluntarily notify us in advance of
1659 potential shortages so that we can do what we do to mitigate
1660 them. We work with manufacturers to mitigate. We have even
1661 allowed drugs to be shipped with filters, with instructions
1662 to filter the drug because it had particulates if we were
1663 sure that the filter wouldn't take out the agent as well and
1664 we had verified that. So we do those risk mitigation
1665 efforts. We even allow importation of unapproved drugs from
1666 other countries temporarily to fill the gap for our patients.
1667 And we have a web page and we work with the associations and

1668 with the physician community to try and figure out how to
1669 mitigate these shortages. But at the end of the day, if
1670 there is no drug there that can be had, we are all in
1671 trouble.

1672 Mr. {Engel.} I agree. Let me ask you this final
1673 question which also ties in with the drug shortage problem.
1674 I have heard from healthcare providers and patients that
1675 there is an added layer of difficulty in addressing shortages
1676 in this area because they say that the DEA limits the amount
1677 of active pharmaceutical ingredient a company can purchase
1678 and manufacture. I have also heard from parents who are
1679 frustrated when they have struggled to obtain generic forms
1680 of their children's ADHD medications in recent months. So I
1681 do recognize that the DEA has to do its part to ensure that
1682 controlled substances are not being abused, but how can DEA
1683 and FDA work together to ensure that the shortages of
1684 controlled substances such as the ADHD medications or pain
1685 medications like fentanyl are quickly addressed and access to
1686 these to patients with a clear need?

1687 Dr. {Woodcock.} Yes, we worked very closely with the
1688 DEA, and my understanding is that the manufacturers have
1689 received their 2012 quotas for the ADHD drugs and we expect
1690 that situation to be ameliorated very rapidly. But we do
1691 work very closely with them. We provide information to them

1692 every year that is very relevant to them setting the quotas
1693 of these various drugs, how much we expect will be needed.
1694 So we have a very close relationship.

1695 Mr. {Engel.} Okay, thank you.

1696 Thank you, Mr. Chairman.

1697 Mr. {Pitts.} The chair thanks the gentleman.

1698 Okay, I think that concludes panel one. The chair would
1699 like to thank Dr. Woodcock and her panel for your excellent
1700 testimony.

1701 Dr. {Woodcock.} Thank you.

1702 Mr. {Pitts.} And excuse panel one and call panel two to
1703 the witness table. And while they are coming, without
1704 objection, the chair would like to enter into the record four
1705 documents: a statement by the American Academy of Pediatrics,
1706 one by the American Society of Health System Pharmacists,
1707 another by the National Community Pharmacists Association,
1708 and one by the Biotechnology Industry Organization. And it
1709 has been shared with minority. Without objection, they will
1710 be entered into the record.

1711 [The information follows:]

1712 ***** COMMITTEE INSERT *****

|
1713 Mr. {Pitts.} All right. The chair will call panel two
1714 to the table and would like to thank you all for agreeing to
1715 testify before the subcommittee today. And I would like to
1716 quickly introduce our panel. First, Ms. Heather Bresch is
1717 the CEO of Mylan, Inc; second, Mr. David Gaugh is the vice
1718 president of regulatory sciences at the Generic
1719 Pharmaceutical Association; and Dr. Bill Greene is the chief
1720 pharmaceutical officer at St. Jude Children's Research
1721 Hospital. Again, thank you all for coming. We have your
1722 prepared statements which will be entered in the record and
1723 we ask you to summarize your opening statement 5 minutes.

1724 Ms. Bresch, we will begin with you. You are recognized
1725 for 5 minutes to summarize your testimony.

|
1726 ^STATEMENTS OF HEATHER BRESCH, CHIEF EXECUTIVE OFFICER,
1727 MYLAN, INC.; DAVID GAUGH, VICE PRESIDENT, REGULATORY
1728 SCIENCES, GENERIC PHARMACEUTICAL ASSOCIATION; AND WILLIAM
1729 GREENE, PHARM.D, BCPS, FASHP, CHIEF PHARMACEUTICAL OFFICER,
1730 PHARMACEUTICAL SERVICES, MEMBER, PHARMACEUTICAL SCIENCES, ST.
1731 JUDE CHILDREN'S RESEARCH HOSPITAL

|
1732 ^STATEMENT OF HEATHER BRESCH

1733 } Ms. {Bresch.} Thank you and good morning, Chairman
1734 Pitts and Ranking Member Pallone and members of the
1735 subcommittee, and thank you for the opportunity to testify
1736 today.

1737 I am Heather Bresch, CEO of Mylan, Inc., the largest
1738 global generics company in the world headquartered in the
1739 United States. Mylan was founded 50 years ago in West
1740 Virginia, and for the first 45 years of our history, Mylan
1741 was a domestic company that served the U.S. market. In 2007,
1742 we transformed into a global company. Today, we provide
1743 products in more than 150 countries, have a global workforce
1744 of more than 18,000, including more than 5,000 employees in
1745 the United States. Our largest drug manufacturing facility
1746 is located in Morgantown, West Virginia, where we produce

1747 nearly 20 billion doses of medicine each year. We also have
1748 multiple facilities outside of the U.S. that produce drugs
1749 that are distributed in this country and which are inspected
1750 by the FDA. Today, 1 out of every 11 prescriptions dispensed
1751 in the United States is a Mylan product. In light of our
1752 success in the global market, Mylan is adding manufacturing
1753 jobs around the globe, and we would to not only maintain what
1754 we already have here in the United States, but we would also
1755 like to expand our U.S. presence.

1756 As we transform from a domestic to a global company, we
1757 were surprised to discover that FDA is still operating as a
1758 domestic agency and is not equipped with the resources or
1759 legal authority to regulate the now global drug industry that
1760 serves the United States. In fact, FDA is governed by a 1938
1761 law, which has been largely unchanged since its initial
1762 passage and does not give FDA the full authority it needs to
1763 oversee the global industry.

1764 Unfortunately, the 1938 law also creates an unlevel
1765 playing field for American manufacturers by requiring U.S.
1766 manufacturers to be inspected every 2 years while the law is
1767 silent on foreign drug manufacturers. As a result, two
1768 standards are created--one for the United States'
1769 manufacturers and one for foreign. U.S. manufacturers
1770 actually have a perverse incentive to move existing U.S. jobs

1771 abroad where they will face less regulatory scrutiny and also
1772 can avoid the second highest combined federal state corporate
1773 tax rate of 39 percent.

1774 As the Pew Health Group reported to this subcommittee
1775 last week, complying with quality systems and FDA regulations
1776 represents approximately 25 percent of a drug manufacturer's
1777 operating cost. This disparity in standards raises very real
1778 and profound questions about the integrity and quality of the
1779 drug supply in the U.S. Clearly, every consumer should have
1780 the peace of mind of knowing that every drug product
1781 dispensed in the U.S. is held to the same standard of quality
1782 regardless of whether the product originated in the United
1783 States or outside of its borders.

1784 Over the last several years, the number of foreign
1785 facilities supplying the U.S. has grown by 185 percent, while
1786 at the same time, FDA inspection rates have decreased by
1787 nearly 57 percent according to the FDA. FDA estimates that
1788 up to 40 percent of drugs now consumed by U.S. patients are
1789 manufactured abroad and 80 percent of the active ingredients
1790 used in drugs come from foreign countries.

1791 The growth in the number of foreign facilities coupled
1792 with a significant increase in generic drug application has
1793 caused FDA's workload to be far outpaced by its resources,
1794 and as a result, the time it takes to get a generic drug

1795 approved has nearly doubled with more than 2,700 generic
1796 applications awaiting approval from FDA today. Now more than
1797 ever Americans need more timely access to more affordable
1798 generic medicine which has saved patients and the government
1799 more than 930 billion in the last decade alone.

1800 With a 50-year history of working closely with Congress
1801 and the FDA, Mylan is pleased that the generic industry has
1802 stepped up first and addressed an industry-wide issue
1803 impacting brand and generics to help address FDA's challenge
1804 of carrying out its mission within a global industry,
1805 especially given the current scarcity of government
1806 resources.

1807 The landmark and novel user fee program is aimed at
1808 three critical components: safety, access, and transparency.
1809 Through GDUFA, FDA will receive approximately 1.5 billion in
1810 new funding over the next 5 years, and in return, FDA has
1811 agreed to more timely reviews of generic drug applications,
1812 increased transparency, and by any old good manufacturing
1813 practice surveillance inspections of all generic finish
1814 dosage form and active pharmaceutical ingredient
1815 manufacturers, foreign and domestic, on a risk-adjusted
1816 basis, among other benefits outlined in a negotiated goals
1817 letter.

1818 Strengthening the supply chain, a key aim of GDUFA

1819 through routine GMP inspections for all facilities, as well
1820 as transparency initiatives that require the identification
1821 and registration of facilities involved in the supply chain
1822 will also provide a more holistic solution to current drug
1823 shortages. Additionally, decreased review times will ensure
1824 more timely access to new generic products, including those
1825 that addressed an unmet medical need or those in short
1826 supply.

1827 While the generic industry and API industries will help
1828 provide the financial resources to globalize the FDA, it is
1829 imperative for Congress to update the 1938 law to ensure the
1830 integrity of the supply chain and a level playing field so
1831 companies like Mylan are not disadvantaged to grow American
1832 manufacturing jobs. A level playing field will also benefit
1833 foreign facilities as well as small and first-time entrants
1834 who are currently disadvantaged by delays in new product
1835 approvals because of a lack of a recent inspection.

1836 We urge Congress to adopt GDUFA as negotiated and move
1837 forward in updating the 1938 law. Only by taking these steps
1838 can we provide more timely access to more affordable
1839 generics, ensure competitiveness by leveling the playing
1840 field for American manufacturers, and equip FDA with the
1841 authority it needs to become a global agency to ensure the
1842 integrity of the global drug supply chain.

1843 Thank you. And I would be happy to address any
1844 questions of the committee.

1845 [The prepared statement of Ms. Bresch follows:]

1846 ***** INSERT 2 *****

|
1847 Mr. {Pitts.} Thank you. Mr. Gaugh, you are recognized
1848 for 5 minutes to summarize your opening statement.

|
1849 ^STATEMENT OF DAVID GAUGH

1850 } Mr. {Gaugh.} Thank you. Good morning, Chairman Pitts,
1851 Ranking Member Pallone, and members of the subcommittee.
1852 Thank you for inviting me to testify on these very timely and
1853 important issues. I am David Gaugh, Vice President for
1854 Regulatory Sciences at the Generic Pharmaceutical Association
1855 and a licensed pharmacist. GPhA represents the manufacturers
1856 and distributors of finished-dose generic pharmaceuticals,
1857 bulk pharmaceutical chemicals, and suppliers to the generic
1858 industry. Generic pharmaceuticals fill 78 percent of all
1859 prescriptions dispensed in the United States but consume just
1860 25 percent of the spending for prescription medicines.

1861 I would like to begin by commending the committee for
1862 your continued focus on these most important issues that you
1863 are examining today. Though I have just begun my time with
1864 GPhA, I have been working in and around the generic industry
1865 for more than 2 decades and have witnessed firsthand the
1866 industry's remarkable growth and the vital role it plays in
1867 the lives of Americans every day. This growth of the generic
1868 industry has also served to underscore the critical
1869 importance and the role of the Food and Drug Administration.
1870 As shown by these two historic user fee agreements and our

1871 continued efforts to address drug shortages, the level of
1872 cooperation between the industry and the FDA has never been
1873 greater. It is our hope this collaboration will continue and
1874 even extend throughout the interactions for future activities
1875 with the Agencies.

1876 However, the Agency remains underfunded and the
1877 responsibilities of ensuring safe and effective access for
1878 affordable medications is shared with the entire
1879 pharmaceutical industry, not just with the FDA. This is why
1880 the generic industry has stepped up to the plate, and I would
1881 be pleased to provide some examples.

1882 Currently, well more than 2,000 generic drug
1883 applications are awaiting approval for the FDA Office of
1884 Generic Drugs and average approval time for these
1885 applications is now stretched to 32 months. Unfortunately,
1886 the backlog keeps growing for these generic drugs, keeps off
1887 market competitors, and prevents the prices from continuing
1888 to go down further. The proposed Generic Drug User Fee, or
1889 GDUFA, that we are discussing today will provide the FDA with
1890 nearly \$1.5 billion over the next 5 years to help alleviate
1891 this backlog and expedite consumers to new generic drugs. It
1892 will also take the historic step of holding all players
1893 contributing to the U.S. generic drug system, both foreign
1894 and domestic, to the same inspection standards and enhance

1895 FDA's ability to identify and require the registration of
1896 active pharmaceutical ingredients and finish dosage from
1897 manufacturers involved in the production of the products
1898 being sold in the U.S.

1899 It is paramount that as we work and save the future of
1900 our country's generic industry, we also work with the FDA to
1901 bring them into the 21st Century and ensure that the Agency's
1902 authority to achieve its mission and the goals are kept up to
1903 date. This is exemplified by the user fee program we are
1904 discussing today, both GDUFA and the biosimilar fee
1905 structure.

1906 During the biosimilar fee negotiations, GPhA expressed
1907 its support for user fee funding to provide FDA with adequate
1908 resources to apply consistent regulatory standards to all
1909 biologics. Both industry and patients will benefit from this
1910 user fee program by gaining a higher degree of certainty in
1911 the timeliness of the applications, the review, and their
1912 approval. It is important to emphasize that the funding
1913 provided by these user fee programs is in addition to and not
1914 a substitute for congressional appropriations.

1915 And while the programs provide an excellent framework
1916 for the industry to help support the growing global needs of
1917 the FDA, they do not completely solve the problems. For
1918 example, some manufacturers are using the REMS program as a

1919 way to delay generic competition. For products that require
1920 a full REMS and distribution in accordance with restricted
1921 systems, REMS manufacturers are making it difficult for the
1922 generic manufacturers to acquire samples of products so that
1923 they can actually run the tests on the products to be able to
1924 produce the exact bioequivalent product in a generic form.
1925 GPhA also supports the adoption of a federal drug tracking
1926 system with uniformed standards across all States to prevent
1927 a patchwork by state law.

1928 Now, let me address the drug shortage crisis. The
1929 generic pharmaceutical industry has spearheaded the
1930 development of an unprecedented multi-stakeholder
1931 collaboration, which we believe will accelerate the recovery
1932 of certain critical drugs in short supply that are in patient
1933 need. This private sector solution, which we have labeled as
1934 the Accelerated Recovery Initiative, is designed to provide a
1935 more accurate, timely, and comprehensive view of the critical
1936 drugs and drug shortage, provide greater visibility to
1937 potential shortages of those critical drugs that are
1938 established for potential loss, and voluntary production
1939 adjustments to lessen and even eliminate certain current drug
1940 shortages. This initiative is predicated on voluntary
1941 communication between an independent third party and all key
1942 stakeholders involved in the approval, the manufacturing, and

1943 the distribution of drugs that are in shortage.

1944 In conclusion, Mr. Chairman, it is our hope that
1945 Congress will act on these historic user fee proposals as an
1946 expeditious process. Nothing is more important to our
1947 industry than ensuring patients have access to life saving
1948 generic medications they require, and with a joint effort
1949 among all involved, we believe we can continue to make
1950 significant steps towards accomplishing this goal.

1951 Thank you, and I look forward to your questions.

1952 [The prepared statement of Mr. Gaugh follows:]

1953 ***** INSERTS 3, 4 *****

|
1954 Mr. {Pitts.} The chair thanks the gentleman and now
1955 recognizes Dr. Greene for 5 minutes to summarize your opening
1956 statement.

|
1957 ^STATEMENT OF WILLIAM GREENE

1958 } Mr. {Greene.} Chairman Pitts and other members of the
1959 committee, I am grateful for the opportunity to address you
1960 today. As a representative of St. Jude's Children's Research
1961 Hospital and also a representative of colleagues at
1962 children's hospitals throughout the United States, as you
1963 know I am chief pharmaceutical officer at St. Jude and at St.
1964 Jude we are committed to developing research that leads to
1965 new cures for children with catastrophic diseases. We are
1966 also committed to providing unsurpassed clinical care for
1967 those patients. I am really grateful that you would offer me
1968 time to share some comments.

1969 My short testimony--if we can have some slides here--I
1970 would like to share three ways Congress can help alleviate
1971 drug shortages for the pediatric community. But first, I
1972 would like to begin by putting a face to my discussion, and
1973 it doesn't look like the face will be able to be displayed.

1974 I can tell the story of Lucy, who is a 5-year-old from
1975 Covington, Tennessee. Lucy and her family have given me
1976 permission to share her story as a way of illustrating the
1977 challenges that drug shortages pose for patient care and for
1978 the caregivers that are providing that care. She is being

1979 treated for medulla blastoma, which is a type of brain
1980 cancer. She has been doing well, and last spring she was
1981 being treated in her prescribed course of treatment and was
1982 being supported by intravenous nutritional support. She
1983 began to develop symptoms, rapid eye movements, blurred
1984 vision, other visual changes, some gait changes that caused
1985 her care team to suspect that her cancer was relapsing. So
1986 she was admitted to the hospital and worked up. Fortunately,
1987 during that time, she was treated with intravenous thiamin.
1988 She experienced a dramatic recovery and was able to continue
1989 with her treatment course.

1990 The interesting background on this issue is that the
1991 cause of the thiamin deficiency was very simple. We were
1992 simply unable to secure intravenous preparations of
1993 multivitamins to add to her intravenous nutritional support.
1994 That caused the thiamin deficiency, the thiamin deficiency
1995 caused the symptoms, the symptoms resulted in a hospital
1996 admission. This was a preventable admission and it should
1997 not have happened.

1998 You are aware that the number of drug shortages
1999 occurring in the United States has increased dramatically in
2000 recent years. While not all of these shortages have directly
2001 affected St. Jude, the number of shortages affecting us have
2002 increased dramatically. If I were able to show my second

2003 slide, I would be able to illustrate to you that we have
2004 experienced a 10-fold increase in the number of shortages
2005 requiring action at our organization since 2008. In the last
2006 2 months alone, January and December, I have had to issue
2007 communications to our clinical staff on 14 separate
2008 occasions. Now, once that requires my action, those are
2009 important drug shortages that impact patient care--14 times
2010 in the last 2 months.

2011 Our drug shortages threaten our Nation's healthcare
2012 system and especially children in three distinct ways.
2013 First, we know that we cannot always provide the best care
2014 for these patients. Second, we know that shortages do affect
2015 research that cause modifications for protocols, sometimes
2016 delays in research and terminations. We know that at least
2017 85 children's oncology group protocols that have been
2018 affected by shortages. And third, we know that all of these
2019 shortages definitely add real cost to the system. I know the
2020 subcommittee has previously heard testimony of this type.
2021 Much data has been shared. Many of the comments today have
2022 been very interesting and helpful. It is now time for
2023 immediate action.

2024 I have three points I would like to make about what
2025 Congress can do to help. First, I urge Congress immediately
2026 to pass legislation to give the Food and Drug Administration

2027 the tools that it needs to prevent and minimize the impact
2028 these shortages have on pediatric care and research. The FDA
2029 has been effective in minimizing the impact of shortages when
2030 appropriate communication is made to the Agency. Their
2031 efforts have avoided almost 200 shortages in 2011. Congress
2032 can strengthen their reporting system by enacting H.R. 2245,
2033 Senate Bill 296, to give the FDA more complete knowledge of
2034 permanent and temporary supply chain disruptions in advance
2035 and allowing the FDA to facilitate its communications with
2036 caregivers like me.

2037 Second, I urge Congress to give the FDA the resources
2038 and authority it needs to combat drug shortages in a
2039 proactive manner. While the FDA's efforts have been
2040 laudable, these efforts have been largely reactive. Once a
2041 shortage has evolved, we know patients are going to be
2042 affected. The Agency must have what it needs to develop
2043 proactive approaches to predict and prevent shortages and the
2044 FDA should have sophisticated systems in place facilitating
2045 forecasting, prediction, and enabling proactive work with
2046 suppliers and purchasers to prevent shortages from ever
2047 occurring. Further, other relevant agencies such as the DEA
2048 must work closely, collaboratively, with the FDA to combat
2049 these shortages.

2050 Third, Congress must ensure that in any solution it

2051 develops, pediatric protections are built in and pediatric
2052 experts are broadly engaged. Children require medications in
2053 special strengths, packaged in smaller dose sizes, dye-free
2054 and preservative-free when possible. Hospitalized children
2055 frequently require intravenous medications, and in many
2056 cases, few alternatives exist for them when a drug is in
2057 short supply. For these reasons, the expertise of pediatric
2058 practitioners who are familiar with the nuances and
2059 intricacies of the care of children must be included in
2060 developing solutions for shortages.

2061 Finally, I would like to conclude by recognizing that
2062 the underlying causes of drug shortages are complex.
2063 Solutions offered today will not solve the many reasons drug
2064 shortages exist and continue to increase in frequency.
2065 Before enacting legislation focused on addressing these
2066 underlying factors, I urge you to carefully and
2067 comprehensively study and understand these factors and the
2068 downstream impact of any proposed solutions with input from
2069 healthcare professionals and other stakeholders. We must
2070 return to a state that used to exist when I was a younger
2071 practitioner, a state when we had a consistent, reliable, and
2072 safe supply chain of needed pharmaceutical products. Nothing
2073 less is acceptable.

2074 Thank you for your dedication to this issue and for

2075 allowing me minutes to speak as a provider and caregiver
2076 representing children throughout this country who have been
2077 affected by these shortages. Thank you.

2078 [The prepared statement of Mr. Greene follows:]

2079 ***** INSERTS 5, 6 *****

|
2080 Mr. {Pitts.} The chair thanks the panel for your
2081 opening statements. We will now go to questions and I will
2082 recognize myself for 5 minutes for that purpose.

2083 Ms. Bresch, how will the Generic Drug User Fee Agreement
2084 bring predictability and efficiency to FDA's review of
2085 generic drugs?

2086 Ms. {Bresch.} Thank you. As I think you have heard
2087 this morning, especially through Dr. Woodcock's testimony,
2088 the need for the resources to truly globalize the FDA is of
2089 utmost importance. So as I mentioned, the fact that the
2090 generic industry stepped up to provide those resources, the
2091 fees are split primarily in two buckets, about 70 percent
2092 going towards the inspection and fees for facilities and
2093 about 30 percent for the applications. So we believe that
2094 with the goals and the metrics laid out in GDUFA that that
2095 parity, not just from a timing perspective but also the rigor
2096 at how inspections are performed because, you know, I can
2097 tell you as having facilities around the world inspected by
2098 many regulatory agencies, the FDA does have the gold standard
2099 and I think it is very important to raise the bar for the
2100 rest of the world, not let the United States' bar come down.

2101 Mr. {Pitts.} Will this predictability and efficiency
2102 bring down the cost of generic drugs and what are the metrics

2103 that are included in the goals letter to ensure that progress
2104 is made on the review of generic applications?

2105 Ms. {Bresch.} So as we have noted, that approval time
2106 today for generic drugs is about 31 months, almost double
2107 that in recent years. So the goals the metrics laid out
2108 bring that back down to about 10 months within 5 years. So
2109 it certainly keeps the competitive nature of our industry
2110 very much at the forefront while, as we level that playing
2111 field, making sure that it is not just competition at any
2112 cost. I think what is important to remember that the
2113 competition is important if everybody is held to the same
2114 standard. So the certainty comes with the reduction of
2115 approval time but making sure that we are having good
2116 competition, not just any competition.

2117 Mr. {Pitts.} Mr. Gaugh, why is the new Biosimilars User
2118 Fee Program important to the generic industry and to patients
2119 and what are the metrics included in the goals letter to
2120 ensure that progress is made in that regard?

2121 Mr. {Gaugh.} Well, it is extremely important to the
2122 American public to have access to the biosimilar pathway of
2123 products. As you heard Dr. Woodcock say today, today is the
2124 first day that they have announced that they are going to
2125 release the guidelines for the biosimilars. So
2126 unfortunately, until we see those guidelines, it is going to

2127 be hard for me to answer the rest of the question. But it
2128 extremely important to have that affordable access to the
2129 American public. And you will find that many of the
2130 companies that GPhA represents already have these products
2131 produced and approved in foreign countries, both Europe and
2132 other markets.

2133 Mr. {Pitts.} Thank you.

2134 Dr. Greene, talk a little bit about how drug shortages
2135 affect St. Jude and how many drugs used at your hospitals
2136 regularly go into shortage.

2137 Mr. {Greene.} Thank you for that question. We deal
2138 with shortages on a continual basis. I believe Mr. Engel
2139 referred to Montefiore and the number of hours that they have
2140 dedicated to managing drug shortages. I believe you have
2141 mentioned 100 or 120 hours per week of total personnel time.
2142 That is not a gross exaggeration in any form or fashion. As
2143 I mentioned, I am continually engaged in interacting with my
2144 clinical staff on what are the shortages, what are the
2145 alternatives, when we have fentanyl, when we don't have
2146 fentanyl, when we have Zofran, when we don't have Zofran,
2147 when we have multivitamins, when we have mannitol, what are
2148 we doing when it goes away. It has a dramatic impact and it
2149 diverts significant resources away from actually taking care
2150 of the patients because we are focusing on one of the most

2151 basic elements of care and that is simply do we have the
2152 product available for us? So it is a very dramatic impact on
2153 us on a day-in, day-out basis. Some days are better than
2154 others but some days are simply very traumatic in trying to
2155 provide that care.

2156 Mr. {Pitts.} Can you walk us through, Dr. Greene, what
2157 happens from your perspective when there is a drug shortage?
2158 Who notifies you? How much warning do you get? What do you
2159 need to do to notify people in your organization? Is there
2160 any way at present to anticipate a shortage and what
2161 preparations do you need to put in place at the hospital
2162 level?

2163 Mr. {Greene.} You know, I made reference in my
2164 testimony the need to support the proposed legislation that
2165 effectively builds the tools to allow for early warning types
2166 of systems. Historically, we are not aware of a drug
2167 shortage evolving until we simply place an order, we check
2168 our inventory when it comes in, and we realize after 1 day, 2
2169 days, or 3 days, we keep getting shorted on the order. We
2170 don't know about it. Nobody tells us the shortage is there.
2171 So effectively, you place an order, you get the drug or you
2172 don't, and of course, the shortage is recognized when we
2173 don't get it the day after we order it. We place another
2174 order, we again shorted in it, and then finally you begin to

2175 realize there is something going on here.

2176 Now, fortunately, at the University of Utah Drug
2177 Information Center and American Society of Health System
2178 Pharmacists now have a very useful tool that allows
2179 organizations to become aware of the experience of other
2180 organizations healthcare systems that have experienced
2181 shortages so that, for example, I might report to that system
2182 that we are having trouble getting methotrexate and that
2183 might be the first notification that we are beginning to see
2184 problems with methotrexate in the country. And that way
2185 other organizations become aware of that. So there is no
2186 warning in too many cases and we simply have to be reactive
2187 in dealing with those problems.

2188 Mr. {Pitts.} Okay. The chair thanks the gentleman and
2189 now recognizes the ranking member for 5 minutes for
2190 questions. Mr. Pallone?

2191 Mr. {Pallone.} Thank you, Mr. Chairman.

2192 I wanted to ask a question, Ms. Bresch first, if I
2193 could. In your testimony, you emphasized that the imbalance
2194 of inspection requirements between U.S. and foreign
2195 manufacturing facilities creates an uneven playing field for
2196 pharmaceutical plants in the U.S., and certainly one way to
2197 help level the playing field, which was mentioned by our
2198 previous panel, is to apply a risk-based oversight system to

2199 all manufacturing facilities, both foreign and domestic.
2200 However, my question is to ensure real parity for all
2201 manufacturing locations, do you think that a minimum
2202 inspection frequency is also necessary and should that be
2203 defined in the statute that we would pass.

2204 Ms. {Bresch.} I believe that risk-based is appropriate
2205 but I do believe that defining how that risk-based works is
2206 incredibly important. I mean if I give the example--I talk
2207 about our facility in Morgantown, West Virginia. There are
2208 two full-time employees by the FDA who live in Morgantown,
2209 West Virginia, for just our facility. So if the risk-based
2210 is not defined properly, our concern is that it will be easy
2211 to go to where FDA has been going and that compliance-based
2212 will be extremely important to define that formula. So I
2213 believe that the legislation needs to have a very well
2214 defined formula and that there should be some minimum that a
2215 facility would need to have been inspected by.

2216 Mr. {Pallone.} Okay. Thank you.

2217 Let me ask Mr. Gaugh, I am interested in this
2218 Accelerated Recovery Initiative, or ARI--I mentioned it
2219 previously also, I think before the last panel--that you
2220 described in your testimony. It sounds like a promising
2221 effort that would help industry address or prevent shortages,
2222 and I am interested in hearing exactly how it would interface

2223 with the FDA. Could you explain what the role of the FDA
2224 would be in that initiative and particularly I would like to
2225 learn what the third party would be able to do that the FDA
2226 does not do and whether you see this initiative as
2227 potentially complementary to legislation that would mandate
2228 FDA notification? Or is it your hope that it would be
2229 instead of legislation?

2230 Mr. {Gaugh.} Thank you. From the standpoint of pulling
2231 this together, as I said earlier in my verbal testimony but
2232 also in the written testimony, this will be a multi-
2233 stakeholder event. And there are many questions that were
2234 asked of Dr. Woodcock that would be addressed by the ARI.
2235 For example, as we were talking about the grey market and I
2236 can't remember--I think it was Mr. Cassidy that asked about
2237 how we know how much product different organizations, a
2238 hospital can get when they order or how much is available to
2239 them. That would mean that in this ARI, the key stakeholders
2240 would be the manufacturers, the wholesalers and distributors,
2241 purchasing organizations, the FDA most importantly, and then
2242 the third party, as you mentioned, which would be an
2243 independent third party.

2244 The issues that we have addressed in the small group
2245 that is pulling the ARI together is that this is a very
2246 competitive marketplace, of course, and it would be fraught

2247 with some FTC potential issues if not handled in an
2248 appropriate fashion. So the appropriate fashion that we have
2249 come up with to this point is an independent third party that
2250 will be a blinding party if you will so they are the only
2251 party that sees all information coming from all the
2252 competitive companies.

2253 To answer your question about why the FDA couldn't
2254 perform this, there are multiple reasons. One, it isn't
2255 currently in their responsibility of duties as you see the
2256 responsibilities. Number two, Dr. Woodcock talked about the
2257 limited resources they currently have, which is very true.
2258 The drug shortage was only four or five people up until a few
2259 months ago. It has now been doubled, I believe, to seven or
2260 eight people. So that would be a limiting factor. The other
2261 piece is the third party is going to have to be somebody who
2262 really understands production planning extremely well and can
2263 take production planning reports from the multiple different
2264 companies to make determination and decisions on who could or
2265 who could not produce products to help alleviate this drug
2266 shortage. That is not something that currently exists within
2267 the--

2268 Mr. {Pallone.} Just because I am running out of time,
2269 it sounds to me that in terms of the question I asked that
2270 you are saying that the initiative, the ARI is complementary

2271 to legislation that we would initiate. In other words, not
2272 that it would be instead of, but because of the need to work
2273 together and certain things that can't be done, this would
2274 have to be something that we would have to work out in terms
2275 of the legislation. Is that accurate?

2276 Mr. {Gaugh.} That is correct. That is accurate.

2277 Mr. {Pallone.} Okay. All right. Thanks so much.

2278 Mr. {Gaugh.} You are welcome.

2279 Mr. {Pitts.} The chair thanks the gentleman, recognizes
2280 the vice chairman of the committee, Dr. Burgess, for 5
2281 minutes for questions.

2282 Dr. {Burgess.} Thank you, Mr. Chairman.

2283 And Mr. Gaugh, if I could stay with you for a moment.

2284 And let me just ask you and I know this is a wide-ranging
2285 question so I am going to ask you to be as brief as you can,
2286 but in your opinion, what are the reasons that a drug goes
2287 into shortage?

2288 Mr. {Gaugh.} I am sorry. Can you repeat--

2289 Dr. {Burgess.} What are the reasons that a drug goes
2290 into shortage?

2291 Mr. {Gaugh.} Dr. Woodcock described the overall
2292 situation with drug shortage, so it really is a demand versus
2293 supply situation right now. So the demand continues to
2294 increase in the United States with the graying of America, et

2295 cetera. So demand continues to go up. The currently
2296 available supply is going down, so as she talked about in the
2297 injectable industry in particular, there is a defined
2298 quantity of production capability in the U.S. Currently,
2299 most of the companies that are under the production
2300 capability piece are in remediation efforts due to their
2301 compliance or their lack of compliance situation. So the
2302 available capacity today is less than it was about a year and
2303 a half ago.

2304 Dr. {Burgess.} And here is the thing. The
2305 manufacturing processes in many of these drugs are not new.
2306 They have been around for a long time. The FDA has been
2307 doing inspections for years. The companies have had to get
2308 the raw materials for years. They have been making
2309 injectables for years. So why the acceleration in the last 5
2310 years?

2311 Mr. {Gaugh.} If we are still just talking about sterile
2312 generic injectables, the basic five companies that have the
2313 majority of the production capability, these are aged
2314 facilities. So as the manufacturing lines are becoming
2315 older, they need to be replaced, refurbished, upgraded.
2316 Specifically, also, the specifications, the criteria that
2317 need to be met are changing year after year. Those have to
2318 be implemented. Sterile injectable production is a very

2319 complex process. It takes time to upgrade those systems, and
2320 when you do upgrade them, you have to take them down for a
2321 period of time.

2322 Dr. {Burgess.} Right. But don't you find it odd that
2323 it really has been a snowball effect? I can remember in the
2324 2004 presidential election, in one of the debates that fall,
2325 flu vaccine had been contaminated with serratia. We got it
2326 from an overseas source and President Bush was just pummeled
2327 for this flu vaccine shortage. And now the shortages are
2328 happening all the time. That level of scrutiny doesn't seem
2329 to be being applied to the fact that more and more drugs are
2330 drifting off into a shortage situation. Why is that?

2331 Mr. {Gaugh.} Because I would say the level of scrutiny
2332 that is upon those companies by the FDA has increased over
2333 the last 3 to 4 years, and that level of scrutiny is what--

2334 Dr. {Burgess.} But the shortages are going to be
2335 manifested by the clinicians not having the compound to
2336 deliver to their patients, not the Food and Drug
2337 Administration saying aha, we have identified a shortage in
2338 your line. It is because at the end of the line, the doctor
2339 and the patient are saying I can't get this stuff. So let me
2340 ask you this. There are some new branded drugs that are
2341 complex molecules, difficult to manufacture, and there are 10
2342 to 15 generic oncology drugs that have been around forever

2343 and are quite basic in their formulation, and those are the
2344 ones that are in shortage, not the complex new molecules. So
2345 why is it that the complex branded drugs are readily
2346 available and the basic generic drugs are in short supply?

2347 Mr. {Gaugh.} Typically, the complex brand molecules you
2348 are talking about are manufactured in one facility, one line
2349 for that particular product. Or do you look at the generic
2350 injectables. Those companies produce anywhere from 50 to 120
2351 different molecules on their different lines. So it is a
2352 supply-and-demand issue again within that facility of the
2353 number of products that are made.

2354 Dr. {Burgess.} I brought this up in my opening
2355 statement. Do you think there is the possibility that we
2356 have perhaps made things a little too tight, made the margins
2357 a little too tight where it is difficult for companies to
2358 justify continued manufacture if they have a difficulty in
2359 their manufacturing process or for other companies to step in
2360 and fill the gap if a company has to withdraw from the
2361 manufacturing?

2362 Mr. {Gaugh.} In the market--

2363 Dr. {Burgess.} We just don't have the profit margins
2364 built in under current constraints?

2365 Mr. {Gaugh.} Profit margin could be one of the
2366 causative effects, but it is not one of the major causative

2367 effects, no.

2368 Dr. {Burgess.} Okay.

2369 Mr. {Gaugh.} It is still a demanding market in the U.S.
2370 and you can change the price as needed.

2371 Dr. {Burgess.} Very well. Dr. Greene, let me just ask
2372 you a question. You heard Dr. Cassidy on our side, you heard
2373 Lois Capps on the other side of the dais reference what they
2374 suspect was a problem in the grey market where some hospitals
2375 might be buying up a compound that is going into shortage and
2376 then reselling it at a much higher markup. I mean Dr.
2377 Cassidy has some specific questions. You deal in hospital
2378 purchasing all the time. Was he on the mark there or was
2379 that off?

2380 Mr. {Greene.} Someone certainly is getting product
2381 somewhere and, you know, maybe it is an entrepreneurial way,
2382 but they are taking advantage of shortages to make dramatic
2383 markups. Now, how they get the product, I don't know. I
2384 would be very, very surprised if any hospital is actually
2385 purchasing it for the purpose of diverting it to the grey
2386 market. We know that it happens; we just don't know where
2387 these individuals get their drug. And that is one of the
2388 reasons why St. Jude, we do not purchase off of a grey
2389 market.

2390 Dr. {Burgess.} Well, where would be a more likely place

2391 to look, then, if it is not the hospital purchasing?

2392 Mr. {Greene.} I wish I could explain that. I don't
2393 know. I know that there are thefts. There are reports of
2394 tractor-trailer loads of drugs that have been simply stolen
2395 and you don't ever know where those go and how they get into
2396 the marketplace and so I simply do not know where those drugs
2397 come from.

2398 Dr. {Burgess.} You agree that it is a problem?

2399 Mr. {Greene.} I don't know that it contributes
2400 dramatically to shortages. I think it is a problem in the
2401 context that it provides potentially very expensive and
2402 potentially harmful products for use in patients.

2403 Dr. {Burgess.} All right. Thank you for your time.

2404 I yield back, Mr. Chairman.

2405 Mr. {Pitts.} The chair thanks the gentleman and yields
2406 to the ranking member emeritus, Mr. Dingell, for 5 minutes
2407 for questions.

2408 Mr. {Dingell.} Mr. Chairman, I thank you.

2409 These questions go to Ms. Bresch. First I want to
2410 welcome you to the committee. Thank you. And second, I want
2411 to thank you for your leadership in this matter and tell you
2412 how much it has meant to me. These questions will be all yes
2413 or no. Do you agree that both FDA and the industry have a
2414 responsibility to ensure the security of our drug supply

2415 chain? Yes or no?

2416 Ms. {Bresch.} Yes.

2417 Mr. {Dingell.} Do you agree that the knowledge of your
2418 suppliers is important? Yes or no?

2419 Ms. {Bresch.} Yes.

2420 Mr. {Dingell.} Does Mylan have systems in place to know
2421 their suppliers and monitor manufacturing quality? Yes or
2422 no?

2423 Ms. {Bresch.} Yes.

2424 Mr. {Dingell.} It would be nice if you had more
2425 assistance in this, however, from FDA, would it not?

2426 Ms. {Bresch.} Yes.

2427 Mr. {Dingell.} Does Mylan have systems in place to
2428 demonstrate quality control? Yes or no?

2429 Ms. {Bresch.} Yes.

2430 Mr. {Dingell.} Should all companies making drugs for
2431 the United States know their suppliers and have quality
2432 systems in place?

2433 Ms. {Bresch.} Yes.

2434 Mr. {Dingell.} Should all companies making drugs for
2435 the U.S. be able to demonstrate quality control? Yes or no?

2436 Ms. {Bresch.} Yes.

2437 Mr. {Dingell.} Should companies be using risk analysis
2438 to target safety risks? Yes or no?

2439 Ms. {Bresch.} Yes.

2440 Mr. {Dingell.} Do you need to have the same kind of
2441 attention given to the supplies and the commodities and the
2442 other things that go into the pharmaceuticals that you sell
2443 as finished products?

2444 Ms. {Bresch.} Yes.

2445 Mr. {Dingell.} Do you agree that strong quality
2446 management systems and risk analysis will help companies to
2447 ensure the safety and quality of the finished drug product?

2448 Ms. {Bresch.} Yes.

2449 Mr. {Dingell.} I want to turn now to inspections. The
2450 brand industry has noted that its user fees go to pay for a
2451 preapproval inspection which could include an inspection of a
2452 foreign facility. Is preapproval inspection the same as a
2453 GMP inspection? Yes or no?

2454 Ms. {Bresch.} No.

2455 Mr. {Dingell.} Please explain the difference.

2456 Ms. {Bresch.} The way PDUFA was written and is
2457 implemented is really focused on the speed for an individual
2458 product. So a preapproval inspection is on a certain product
2459 which could be made on one line in a facility, and once that
2460 product is approved, it would never require the FDA to come
2461 back and inspect that line. GMP inspection covers the entire
2462 facility and ensures that that facility is complying to good

2463 manufacturing practices.

2464 Mr. {Dingell.} And you do desperate need Food and Drug
2465 to come back for that purpose to ensure that good
2466 manufacturing processes are being carried out at the plant
2467 being inspected. Is that right?

2468 Ms. {Bresch.} Absolutely. I think as we have heard a
2469 lot today, the vigilance that is required is on an ongoing
2470 basis. Just because you meet GMP inspection or are GMP
2471 compliant, that does not mean you are GMP compliant for the
2472 rest of that facility's life. And that is why earlier when
2473 asked about a risk-based approach to inspections and that we
2474 still believe that there would be a minimum number of years
2475 that the FDA would need to be back in that facility because
2476 it requires ongoing constant vigilance.

2477 Mr. {Dingell.} Now, you stated in your testimony that
2478 the federal Food and Drug and Cosmetic Act should be updated
2479 to require parity of inspections for domestic and foreign
2480 facilities. Why does Congress need to change the statutory
2481 language when FDA has already agreed to do on a voluntary
2482 basis in the Generic Drug User Fee Act?

2483 Ms. {Bresch.} Well, and I want to thank you for your
2484 leadership in this area for many years. I think to have an
2485 agency as important as the FDA to be governed by a 1938 law
2486 that was written from a very domestic standpoint and yet we

2487 are needing and demanding the FDA to govern a global
2488 industry. So if we are not going to have the global industry
2489 return to a domestic one, we have no choice but to have the
2490 1938 law be representative of the world that the FDA needs to
2491 operate in today. I think we heard Dr. Woodcock speak about
2492 the fact that there is just a different standard. For
2493 products manufactured in the United States, it is assumed to
2494 be adulterated unless proven that it has been made to GMP,
2495 yet if we are importing drugs, the standard that we hold
2496 those imports to are we have to show and prove that they are
2497 not up to GMP or we have to let them in. So I believe that
2498 that 1938 law desperately needs--

2499 Mr. {Dingell.} To be changed.

2500 Ms. {Bresch.} --to be updated so that the FDA has all
2501 the ability to make all the decisions and necessary demands
2502 to ensure the safety in the supply chain integrity on a
2503 global basis.

2504 Mr. {Dingell.} Now, it is also grossly unfair to
2505 surround American manufacturers with all these requirements
2506 while literally FDA is able to surround foreign manufacturers
2507 with virtually none, isn't that right?

2508 Ms. {Bresch.} Absolutely. Again, we talk about the
2509 competitive nature of this industry, so we are forced to
2510 compete really at any cost. So we are competing every day

2511 from competition and companies around the globe that perhaps
2512 don't hold their facility to the same standard as we do. We
2513 have facilities all over the world, as I mentioned, that make
2514 product for the United States and we hold all of our
2515 companies to the same GMP whether that facility is in the
2516 United States or outside of the United States. So the need
2517 for the competitiveness as a U.S. manufacturer is very
2518 unlevel at the moment, and unfortunately, as a manufacturer
2519 who employs many American jobs, like I said, we would like to
2520 not only maintain those but to increase them. And right now
2521 we are disincentivized to do so.

2522 Mr. {Dingell.} Mr. Chairman, I have used all my time
2523 but could I have one more question?

2524 Mr. {Pitts.} You may proceed.

2525 Mr. {Dingell.} Ma'am, the Generic Drug User Fee Act
2526 Agreement is unique in that it recognizes that FDA needs new
2527 resources and new authorities to properly oversee what is now
2528 a globalized industry as you have been pointing out to us. I
2529 happen to believe that the Food, Drug, and Cosmetic Act
2530 should and needs to be updated to reflect the global nature
2531 of our drug supply, again as you were pointing out, and to
2532 adequately equip FDA with the authority to properly ensure
2533 the safety of our drug supply, and that would include the
2534 commodities that go in an unfinished state. This committee

2535 has worked in a bipartisan manner to secure the safety of
2536 consumer products in our food supply, and I hope that we can
2537 do so for pharmaceuticals.

2538 I want to commend you for what it is you have done today
2539 and for your guidance and counsel in these matters. It has
2540 been most helpful and you go with my thanks and I think the
2541 thanks of the committee.

2542 Mr. Chairman, thank you for your courtesy.

2543 Mr. {Pitts.} The chair thanks the gentleman and
2544 recognizes the gentleman from Illinois, Mr. Shimkus, for 5
2545 minutes for questions.

2546 Mr. {Shimkus.} Thank you, Mr. Chairman. Again, I do
2547 appreciate the panel and your time today.

2548 Ms. Bresch, you are from West Virginia, is that correct?
2549 I mean the facility is in West Virginia, is that what you
2550 said?

2551 Ms. {Bresch.} That is where our largest facility is.
2552 We have facilities all over the United States.

2553 Mr. {Shimkus.} Okay. Do you know how many drug
2554 manufacturing facilities are in the State of West Virginia?

2555 Ms. {Bresch.} I don't know of any other.

2556 Mr. {Shimkus.} At the West Virginia facility, there are
2557 two FDA inspectors 24/7?

2558 Ms. {Bresch.} They live in Morgantown, yes.

2559 Mr. {Shimkus.} And they are dedicated solely to your
2560 facility?

2561 Ms. {Bresch.} I can't speak to what they are dedicated
2562 to but I can tell you that they live in Morgantown, West
2563 Virginia, and like I said, we are the only pharmaceutical
2564 company--

2565 Mr. {Shimkus.} I mean do they come in every day to your
2566 facility?

2567 Ms. {Bresch.} They are not necessarily in our facility
2568 every day so that is why I am saying I am sure the FDA can
2569 utilize them in other manners. My point is being that we
2570 have countries that don't have an FDA employee, so when you
2571 think about Morgantown having two, it can just demonstrate
2572 the unlevel playing field.

2573 Mr. {Shimkus.} Yeah, I would like to have two in China
2574 maybe.

2575 Ms. {Bresch.} Or maybe 200, but yes.

2576 Mr. {Shimkus.} Yeah, at least two would be a start.

2577 Ms. {Bresch.} Exactly.

2578 Mr. {Shimkus.} But I think that raises an issue and I
2579 do appreciate your comments. I have been focused on this
2580 risk-based system for a long time and it is not to walk away
2581 from U.S. facilities but it is to recognize the fact that as
2582 Chairman Emeritus Dingell said, I mean you had an inspector

2583 onsite, you have got programs and plans and systems to
2584 obviously check that yourself. We also have a pretty good
2585 litigious environment that also keeps U.S. Manufacturing
2586 facilities somewhat cognizant of the safety and efficacy of
2587 what they are doing in the facility. So I think there would
2588 be, if we did aggressively move in a risk-based approach,
2589 there would be a return. It is not like they are never going
2590 to come back to Morgantown, West Virginia, and check in on
2591 you.

2592 Ms. {Bresch.} And we want them to. And I think that is
2593 the point of the vigilance that I spoke about. It is that
2594 need, you know, we say all the time there are good actors out
2595 there and bad actors everywhere, United States included. It
2596 is just the rigor that the FDA has to inspect the U.S., we
2597 find those quicker or perhaps never in some other countries.

2598 Mr. {Shimkus.} Thank you. Dr. Greene, I apologize for
2599 you not getting your charts and stuff up on the overhead
2600 because we were able to pull it from your testimony. And
2601 this is pretty stark. And I would guess you are pretty
2602 concerned that trend line is not changing any time soon, is
2603 that correct?

2604 Mr. {Greene.} It doesn't portend good things for the
2605 future if it continues in the same direction.

2606 Mr. {Shimkus.} And so from the other members in this

2607 discussion, it seems like we kind of mealy-mouth around
2608 trying to really identify the problem. We talked about this
2609 in the last hearing and I was just asking a basic question
2610 because I am a conservative competitive market corporate
2611 Republican, believer in supply-and-demand principles. Why is
2612 that not working here? Why isn't there a signal being sent
2613 to manufacturers, hey, there is a demand that is not being
2614 filled. Can you not send a price signal--

2615 Mr. {Greene.} Right.

2616 Mr. {Shimkus.} --that would then generate an interest,
2617 especially as Dr. Burgess said. Some of this stuff isn't
2618 really the high-tech type stuff. I mean when the mention of
2619 saline solution with vitamins inside of it you are thinking
2620 he is telling me that, that stuff we do all the time. For
2621 that to be a limited availability, that is crazy talk.

2622 Mr. {Greene.} Yeah, I am not qualified to really
2623 comment on whether the economics are dramatically a part of
2624 this or not. I would leave that to the economists. It would
2625 seem to me that--

2626 Mr. {Shimkus.} Well, let me ask if anyone else can
2627 talk--I mean part of hearings is trying to find an answer.
2628 So go ahead, Mr. Gaugh.

2629 Mr. {Gaugh.} So economics can be a piece of it,
2630 absolutely, but are they the driving factor? They are not

2631 the driving factor.

2632 Mr. {Shimkus.} Okay, when you say the economics could
2633 be, so drill down a little bit.

2634 Mr. {Gaugh.} So in drilling down a little bit, the
2635 economics, yes, if a product in the competitive market space
2636 went down so far that there was no more margin, you would
2637 make a decision potentially to get out of that market, but
2638 this is a free market environment and you can raise that
2639 price back up and get--

2640 Mr. {Shimkus.} That is what I would assume but it
2641 doesn't seem that the market signals are being sent when
2642 there is a limit that the price is going up to encourage
2643 people that are in the market.

2644 Mr. {Gaugh.} Right. And the issue we are talking about
2645 now is sterile generic injectables. When you look at that
2646 line on the graph that he had, the majority are those. It is
2647 purely a capacity limitation to be able to produce those
2648 products.

2649 Mr. {Shimkus.} So the market signal would send if they
2650 can get a return on investment, it would send a signal to the
2651 manufacturers, expand to meet the demand, but the signal is
2652 not being sent.

2653 Mr. {Gaugh.} It is being sent but expand is a 7-year
2654 proposition typically from the day that you--

2655 Mr. {Shimkus.} Okay. But why is that?

2656 Mr. {Gaugh.} The day you break ground until you are
2657 approved by--

2658 Mr. {Shimkus.} Rules, regulations, siting, permitting,
2659 all this other junk?

2660 Mr. {Gaugh.} The FDA approval is an 18-month process--

2661 Mr. {Shimkus.} There is a--okay.

2662 Mr. {Gaugh.} --and that is just to get the site
2663 approved and then to move the products into that site is an
2664 additional--

2665 Mr. {Shimkus.} Well, and that is a great--and my time
2666 has expired, Mr. Chairman, and I appreciate it, but I think
2667 that is where some of this debate needs to be. How do we
2668 move aggressively, safely to allow expansion to meet these
2669 shortages? Because this is ridiculous and we shouldn't put
2670 up with it. And I yield back my time.

2671 Mr. {Pitts.} The chair thanks the gentleman and
2672 recognizes the gentleman from New York, Mr. Engel, for 5
2673 minutes for questions.

2674 Mr. {Engel.} Well, thank you. Thank you, Mr. Chairman.

2675 Mr. Gaugh, I want to follow up on something that Dr.
2676 Burgess mentioned before. In your written testimony, you
2677 stated that your trade association acknowledged that roughly
2678 half of all reported shortages are associated with

2679 manufacturing problems. Why do you believe that there has
2680 been such a significant increase in manufacturing-related
2681 issues in recent years and can you please elaborate on what
2682 steps the manufacturers of generic medications are taking to
2683 address this problem? Obviously, we cannot neglect patients'
2684 safety and so it is a matter of great concern.

2685 Mr. {Gaugh.} So if I understand your question
2686 correctly, you look at the environment today--and again I am
2687 going to focus on the sterile generic injectables--roughly 25
2688 to 30 percent of the currently available capacity is not
2689 available for production due to remediation efforts. So if
2690 you take that 30 percent roughly out of production, that is
2691 the majority cause of these drug shortage situations.

2692 Mr. {Engel.} All right, thank you. Dr. Greene, you had
2693 commented on a comment I had made involving Montefiore
2694 Medical Center having to take hours to, you know, make sure
2695 the things are ameliorated. I want to give you a chance to
2696 elaborate on that a little more.

2697 Mr. {Greene.} Specific to St. Jude I presume?

2698 Mr. {Engel.} Yes.

2699 Mr. {Greene.} Yeah, one of the things we have simply
2700 developed is a standard practice every week is one of the
2701 questions we do in our routine administrative discussion is
2702 what is our latest state of drug supply issues? What are

2703 they? What is their acuity? Do we move them out into the
2704 clinical discussion realm or is this one that we work within
2705 the pharmacy? I have literally three individuals that are
2706 routinely engaged in the discussion and evaluation and follow
2707 up to me every day. That is not all that they do but they
2708 spend a significant amount of their time dealing with these
2709 issues. And part of the problem from my point of view is the
2710 volatility in the supply. I have fentanyl today; no, I don't
2711 have fentanyl tomorrow. It is back. I only have large-
2712 volume files. I don't have small volume. Well, I have got
2713 single-dose vials this week but I don't have the vials that I
2714 need to use to make PCAs. So those are the kinds of issues
2715 that we are dealing with at any given time.

2716 Mr. {Engel.} Thank you. I mentioned to Dr. Woodcock, I
2717 had asked her this question that many of you mention in your
2718 written testimony that the user fees included in GDUFA and
2719 BsUFA are meant to be in addition to a solid base of annually
2720 appropriated funds of the FDA. In fiscal year 2012, the FDA
2721 received a 50 million increase in funding, which was a very
2722 big victory for those of us who felt that happen because the
2723 first proposal was a \$285 million cut in FDA funding for
2724 fiscal year 2012. So would any of you care to elaborate on
2725 why it is so important that the FDA be adequately funded and
2726 how cuts to the FDA could impact your industry or the

2727 patients your associations serve?

2728 Ms. {Bresch.} I will speak to that. I think that as
2729 Dr. Woodcock mentioned the premise has always been the FDA
2730 would have the appropriations and that they would never
2731 solely rely on user fees for any particular industry. And
2732 that is why I think as you see the GDUFA being, you know, a
2733 very novel and landmark user fee, the Agency has obviously
2734 funded the Office of Generic Drugs since 1984 and has been
2735 very successful. Hopefully, the user fee is now
2736 complementing that. I think that when you look at the need
2737 for the Generic Biologics Program, the same does not hold
2738 true and I think that is where we run some risk of having it
2739 being way too weighted on strictly user fees and not having
2740 the appropriate appropriations from the Agency perspective to
2741 carry out their mission.

2742 Mr. {Engel.} Thank you. I agree with you.

2743 Anybody else care to--okay, well, then thank you, Mr.
2744 Chairman. I yield back the balance of my time.

2745 Mr. {Pitts.} The chair thanks the gentleman and
2746 recognizes the gentleman from Louisiana, Dr. Cassidy, for 5
2747 minutes for questions.

2748 Dr. {Cassidy.} If I seem in a hurry, I am missing a
2749 lunch with the greatest chefs in Louisiana, so--oh, my gosh,
2750 I am tasting the food.

2751 Now, Mr. Gaugh, you mentioned, though, that there is no
2752 reason a price signal could not be sent, but there actually
2753 are constraints on how 340B will allow a company to raise its
2754 pricing. And you will know more about 340B than I but I am
2755 struck that this price signal Shimkus is after is dampened by
2756 the 340B process.

2757 Now, Dr. Greene, you are St. Jude's?

2758 Mr. {Greene.} That is correct.

2759 Dr. {Cassidy.} Now, I think I know but correct me if I
2760 am wrong that pediatric IV immunoglobulin, because of a
2761 shortage, was taken out of the 340B program. One, is that
2762 correct? And two, if correct, how has that affected supply?

2763 Mr. {Greene.} Well, it is my understanding that that is
2764 correct. We have not to my knowledge in the time that we
2765 have been engaged in the 340B program, it has only been about
2766 a year and a half now I suppose, not quite that long. I
2767 don't think we have ever been able to purchase any consistent
2768 supplies of IV IG in the 340B program, and yes, I would say
2769 that that is true. The supply has been available to us; it
2770 is just that we have had to pay the regular market rate
2771 defined through our group purchasing organization.

2772 Dr. {Cassidy.} So that is interesting. And again, I
2773 think IV IG was taken off of 340B pricing. I think that is
2774 true. So now the supply is there and it was absolutely taken

2775 off because it was never available before. I think I know
2776 that but I am a little rusty on my thought.

2777 Mr. Gaugh, you are nodding your head yes. Is that a
2778 correct--

2779 Mr. {Gaugh.} That is correct.

2780 Dr. {Cassidy.} I remember that correctly?

2781 So if you will, the restoration of a price signal
2782 restored supply. I will just point that out. Now, Dr.
2783 Greene, you also mentioned St. Jude's--everybody knows St.
2784 Jude's--that you have had a hard time at times in your
2785 testimony you said you could not get chemotherapeutic agents.
2786 But you all are big so I presume you obtained them someplace.
2787 I was kind of interested in the grey market. Do you get them
2788 from other hospitals, do you buy them from third parties, do
2789 you go into the grey market? I am not asking you to indict
2790 yourself but I am trying to understand what do companies do
2791 when they can't get this drug?

2792 Mr. {Greene.} I can think of two specific examples in
2793 the last year, one was cytarabine--we use a lot of that for
2794 treatment of our ALL patients--and it got to the point where
2795 we had to consider seriously whether we could accept new
2796 patients for treatment of ALL.

2797 Dr. {Cassidy.} I knew it at the time so if you could
2798 cut to the chase, how did you supplement your supply?

2799 Mr. {Greene.} Well, we were diligent first on the
2800 marketplace to try to find any source but also communicated
2801 with colleagues at other organizations. I had other
2802 hospitals in the region--

2803 Dr. {Cassidy.} Did you ever go on the grey market?

2804 Mr. {Greene.} Oh, no. No, we do not buy from grey
2805 market.

2806 Dr. {Cassidy.} Okay. Ms. Bresch, I am struck when I
2807 asked in a previous time why don't you just backtrack? Okay,
2808 here is a hospital that buys on the grey market. Why don't
2809 you just take this all the way back and find out where the
2810 source of the grey market was? Because different hearing but
2811 same topic, oh, we don't know where it is coming from. You
2812 don't know where it is coming from? Why don't you just call
2813 up hospital X and say who did you buy it from? Now, you are
2814 on this end, not that end, but how would you comment upon how
2815 we are tracking drugs?

2816 Ms. {Bresch.} I think you perhaps just answered your
2817 question. We don't track drugs and the FDA does not track
2818 drugs and in fact one of the premises of GDUFA, the generic
2819 industry proposal was the fact that this has led to a very
2820 weak supply chain. So I know there has been a lot of
2821 discussion today on drug shortages about is there a price
2822 point, what is really the cause of it? And I would contend

2823 that one of the issues that we are seeing as a result is this
2824 very weak supply chain we have today. So not only do we not
2825 track--I mean I believe the FDA would tell you they have no
2826 idea where some products are manufactured throughout the
2827 world, they have no even idea where the facility is--

2828 Dr. {Cassidy.} So when people buy online from oversea
2829 pharmacies, we have no clue whether that pharmacy is doing
2830 GMP, the manufacturers, or even whether it is counterfeit
2831 drug, correct?

2832 Ms. {Bresch.} You don't have any idea if you walk into
2833 your corner pharmacy here in Washington, D.C. You don't even
2834 have to go online. Today, you have no idea where the product
2835 you are buying comes from.

2836 Dr. {Cassidy.} My jaw drops.

2837 Ms. {Bresch.} I couldn't agree more and that is why
2838 sterilization which has been a topic, I know of some other
2839 hearings, and the need for us to be able to track and trace,
2840 we highly agree that that needs to happen--

2841 Dr. {Cassidy.} Now, let me stop just because we have 18
2842 seconds left before I return to my Louisiana seafood, how
2843 would you all define the grey market? I am just curious what
2844 is a working definition in your mind?

2845 Mr. {Gaugh.} Entrepreneurial America is how we define
2846 it.

2847 Dr. {Cassidy.} So you wouldn't see a problem with it or
2848 you would just say that--

2849 Mr. {Gaugh.} Oh, I do see a problem with it,
2850 absolutely, but it is not illegal that we are aware of. It
2851 is a brokerage firm if you will so it is people--

2852 Dr. {Cassidy.} So it is not a black market in the sense
2853 that it is legal. On the other hand, it is a grey market
2854 created by price distortions and shortages?

2855 Mr. {Gaugh.} Exactly.

2856 Dr. {Cassidy.} Would you agree with that, Dr. Greene?

2857 Mr. {Greene.} I would. And there is no pedigree that
2858 runs through the grey market process and that is why you
2859 can't trace it back through the grey market.

2860 Dr. {Cassidy.} Okay.

2861 Mr. {Greene.} You can trace it to a certain level but
2862 not completely because the pedigree doesn't exist in a grey
2863 market environment.

2864 Dr. {Cassidy.} Okay. Thank you all. I yield back.

2865 Mr. {Pitts.} The chair thanks the gentleman and now
2866 recognizes the gentlelady from Colorado, Ms. DeGette, for 5
2867 minutes.

2868 Ms. {DeGette.} Thank you very much, Mr. Chairman. And
2869 thank you for the comity that you have given to allow me to
2870 question as a member of the full committee.

2871 Dr. Greene, I wanted to ask you what would you be able
2872 to do with these patients if you were informed in a timely
2873 fashion of an impending drug shortage?

2874 Mr. {Greene.} Well, of course, it would depend upon the
2875 severity and the shortage and what details would come out of
2876 that, but the first step we would assess is the number of
2877 patients that would be dependent upon that drug, the number
2878 of patients affected, the alternatives that we would have to
2879 consider and their relative risk-benefit compared to the
2880 first drug of choice that would--

2881 Ms. {DeGette.} Let me ask you this because you said
2882 that you were supporting House Bill 2245--

2883 Mr. {Greene.} Yes.

2884 Ms. {DeGette.} --which gratified me because I am the
2885 prime sponsor of that bill--

2886 Mr. {Greene.} We are grateful for that, too.

2887 Ms. {DeGette.} --along with Congressman Rooney. It is
2888 a bipartisan bill that has Democratic and Republican
2889 cosponsors, so what that does is it basically expands the
2890 current FDA voluntary reporting program and makes it--

2891 Mr. {Greene.} Right.

2892 Ms. {DeGette.} --mandatory. Who would that help you be
2893 able to do your job better in treating these patients?

2894 Mr. {Greene.} In short, it would alert us to situations

2895 that we could do something about before it reached us. We
2896 could modify our dosing approaches; we could take additional
2897 steps to minimize waste. You know, there are sometimes
2898 alternatives depending on the drug that we could easily
2899 switch to before we deplete our on-hand supply. There are a
2900 number of on-hand things we could do.

2901 Ms. {DeGette.} Now, you would agree with all of us that
2902 this legislation and just doing reporting, that doesn't solve
2903 the underlying problems. It just mainly helps you deal with
2904 that chart that some folks were showing where you have these
2905 terrible shortages and it impacts patient treatment, right?

2906 Mr. {Greene.} That is correct.

2907 Ms. {DeGette.} Now, Ms. Bresch, I am going to assume
2908 you don't like the idea of drug shortages either, do you?

2909 Ms. {Bresch.} No.

2910 Ms. {DeGette.} And I would assume, Mr. Gaugh, you don't
2911 like them either, right?

2912 Mr. {Gaugh.} Do no.

2913 Ms. {DeGette.} And I know, Ms. Bresch, your company
2914 right now in fact participates in the voluntary FDA reporting
2915 program right now. You have got four drugs, largely
2916 injectables, that are right now on the shortage list, right?

2917 Ms. {Bresch.} But to my knowledge, our shortage is
2918 because we have helped fill the capacity because another

2919 manufacturer--

2920 Ms. {DeGette.} Right. No, I am just saying you
2921 participated in that program, right?

2922 Ms. {Bresch.} Yeah, absolutely.

2923 Ms. {DeGette.} And it has worked for you, right?

2924 Ms. {Bresch.} Yes, for years.

2925 Ms. {DeGette.} And for years. And what you are
2926 suggesting I think is really important, which is if we
2927 modified some of the underlying laws that have been on the
2928 books for decades and decades, that might help solve the
2929 underlying problem of drug shortages, right?

2930 Ms. {Bresch.} Absolutely. I believe strengthening the
2931 supply chain--

2932 Ms. {DeGette.} Right.

2933 Ms. {Bresch.} --would go a long way.

2934 Ms. {DeGette.} Right, and expediting the approval
2935 process and everything else--

2936 Ms. {Bresch.} Absolutely.

2937 Ms. {DeGette.} --right? And Mr. Gaugh, you are
2938 nodding, too. You think so, too, right?

2939 Mr. {Gaugh.} Yes, I would agree.

2940 Ms. {DeGette.} But, you know, it is time to start
2941 fixing the underlying problems even if we pass legislation
2942 right away, which I would support doing that, that is not

2943 going to solve the drug shortage issues that Dr. Greene and
2944 all the other hospitals are dealing with right now, correct?

2945 Mr. {Greene.} That is correct.

2946 Ms. {DeGette.} Yeah. And so I know Mr. Gaugh, your
2947 association has proposed this Accelerated Recovery
2948 Initiative, which would be a voluntary collaboration for the
2949 industry to work on some reporting issues, correct?

2950 Mr. {Gaugh.} Yes.

2951 Ms. {DeGette.} And you are not moving forward with that
2952 until you make sure that the FTC has addressed your antitrust
2953 issues, right?

2954 Mr. {Gaugh.} We are moving forward in a parallel path
2955 if you will, yes.

2956 Ms. {DeGette.} Right, but if there is antitrust issues,
2957 you are going to have to address those. Now, that particular
2958 program, it is not either/or with the FDA reporting program,
2959 right? You could have both the industry program and the FDA
2960 program, right?

2961 Mr. {Gaugh.} Yes, and it would be in support of it. We
2962 have already presented to the FDA and they are in agreement
2963 in concept with the process.

2964 Ms. {DeGette.} Yeah. And by the way, I am in agreement
2965 with the concept, too. I like the concept of having industry
2966 having a reporting process but also having the FDA have a

2967 reporting process. Now, has your association taken a
2968 position on House Bill 2245? That is the legislation that I
2969 talked about.

2970 Mr. {Gaugh.} Not the notification process. We agree
2971 with notification; it is the details that would be in that.

2972 And--

2973 Ms. {DeGette.} Have you looked at my bill?

2974 Mr. {Gaugh.} Oh, absolutely, yes.

2975 Ms. {DeGette.} And what is your position on my bill?

2976 Mr. {Gaugh.} And have spoken with your staffers as
2977 well.

2978 Ms. {DeGette.} Sorry?

2979 Mr. {Gaugh.} And have spoken with your staffers as
2980 well, yes.

2981 Ms. {DeGette.} I heard that rumor. And what is your
2982 position on my bill?

2983 Mr. {Gaugh.} We support the communication process as
2984 far as industry communicating to the FDA when drug shortages
2985 are known. The devil, as I said, is in the details on--

2986 Ms. {DeGette.} What details do you have a concern
2987 about?

2988 Mr. {Gaugh.} The mandatory timing of those, so, you
2989 know, the 6-month or the 1-year notification process as long
2990 as we are aware of that is appropriate, but in many cases we

2991 are not aware--

2992 Ms. {DeGette.} So it is just some technical language
2993 that you think we could work out?

2994 Mr. {Gaugh.} Technical, yes, absolutely.

2995 Ms. {DeGette.} And we look forward to working with you.

2996 Thank you very much, Mr. Chairman.

2997 Mr. {Gaugh.} Thank you.

2998 Mr. {Pitts.} The chair thanks the gentlelady. The
2999 chair thanks panel two for your testimony, excellent
3000 information.

3001 That concludes our second panel. And I would like to
3002 thank all of the witnesses and members for participating in
3003 today's hearing and remind members that they have 10 business
3004 days to submit questions for the record, and I ask the
3005 witnesses to respond promptly to the questions. Members
3006 should submit their questions by the close of business on
3007 Friday, February the 24th.

3008 Without objection, the Subcommittee is adjourned.

3009 [Whereupon, at 1:08 p.m., the Subcommittee was
3010 adjourned.]