

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

1 {York Stenographic Services, Inc.}

2 RPTS ALDINGER

3 HIF046.140

4 ``REAUTHORIZATION OF MDUFA: WHAT IT MEANS FOR JOBS,
5 INNOVATION AND PATIENTS''
6 WEDNESDAY, FEBRUARY 15, 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 10:16 a.m.,
12 in Room 2322 of the Rayburn House Office Building, Hon. Joe
13 Pitts [Chairman of the Subcommittee] presiding.

14 Members present: Representatives Pitts, Burgess,
15 Shimkus, Rogers, Murphy, Blackburn, Gingrey, Latta, McMorris-
16 Rodgers, Lance, Cassidy, Guthrie, Barton, Bilbray, Bass,
17 Pallone, Dingell, Towns, Engel, Capps, Schakowsky, Eshoo,
18 Matheson, Christensen and Waxman (ex officio).

19 Staff present: Clay Alspach, Counsel, Health; Nancy
20 Dunlap, Health Fellow; Debbie Keller, Press Secretary; Ryan
21 Long, Chief Counsel, Health; Carly McWilliams, Legislative
22 Clerk; Chris Sarley, Policy Coordinator, Environment and
23 Economy; Heidi Stirrup, Health Policy Coordinator; Alli Corr,
24 Democratic Policy Analyst; Eric Flamm, FDA Detailee; Karen
25 Nelson, Democratic Deputy Committee Staff Director for
26 Health; and Rachel Sher, Democratic Senior Counsel.

27 Mr. {Pitts.} This subcommittee will come to order.

28 The chair recognizes himself for 5 minutes for an
29 opening statement.

30 Congress first authorized a medical device user fee
31 program in 2002, in the Medical Device User Fee and
32 Modernization Act, MDUFMA. We last reauthorized the program
33 in the Medical Device User Fee Amendments of 2007, MDUFA,
34 which expires September 30, 2012.

35 While I am glad that FDA and industry have reached
36 recently a proposed medical device user fee agreement, the
37 committee did not receive it by the January 15, 2012,
38 deadline, as set in statute. As it is already late, I would
39 encourage FDA and the Administration to expedite their review
40 of the agreement so that the committee receives it at the
41 earliest possible date.

42 The proposed agreement will provide \$595 million in user
43 fees for fiscal year 2013 through fiscal year 2017, a sum
44 that is more than double the current user fee level of \$287
45 million.

46 A key goal of the agreement is to increase
47 predictability and transparency. Under the agreement,
48 together with regular Congressional appropriations, FDA
49 should be able to hire 240 full-time review process

50 employees, including 140 reviewers specifically for devices,
51 over 5 years. The increased user fees will pay for
52 additional training for device reviewers and information
53 technology upgrades to improve the review process. With
54 these new resources, FDA has agreed to measure review time in
55 calendar days, not FDA days, which is an important step to
56 providing increased predictability.

57 Under the proposed agreement, FDA and industry will
58 communicate more often, and earlier in the review process,
59 where FDA will provide the feedback that manufacturers need
60 to go forward.

61 The United States is the world leader in medical device
62 innovation. This not only benefits patients who need new,
63 innovative treatments, it benefits our economy. In 2008,
64 according to the Lewin Group, the medical device industry
65 employed 422,778 workers nationwide, paid \$24.6 billion in
66 earnings, and shipped \$135.9 billion worth of products.

67 In 2008, in my home State of Pennsylvania, the medical
68 device industry employed 22,233 people and paid Pennsylvania
69 workers over \$1.1 billion in earnings.

70 These are good jobs. Nationally, jobs in medical
71 technology pay almost 40 percent higher compared to the
72 national earnings average.

73 What is best for patients and what is best for jobs is

74 to have a device review process that is clear, transparent,
75 predictable and accountable, and I hope that that is what the
76 proposed agreement accomplishes.

77 I would like to thank all of our witnesses on today's
78 panels.

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

80 ***** COMMITTEE INSERT *****

|
81 Mr. {Pitts.} I would like to yield the remaining time
82 to Dr. Burgess, the vice chairman of the committee.

83 Dr. {Burgess.} Thank you, Mr. Chairman, and Dr. Shuren,
84 again, thank you for being here. You are going to hear today
85 some concerns from people on the dais and from our subsequent
86 panel, from patients and innovators.

87 As the chairman points out, funding was increased in
88 fiscal year 2008 and fiscal year 2010 by nearly 35 percent,
89 and during that time the average review time for lower-risk
90 devices increased by 43 percent, higher-risk devices by 75
91 percent, so we have got an official Washington conundrum.
92 Resources are increasing, performance is decreasing, and you
93 need to be the very best you can but it doesn't look like we
94 are there yet. Delays in reviews through inconsistencies
95 certainly harm public health but they also stifle innovation
96 and cost jobs.

97 We don't want the FDA to approve anything that harms
98 patients, and that is your mission, but a little
99 predictability could go a long way. The industry should not
100 have to double user fees in order to get the very basics of
101 customer service. So the question is, have you become more
102 interactive, predictable and innovative? Those should be the
103 goals of the basic agreement but they also are tenets of a

104 well-run organization. We worry about the jurisdictional
105 creep that has been going on where you seek to grab as much
106 regulatory territory as possible, oftentimes through draft
107 guidance, absent legislative direction. Things like mobile
108 apps and laboratory-developed tests are things that you want
109 to do but we are not sure you are doing what you are supposed
110 to do. We shouldn't enable your efforts to duplicate efforts
111 of other federal agencies.

112 Mission creep may be a cry for help, and Doctor, this
113 morning we are here to try to provide that help for you. But
114 some days we wonder if you don't need a bigger check but you
115 need a check on what is exactly happening at the level of
116 your agency. We want to help. I think we all admit that
117 there are problems in our device approval regimen that hurt
118 patients and it is just critical that we get it right for
119 them.

120 I yield back the balance of my time, Mr. Chairman.

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

122 ***** COMMITTEE INSERT *****

|
123 Mr. {Pitts.} The chair thanks the gentleman and now
124 recognizes the ranking member of the subcommittee, Mr.
125 Pallone, for 5 minutes for opening statement.

126 Mr. {Pallone.} Thank you, Chairman Pitts. I welcome
127 every here for our third installment of the UFA hearings.

128 Today we will be discussing the reauthorization of the
129 Medical Device User Fee Agreement, known as MDUFA, and let me
130 say at the outset that we are all very relieved and
131 encouraged by the current circumstances. There was grave
132 concern that the parties would be unable to reach a
133 compromise, and I am happy that things are moving forward.

134 While there is still no legislative language, there is
135 an agreement in principle that we will be discussing at
136 length. It includes \$595 million in fees over 5 years,
137 specific goals for total review times, additional meetings
138 with sponsors, third-party analysis of the FDA's review
139 process as well as other program improvements. In addition,
140 I understand that the additional funding would allow FDA to
141 hire over 200 new full-time workers by the end of the 5-year
142 program.

143 Now, we have consistently heard for a long time about
144 the need for FDA to improve the predictability, consistency
145 and transparency of its premarket review program. This

146 agreement will not solve all of those issues overnight but it
147 certainly sets FDA on a good path moving forward with
148 important tools and more resources at their disposal. It
149 also provides the industry with some much-needed insight into
150 the review process and better metrics to measure the FDA's
151 performance, and these are quality enhancements that should
152 allay those concerns.

153 I know that Congress and the FDA greatly appreciate the
154 industry's investment in this program. This proposal
155 represents a strong compromise, and I commend the hard work
156 of both parties in getting to this place I am confident will
157 help the agencies continue to improve efficiencies.

158 Let me also say that I have been encouraged by FDA's
159 commitment both over the past year and as part of this user
160 fee agreement to recognize the need for some internal
161 transformations. Change doesn't happen overnight, and
162 regardless, Dr. Shuren, your center has been more than
163 willing to listen and learn from member stakeholders and
164 industry on how to shift and adapt in ways to make these
165 processes better for companies and consumers. You have
166 recognized some of the inadequacies of the agency and
167 maintained an open mind on fixing what is broken. At the
168 same time, you have also maintained the policies are
169 important to patient safety and device effectiveness. You

170 and the Commissioner were kind enough to visit my district
171 and talk one on one with me and New Jersey companies about
172 these processes, so I appreciate that and I look forward to
173 working with you to continue to improve the center.

174 Today's hearing will also touch upon a number of FDA
175 policy proposals from my Republican colleagues. In general,
176 I have concerns with some of these bills and I look forward
177 to discussing them further. Specifically, I wonder whether
178 these proposals could make it difficult for the agency to
179 meet its negotiated commitments. I also think it is critical
180 we understand at length the intended impact, justification
181 and potential unintended consequences of these proposals
182 before moving forward.

183 I will just close by stating what I have said a number
184 of times. I agree that MDUFA is of the utmost importance. I
185 agree that FDA should facilitate an environment that doesn't
186 create added unnecessary burdens upon innovating companies,
187 but we must not make FDA policy changes at the expense of
188 patient safety. The public health must be our number one
189 goal above all else. We need to take a long, hard look at
190 any potential policy that could make it more difficult for
191 FDA to protect patient safety, and I know there are a number
192 of witnesses joining us today that will talk about that
193 important aspect. I look forward to that.

194 But I wanted to especially welcome Jim Shull--I hope I
195 am pronouncing it right--from Browns Mills, New Jersey, who
196 is here to share his personal story.

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

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

199 ***** COMMITTEE INSERT *****

|
200 Mr. {Pitts.} The chair thanks the gentleman and now
201 recognizes the chair emeritus of the full committee, Mr.
202 Barton, for 5 minutes for opening statement.

203 Mr. {Barton.} Thank you, Mr. Chairman. I am not going
204 to take 5 minutes. I believe I am supposed to yield to Dr.
205 Murphy.

206 I have an opening statement that I will put in the
207 record. I hate to be the skunk at the garden party, but
208 every now and then I am. These user fees are not something
209 that have been on the books for a hundred years. We first
210 put them in place in 2002 and we have reauthorized them once.
211 Currently, it is about \$287 million, I believe. I think it
212 is a lot to ask this committee to swallow a doubling of the
213 user fee budget to almost \$600 million. I checked yesterday,
214 and I understand that it may be the tradition but I couldn't
215 find that any member or any staff member of the majority or
216 the minority had been involved in these negotiations with the
217 FDA and the industry. If we came in and asked to double the
218 income tax receipts, we would be laughed out of Congress, and
219 to have a proposal put forward that doubles the user fee with
220 the performance or lack thereof that has accompanied the last
221 3 or 4 years is something that I am not going to condone.

222 Now, I haven't talked with Chairman Upton or Chairman

223 Pitts, and I am sure that there is another side to the story.
224 But put me down as extremely skeptical that this is a good
225 deal for the consumer or for the small medical device
226 industry.

227 I had a company in my office just this week, or late
228 last week actually, that has been making a device and
229 marketing it for 30 years, and all of a sudden now they have
230 been asked to have to go through the entire premarket
231 approval process for something. I just don't accept that.

232 So Mr. Chairman, I am extremely glad that you are
233 holding this hearing but don't ask this member to rubberstamp
234 a doubling of a user fee when we have the program performance
235 or lack thereof at this FDA.

236 And with that, I would yield the balance of the time to
237 Dr. Murphy of Pennsylvania.

238 [The prepared statement of Mr. Barton follows:]

239 ***** COMMITTEE INSERT *****

|
240 Mr. {Murphy.} I thank the gentleman.

241 A few weeks ago, several of my colleagues and I met with
242 Professor Ralph Hall, who will be testifying a little bit
243 later today on a panel. At that meeting, Professor Hall
244 explained how the review process at the FDA is driving
245 investment in medical technologies overseas as well as
246 sending jobs overseas. Now, according to Professor Hall, 40
247 percent of venture capitalists have already reduced
248 investment in medical technology in the United States and
249 many more are planning this. About 61 percent of venture
250 capitalists cite regulatory challenges with the FDA as having
251 the greatest impact on their investment decisions.

252 Now, this may seem like financial jargon but in reality,
253 it points to a tragic bottom line: no money, no research, no
254 treatments, no cures. This is about saving lives of people
255 with untreatable diseases who are waiting in line for
256 Washington's rules and bureaucracy to get out of the way and
257 for the treatment and cures to move forward. It is cruelty,
258 not comfort, when a doctor must tell a patient that
259 bureaucratic barriers prevent patients in the United States
260 from getting the treatment that they need.

261 We need to and we must help American patients have
262 better access to the latest, safest medical advancements

263 while also improving FDA's review process to allow more
264 investment in U.S. medical technology. It is something we
265 ought to be doing out of compassion for people who are sick.

266 And with that, I yield back to Mr. Barton.

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

268 ***** COMMITTEE INSERT *****

|
269 Mr. {Barton.} I have no further comments. If there are
270 other members, I will be happy to yield, Mr. Rogers or Mr.
271 Latta, anybody? I yield back to the chairman.

272 Mr. {Pitts.} The chair thanks the gentleman. The chair
273 now recognizes the ranking member of the full committee, Mr.
274 Waxman, for 5 minutes for an opening statement.

275 Mr. {Waxman.} Thank you very much, Mr. Chairman, for
276 holding this important hearing.

277 Our goal today is to start the process of reauthorizing
278 the Medical Device User Fee Act, and I commend FDA and the
279 industry for finally coming together to agree on a user fee
280 proposal. I know it was a hard-fought compromise and I look
281 forward to seeing the details. But I am pleased that there
282 has been an agreement because I have very little faith that
283 Congress is going to provide the appropriations for the FDA
284 to do the job without a user fee. I would prefer we do it
285 that way, and those who don't like the user fee will have to
286 acknowledge that FDA will be short-funded and we won't get
287 these devices approved as quickly as possible.

288 The funds collected under this act will provide FDA's
289 device program with critical dollars that enable the agency
290 to fulfill its public health mission: to ensure that only
291 safe and effective medical devices are marketed in the United

292 States. That is our essential goal here. We should work
293 together on a bipartisan basis to get it done.

294 The real compassion in this country is to make sure that
295 we can get drugs and devices that work and that are safe to
296 consumers, not just to get them out on the marketplace
297 because it is no one's benefit to have drugs that are not
298 safe or medical devices that are not safe or effective. The
299 FDA, the device industry and American patients are counting
300 on us to do our job.

301 I am concerned that some may try to hijack the
302 reauthorization to advance proposals that would put the
303 health of patients at risk. Last year, Republican members of
304 the committee introduced a slate of 10 bills that would make
305 significant and harmful changes, in my view, in FDA's device
306 program. Unless we can reach consensus on these proposals,
307 they should not be inserted into this must-pass
308 reauthorization.

309 The newspapers are full of articles about the dangers of
310 improperly designed medical devices. The prestigious
311 Institute of Medicine concluded that our medical device laws
312 need to be significantly strengthened. But many of these
313 bills ignore the need for reforms that would protect
314 patients. Instead, they read like a wish list assembled by
315 lobbyists for the device industry.

316 The device industry claims that FDA regulation is
317 killing jobs, stifling innovation, and depriving American
318 patients of new medical devices. But there is no evidence to
319 back these up except anecdotes. Anecdotes from some
320 individual companies are not enough. And I think the
321 industry knows that they need an FDA that is going to do its
322 job if they are going to have credibility in the marketplace.

323 I have been appalled by the quality of the so-called
324 ``studies'' that industry is using to advance these bills.
325 Last July, I asked the editors of our Nation's top medical
326 journals to examine the methodology used in the leading
327 industry papers asserting that FDA is too slow, burdensome,
328 and unpredictable. The editors said there were serious
329 methodological flaws in both studies--biased samples, small
330 sample size and botched statistical analysis, just to name a
331 few--rendering them essentially useless as part of any
332 discussion of FDA's regulatory system. None of the editors
333 felt that the methodology of these studies was worthy of
334 publication in a peer-reviewed journal, and yet they are put
335 forward as a reason why we ought to change the law here in
336 Congress.

337 Many in the device industry argue that Europe should be
338 our model and they say new technologies are available years
339 before they are on the market in the United States. But just

340 yesterday, the New England Journal of Medicine published a
341 study by Dr. Aaron Kesselheim finding numerous examples of
342 high-risk devices that were first approved in the E.U. but
343 either showed no benefit, or, worse, had substantial safety
344 risks. I am glad that Dr. Kesselheim is here today to
345 testify about this study.

346 FDA's job is to protect the public health. Part of
347 advancing public health is helping manufacturers win approval
348 for innovative new devices. But FDA's core responsibility is
349 ensuring that only safe and effective devices are permitted
350 on the market.

351 When FDA falls short and allows dangerous devices like
352 surgical mesh and metal-on-metal hip implants to be implanted
353 in patients, the suffering of victims can be incalculable.
354 That is why I joined with Mr. Pallone, Mr. Dingell and Ms.
355 DeGette in requesting that the committee hear from witnesses
356 about the risks from dangerous devices, and I want to thank
357 Subcommittee Chairman Pitts and full Committee Chairman Upton
358 for working with us to allow these witnesses to testify today
359 on the second panel.

360 The reauthorization of MDUFA should be bipartisan, so I
361 urge all members of the committee to work together on this
362 critically important program.

363 Thank you, Mr. Chairman.

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

365 ***** COMMITTEE INSERT *****

|
366 Mr. {Pitts.} The chair thanks the gentleman.

367 Our first panel will have just one witness, Dr. Jeffrey
368 Shuren, Director of the Center for Devices and Radiological
369 Health at the FDA. Dr. Shuren is accompanied today by Mr.
370 Malcolm Bertoni, Assistant Commissioner for Planning for the
371 Office of the Commissioner. We are happy to have you with us
372 today, Dr. Shuren. You are recognized for 5 minutes to
373 summarize your testimony. Your written statement will be
374 entered into the record.

|
375 ^STATEMENT OF JEFFREY SHUREN, DIRECTOR, CENTER FOR DEVICES
376 AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

377 } Dr. {Shuren.} Mr. Chairman and members of the
378 subcommittee, I am Dr. Jeff Shuren, Director for the Center
379 for Devices and Radiological Health, or CDRH, at the FDA.
380 Thank you for the opportunity to testify today.

381 I am pleased to tell you that on February 1, FDA and
382 representatives from the medical device industry reached an
383 agreement in principle on proposed recommendations for the
384 reauthorization of the Medical Device User Fee Act, or MDUFA.
385 These recommendations would authorize FDA to collect \$595
386 million over 5 years to help fund a portion of the agency's
387 medical device review program with FDA agreeing to certain
388 overall performance goals. The final details of the
389 agreement will be resolved very soon, and as required by law,
390 we will hold a public meeting and seek public comment on the
391 proposed package before sending a final package to Congress.

392 When I came to CDRH in 2009, in response to concerns
393 expressed by industry and others, we initiated a review of
394 our device premarket review programs. The following year, we
395 released two reports that concluded, as I have testified
396 before, that we had not done as good a job managing the

397 review programs as we should have. The number one problem we
398 found was insufficient predictability, which was leading to
399 inefficiencies, higher cost to industry and FDA, and
400 sometimes delays in bringing safe and effective products to
401 market.

402 In January 2011, we announced a plan with 25 specific
403 actions that we would take that year to improve the
404 predictability, consistency and transparency of our premarket
405 programs. As of February 2012, 75 percent of these actions
406 plus eight additional actions are already completed or well
407 underway. They are intended to create a culture change
408 toward greater transparency, interaction and the appropriate
409 balancing of benefits and risk. They focus on assuring
410 predictable and consistent decision-making and application of
411 the least-burdensome principle and implementing more
412 efficient regulatory processes.

413 We believe these actions have had and will have a
414 visible, positive impact by providing greater predictability
415 about data requirements through guidance, reducing
416 unnecessary or inconsistent data requests through training
417 and policy and process changes, implementing policies that
418 lead to appropriately balanced benefit-risk determinations,
419 using external experts more extensively and effectively,
420 creating incentives to conduct clinical studies first in the

421 United States, speeding up clinical trial approval decisions
422 and implementing the innovation pathway.

423 Preliminary data indicates that the actions we have
424 taken have started to bear fruit. For example, the backlog
425 of 510(k) submissions that had been steadily increasing from
426 2005 to 2010 decreased for the first time last year.

427 However, we still have much work to do.

428 Reauthorization of MDUFA will provide the resources that
429 CDRH needs to continue improving the device review programs
430 and help reduce the high staff turnover that has adversely
431 affected review predictability and consistency. The proposed
432 MDUFA recommendations we have agreed upon with industry will
433 also include several important process improvements. For
434 example, if a performance goal on a device application is
435 missed, the MDUFA proposal would require FDA and applicants
436 to work out a plan to complete work on the submission,
437 ensuring that no submission is left behind, and requiring new
438 substantive interaction between FDA and an applicant halfway
439 through the targeted time for reviewing the application would
440 help to assure sufficient time for the applicant to properly
441 respond to appropriate questions. Clear criteria for when
442 FDA will refuse to accept a complete application means more
443 efficient use of resources to the benefit of both FDA and
444 industry. These and other proposed enhancements are intended

445 to achieve a shared outcome goal of reduced average total
446 time to decision, which we and industry believe is an
447 important indicator of a successful premarket review program.

448 The agreement in principle we have reached with industry
449 strikes a careful balance between what industry agreed to pay
450 and what FDA can accomplish with the amount of funding
451 proposed. However, we are concerned that even if device user
452 fee resources are increased under MDUFA III, additional new
453 legislative mandates imposed on CDRH could divert resources
454 and undermine FDA's ability to achieve the new performance
455 goals. When PDUFA was last reauthorized in 2007, the
456 addition of new policy-related requirements ultimately
457 resulted in FDA's drug review program having to temporarily
458 suspend meeting its PDUFA review goals in order to meet the
459 statutory mandates. We want to avoid such a situation so
460 that CDRH can focus on meeting the ambitious new proposed
461 PDUFA program goals and achieving timely patient access to
462 safe and effective devices, which is an objective that we
463 share with industry, health care practitioners, patients and
464 consumers, and I know you as well.

465 Mr. Chairman, I commend the subcommittee's efforts and
466 am pleased to answer any questions the subcommittee may have.

467 [The prepared statement of Dr. Shuren follows:]

468 ***** INSERT 1 *****

|
469 Mr. {Pitts.} The chair thanks the gentleman, and I will
470 now begin the questioning and recognize myself for 5 minutes
471 for that purpose.

472 Dr. Shuren, Chairman Upton and I have set a deadline of
473 reauthorizing the user fees by the end of June. We received
474 the three other user fee proposals by January 15th but we did
475 not receive the medical device user fee proposal as required
476 under statute. Given the need to reauthorize the user fees
477 as soon as possible, let me ask you a two-part question.
478 Number one, when will FDA send us the legislative language
479 and proposed agreement for the medical device user fee so
480 that the committee can begin its work, and two, what specific
481 steps does the Administration plan to take to expedite the
482 process so the committee can get the device information as
483 soon as possible?

484 Dr. {Shuren.} So the plan we have put in place and what
485 we have asked of the Administration is for expedited review
486 of a proposal so that we can get the proposal out to you and
487 out to the public as we move into March, and so you will be
488 able to see what we are proposing, we will get the public
489 comments, we will wrap up on that. We have to follow that
490 process. And then we will have the final package. But you
491 will be able to see that proposed package, and our goal is to

492 try to do that in the next few weeks.

493 Mr. {Pitts.} By mid-March?

494 Dr. {Shuren.} That is approximately the time, and that
495 is what we have been asking the Administration to support us
496 in doing.

497 Mr. {Pitts.} All right. The medical device legislation
498 introduced by our committee members and Mr. Paulson of
499 Minnesota contains critical improvements aimed at making
500 FDA's regulation of medical devices both premarket and
501 postmarket more predictable. This predictability is critical
502 to getting life-saving devices to our Nation's patients and
503 their families, as we have heard from Marty Conger, Carol
504 Murphy and Pam Sagan at an our hearing in July. It is also
505 critical in keeping medical device jobs in the United States,
506 as we have heard from numerous innovators throughout the past
507 year.

508 We have heard some argue that these device bills aren't
509 necessary because FDA is fixing the problem. That is a
510 little hard to believe. For example, that is what FDA has
511 told us about the pre-amendment class III devices for the
512 past 20 years, and the problem still isn't fixed. Class III
513 devices are still going through the 510(k) process. Frankly,
514 we don't have 20 years or even 6 months to wait for FDA to
515 fix the problems. Our Nation's patients and innovators need

516 help now. So my question is, will you commit to working with
517 us on this legislation so we can help our Nation's patients
518 and help keep American device jobs here in the United States?

519 Dr. {Shuren.} Mr. Chairman, we would welcome the
520 opportunity to work with you on legislation.

521 Mr. {Pitts.} We will follow up with that. Thank you.

522 What is the status of the unique device identifier rule?

523 Dr. {Shuren.} So we have completed the rule. It is now
524 currently under review at the Administration and we are
525 waiting for their approval to move forward with it.

526 Mr. {Pitts.} Five years ago, the committee passed the
527 reauthorization of the medical device user fee, and when we
528 voted for that bill, we did so expecting that FDA would meet
529 its end of the deal. It appears that that hasn't happened.
530 FDA has failed to meet many of the MDUFA goals, and during
531 the past 5 years, we have seen the total time it takes from
532 submission to FDA decision rise dramatically. Given that
533 track record, why should we believe that you are going to
534 meet the goals you agreed to in the proposed user fee
535 package?

536 Dr. {Shuren.} Well, I won't belabor the point that
537 there are some things that but for the user fee act, we would
538 not have been able to enhance, but we agree, we are not happy
539 with where the program is; industry is not happy with where

540 it is. There are fundamental problems right now. Some of
541 that is on our part, and that is why I made a public
542 commitment to make those changes and started last year,
543 regardless of whether we saw user fee dollars or not, and we
544 are moving forward on those.

545 But by the same token, there are problems with the
546 program that we cannot solve without funding. I have high
547 staff turnover rates, just like the drug program had 10 years
548 ago, because of too much work on their plate. We don't have
549 enough managers to provide good oversight. The ratios are
550 running from 1:14 up to 1:25 under a front-line manager.
551 That is untenable in any business, and I can't solve that
552 with changes in policies and processes. I can only change
553 that with having the people to do the work, enough managers
554 and enough staff to do the work. That is what comes out of
555 the user fee dollars. And together, making those program
556 improvements that we have underway, having the dollars from
557 industry and having smart performance goals in place can help
558 us achieve a successful program and the outcome we all want
559 to see from device review.

560 Mr. {Pitts.} I have just 20 seconds left. What metrics
561 are included in the agreement to make sure you can meet your
562 goal?

563 Dr. {Shuren.} In the MDUFA agreement?

564 Mr. {Pitts.} Yes.

565 Dr. {Shuren.} So there are performance goals that
566 pertain to FDA time but also to the average total time to the
567 decision. So these are the things that happen that are not
568 quite under our control but by putting in certain process
569 improvements of greater engagement and interaction with
570 industry, with the companies as we move forward during the
571 review, our hope is that with that and with the more staff on
572 board, we can actually bring down the total time for making a
573 decision, which we think is an important indicator, through
574 those improvements. We also have goals that go towards--it
575 is predominantly to the performance on different kinds of
576 applications.

577 Mr. {Pitts.} The chair thanks the gentleman and
578 recognizes the ranking member, Mr. Pallone, for 5 minutes for
579 questions.

580 Mr. {Pallone.} Dr. Shuren, I wanted to ask about the
581 510(k) process, and first commend you for the focus you have
582 given to improving it. I have been interested in how to fix
583 it for a long time. In fact, when I was the chairman of the
584 subcommittee, we held a hearing in 2009. Quite frankly, both
585 before and after that hearing, I was of the opinion that the
586 510(k) process was broken, so I am glad that FDA has focused
587 its attention on resources and how to improve it.

588 I have seen your 510(k) action plan and the amount of
589 work that CDRH did on this topic is pretty impressive. What
590 is your sense of the 510(k) program now? Is it operating
591 better? Is there more predictability and consistency? And
592 what steps on your action plan would you categorize as game
593 changers?

594 Dr. {Shuren.} So the program is not where we would like
595 it to be. We are not seeing the performance from it that we
596 would like to have, but we are starting to see some early
597 indicators, if you will, the canaries in the coalmine,
598 suggesting instead of them dying from gas, that actually they
599 are doing better. So starting almost 10 years ago, we saw
600 the requests for additional information on 510(k)'s go up and
601 up and up steadily. We saw total review times going up and
602 up and up. We saw the backlog of 510(k)'s going up and we
603 saw the percent of 510(k)'s being cleared going down. In
604 2011, for the very first time we are seeing the percent of
605 additional requests on 510(k)'s starting to dip for the first
606 time the other direction. We are seeing that the percent of
607 510(k)'s being cleared has been going up. I put all this
608 information, by the way, in my written testimony. In 2012,
609 that number, that percent of clearance actually went up
610 beyond 2011. We are seeing the backlog go down. So all of
611 these are early signs but I don't think you are going to see

612 the real benefit from it until many of our policies go into
613 effect.

614 Game changers right now--simple smart business process
615 improvements to assure that critical decisions like asking
616 for additional information are not made in the lowest parts
617 of our center but they are made at the right level of
618 management, which is why I need enough managers to provide
619 that oversight. In fact, we created a Center Science Council
620 of our most senior people to oversee the most important
621 decisions. We are putting in new policies to incentivize
622 starting clinical trials in the United States earlier. You
623 get the clinical studies started here first, you keep the
624 technology here because the companies come back to the same
625 doctors over and over again, and also having benefit-risk
626 framework that is much more focused on taking into account
627 what patients are willing to tolerate for risk because they
628 are the ones who get the devices, not my reviewers.

629 Mr. {Pallone.} Thank you. Let me ask you about the
630 conflict of interest in these scientific experts for the
631 advisory panels. We have heard from a number of parties that
632 the conflict of interest provisions are not working and are
633 excluding legitimate experts. When the Commissioner was here
634 2 weeks ago, she indicated that there have been challenges at
635 FDA in filling the advisory panels. Would you agree that

636 CDRH is having similar challenges?

637 Dr. {Shuren.} We do face challenges in moving forward,
638 which is why we agree with you. You consider this an
639 important issue; we consider this an important issue. And
640 although we have not found a legislative fix yet that has a
641 significant difference, we think this is something worth
642 exploring. One of the reasons I would like to take the
643 chairman up on his offer to work on legislation focused on
644 this area is one of those areas. We are looking at internal
645 process changes, are there other things we can be doing to
646 sort of reduce those challenges we face.

647 Mr. {Pallone.} I know when you testified before the
648 Senate Health Committee in November, you indicated
649 willingness to engage with the Senators, so I guess I am
650 getting the same assurance from you today on this.

651 Dr. {Shuren.} Yes.

652 Mr. {Pallone.} All right. Chairman Pitts talked about
653 the UDI, and I think it is unfortunate that after 5 years, I
654 think we should be closer on implementation on what I
655 consider a very critical component. But what I wanted to ask
656 you is, could you explain how UDI will interact with other
657 postmarket authorities that FDA has in the device space and
658 other initiatives that you have underway?

659 Dr. {Shuren.} So unique device identifier will allow us

660 to link the use of a device with a patient's experience with
661 the device. So data is collected every day as a part of
662 routine clinical practice, and we can't tap into that without
663 a UDI. That is why that unique device identifier is a game
664 changer, and it will allow us to move forward to have more
665 robust postmarket surveillance systems that then industry and
666 we can take advantage of and health practitioners and others
667 in the following ways. If we have more robust postmarket
668 surveillance, when there are problems, if we can identify
669 them more quickly and get on top of them, it doesn't mean the
670 device comes off the market. It means that we address it,
671 and you don't get the front-page stories in the newspapers
672 because you don't have so many people exposed. You have a
673 better infrastructure that allows companies to conduct
674 postmarket studies at lower cost because the infrastructure
675 is there, and it will allow us to make better use of
676 postmarket data to reduce the burden for premarket data
677 requirements for some devices. In fact, if we are properly
678 authorized, we may be able to even shift some of the
679 premarket data requirements to the postmarket setting. But
680 these are all things we could do in the future and a unique
681 device identifier is critical to making that happen.

682 Mr. {Pallone.} Thank you.

683 Mr. {Pitts.} The chair thanks the gentleman and

684 recognize the vice chairman of the committee, Dr. Burgess,
685 for 5 minutes for questions.

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

687 Dr. Shuren, in this committee we worked on this a lot
688 over the years, and it seems like there is a repetitive
689 stream of people in my office talking about difficulties they
690 are having in this arena. So I don't think there is any
691 question that we have a problem. The problem generally seems
692 to be with predictability and consistency at your agency, and
693 whether we all agree with where the problems are and whether
694 we all agree with how much activity is leaving our shores, I
695 don't think there is any question that some is, and the
696 President's own Jobs Council has raised this issue, and
697 specifically they commented, quoting from them, ``Our medical
698 innovation system is in jeopardy. Investment in life science
699 area is declining at an alarming rate because of the
700 escalating cost, time and risk of developing new drugs and
701 devices. While many factors contribute to the decline, an
702 important factor is the uncertainty surrounding the FDA
703 regulatory environment.''

704 So this is not House Republicans, this is the
705 President's Jobs Council. This is the Administration that is
706 voicing concern with the predictability and consistency
707 within the FDA. How do you respond to what the Jobs Council

708 is telling us?

709 Dr. {Shuren.} I think you can add me and my own staff,
710 who have our own concerns about the program as well, and I
711 will say in terms of the Jobs Council, when they then came
712 out and said what things you might want to look at for the
713 medical device program, one of their recommendations was to
714 have a benefit-risk determination framework that is much more
715 focused on looking at patient tolerance for risk. We
716 appreciate that, because when they came out with that
717 recommendation, we had actually already proposed such a
718 framework over the summer. In fact, we are finalizing it
719 right now and we have committed and are already set to put
720 out the final document and implement it come the end of
721 March.

722 Dr. {Burgess.} But again, you know, I just can't stress
723 this enough. There is a steady stream of people that come in
724 to see me and I suspect other Members of Congress have
725 similar stories where there is a problem, and the problem
726 seems to be centered at the Center for Devices and
727 Radiological Health. It is clearly something that needs your
728 highest attention and I look forward not just to your
729 framework but we actually look forward to some performance on
730 this, and as I reference in the opening statement, we can't
731 just be upping in the dollars and decreasing the performance,

732 and unfortunately, that seems to be the direction we are
733 going.

734 Let me ask you a couple of specifics on some of the
735 things I referenced. Some of the draft guidance that is
736 coming out of your area where it appears that you are
737 increasing your jurisdiction and your territory, and I am not
738 sure that is in everyone's best interest and specifically in
739 your best interest, but what about the draft guidance for
740 industry and staff on the in vitro diagnostic products that
741 are labeled for research use only and investigational use
742 only? This is something that came out of your office, and
743 depending upon the stage of development, such components are
744 officially labeled research use only, investigational use
745 only. That means they are neither sold nor marketed as
746 clinical devices nor offered as services such as laboratory-
747 developed tests, but they may be useful in developing new
748 devices. So now it looks like your agency is wanting to
749 regulate even the devices that are used to help develop the
750 devices. Have I read that correctly?

751 Dr. {Shuren.} Well, components that are being used as a
752 part of the device are part of the device, and we regulate
753 that. You know, the policy--

754 Dr. {Burgess.} Well, let me ask you this then.
755 Specifically, what are some of the deficiencies that you saw

756 that required you to issue this draft guidance?

757 Dr. {Shuren.} That there were companies who were
758 actually saying that this particular device or analyte was
759 for research purposes. They were actually marketing it for
760 commercial use. So this policy is to clarify in terms of
761 what you need to do to be very clear on, is this truly for
762 research and how you handle that, or is this actually being
763 used in patient care, and that is what it is trying to
764 clarify.

765 Dr. {Burgess.} And again, give us an idea of the scope
766 of the problem of this. Is this something that you are
767 bumping up against all the time or is this something that has
768 happened and you are trying to get in front of it?

769 Dr. {Shuren.} No, it is something we have been running
770 into and we continue to see, and that is why we have a policy
771 to clarify it.

772 Dr. {Burgess.} And can you provide us on the committee
773 with some examples of that so we can better understand why
774 this mission creep is going on at your center?

775 Dr. {Shuren.} We would be happy to come back and give
776 you some very specifics, give you a list of examples.

777 Dr. {Burgess.} And once again, this doesn't seem to be
778 the flexibility built into this. It is kind of an all-or-
779 nothing phenomenon, and one of the complaints we get is,

780 there is no flexibility within the Center for Devices and
781 Radiological Health. Is that something that you can help us
782 with?

783 Dr. {Shuren.} First of all, I would say actually we are
784 more flexible than people give us credit for.

785 Dr. {Burgess.} Fair statement, because you are not
786 getting any credit at all right now.

787 Dr. {Shuren.} I know. I mean, I will give you an
788 example. We just recently approved a device for tears in the
789 large artery in the chest, and in terms of flexibility, we
790 actually approved that device based upon just 51 patients
791 followed for just 30 days, very small, not randomized, no
792 controls, and we did it in less than 180 days. So the
793 opportunities are there. The changes we are trying to make
794 in the program are also to ensure we have flexibility where
795 we need to do it but we are also consistent in how we apply
796 it, and like I said, we made some process improvements that
797 just went in the end of last year. There are a lot of policy
798 changes, good policy changes, but as you know, as a federal
799 government agency, we have to get public comment. That is a
800 good thing. We get lots of perspectives. The downside is,
801 it takes more time. So most of the things we are trying to
802 improve actually don't start getting finalized and kicking in
803 until this year.

804 Dr. {Burgess.} We want you to be consistent. That is
805 part of our goal as well, but I would appreciate you
806 providing us some data on this because some of the stuff we
807 are hearing does not comport with what you are telling us.

808 Thank you, Mr. Chairman. I will yield back. Maybe we
809 will have time for a second round.

810 Mr. {Pitts.} The chair recognizes the ranking member of
811 the full committee, Mr. Waxman, for 5 minutes for questions.

812 Mr. {Waxman.} Thank you, Mr. Chairman.

813 Dr. Shuren, one of the bills included in the Republican
814 package would make significant changes to the device center's
815 so-called third-party review program. Currently, that
816 program permits third parties to review certain 510(k)
817 applications and provide recommendations to FDA on whether
818 the agency should clear a particular device, then FDA has 30
819 days to make a final decision. That is what the law is now.
820 The Republican bill would alter this theme to make the third
821 party's recommendation binding on FDA if FDA fails to respond
822 in 30 days. The bill also would expand the types of devices
823 that these third parties are permitted to review to include
824 permanently implantable or life-sustaining or -supporting
825 devices. These outside reviewers are not currently allowed
826 to review these devices. I think these changes are very
827 worrisome. Would FDA be concerned about these kinds of

828 changes to the program?

829 Dr. {Shuren.} We are deeply concerned about these
830 changes. I mean, the hard stop, the default about their
831 decision going into effect if we don't make a decision
832 actually can have the perverse impact also of our being in a
833 position to actually not approve that product. That actually
834 can spell the death knell for the third-party review program,
835 and I don't think that was really the intent behind the bill
836 but that is probably the outcome that will likely happen.

837 Expanding the scope of the devices, I will tell you,
838 there are over a thousand devices that are already eligible
839 for third-party review. I mean, for 510(k), most of the
840 510(k)'s would be eligible. We have gone through the
841 different categories and we have said almost 75 percent--the
842 number may in fact be higher--could then be eligible of that
843 set for third-party review. The problem is, that program
844 hasn't worked all too well, and one of the big challenges we
845 face is that those third parties don't have access to the
846 confidential information that we do. So as a result, they
847 end up coming back sometimes with decisions that are not
848 fully informed.

849 For example, we may have already spoken to a company
850 about what they need to do, they came to us, and then they go
851 separately to a third party. They have no idea what that

852 conversation was, and as a result, they can't take advantage
853 of it. That is the challenge we really face in getting that
854 program--

855 Mr. {Waxman.} Well, I was concerned about this program
856 when we implemented it in 1997. I was never comfortable with
857 the concept of having external third parties who have the
858 potential for conflict of interests on their own reviewing
859 these important devices. So when I read this bill, I was
860 very worried about the changes that they put in place. After
861 hearing your further description of the impact it would have,
862 it makes me even more concerned and I feel very uncomfortable
863 with these further changes. It is like the XL pipeline
864 resolution. When you force a decision, you get a bad
865 decision.

866 Another of the Republican slate of bills, the Premarket
867 Predictability Act of 2011, would make certain changes to
868 three key areas of FDA's device regulation: one, to FDA's
869 oversight over the investigational device exemption, two, to
870 the so-called least-burdensome provisions, and three, to the
871 procedures for appealing decisions through the Center for
872 Devices. I want to start with the changes to the least-
873 burdensome provision because those are the most troubling to
874 me.

875 This language was added to FDA's statute as part of the

876 1997 Food and Drug Administration Modernization Act at a time
877 when the industry was asserting that FDA was requiring too
878 much of device manufacturers and stifling innovation,
879 strikingly similar to what we hear still today, and in
880 essence, these provisions say that FDA must consider the
881 least-burdensome means of demonstrating that a device is
882 effective when the agency makes its approval or clearance
883 decisions. So in other words, FDA should consider whether
884 clinical data are necessary if there are other less-
885 burdensome means for demonstrating that a device can be
886 marketed.

887 The Premarket Predictability Act would change this
888 provision by adding more-specific language like requiring FDA
889 to consider alternative approaches to clinical data in
890 evaluating device effectiveness ``in order to reduce the
891 time, effort and cost'' and directs FDA to consider
892 ``alternatives to randomized controlled clinical trials and
893 the use of surrogate endpoints'' when clinical data are
894 necessary. This seems to me overly prescriptive. Why would
895 Congress be dictating to our premier scientific regulatory
896 body what type of clinical data it should consider? It is
897 also concerning because it seems that it can make it harder
898 for FDA to require clinical data even when the agency
899 believes it is necessary. I know that some of the language

900 in this bill was lifted from FDA's 2002 guidance implementing
901 the least-burdensome provision but it looks like there were
902 some changes to that language that could be significant. Can
903 you comment on this?

904 Dr. {Shuren.} Yes. First, let me say, I support the
905 least-burdensome principle. I think as a general matter, it
906 is good government and I support the policy we put back in
907 our guidance in 2002. That is why I reemphasized it to my
908 staff last year in email. It is why we are actually
909 tailoring our guidance so we apply it specifically to
910 specific devices.

911 I do have concerns regarding this legislation because as
912 it is drafted, we are reading it as lowering the standards in
913 the United States for devices coming on the market, and that
914 concerns us, and also to the extent there is a difference in
915 that language in the bill versus our guidance, we have to
916 reconcile those differences, which means we have to change
917 the current policy. If folks think we have the right policy
918 but we are not applying it consistently, that is a different
919 issue. Now, we do have concerns about not applying it
920 consistently and that is why we put in process improvements
921 to assure that we are getting the right level of sign-off on
922 any decisions for actually trying to ask for more information
923 or doing something different than we did before and oversign

924 on decisions to make sure we are applying the least-
925 burdensome principle. That is the problem we think needs to
926 be fixed and that is the one we are already working on.

927 Mr. {Waxman.} Thank you.

928 Thank you, Mr. Chairman.

929 Mr. {Pitts.} The chair thanks the gentleman and
930 recognizes the chair emeritus of the committee, Mr. Barton,
931 for 5 minutes for questions.

932 Mr. {Barton.} Thank you, Mr. Chairman.

933 I think it is better to have a third-party review than
934 to have it sit on a bureaucrat's desk at the FDA and not get
935 reviewed at all, but that is just me.

936 Mr. Chairman, I want to put into the record a study of
937 October 2011 by the National Venture Capital Association and
938 the Medical Innovation and Competitive Coalition. I am going
939 to put the entire study in the record, but I want to just
940 give some of the bullet points.

941 This study was done in October of last year, and its
942 conclusion and summary is that venture capital companies in
943 the United States are decreasing their investment in
944 biotechnology and medical device startups in the United
945 States. They are reducing their concentration in critical
946 therapeutic areas and they are shifting their focus away from
947 the United States towards Europe and Asia. The primary

948 reason is because of FDA regulatory challenges. In the last
949 3 years, they have decreased by 40 percent their investments
950 in medical devices. In the next 3 years, they expect to
951 decrease it again by 42 percent, and 61 percent of the
952 respondents cited as their primary reason regulatory
953 challenges at the FDA. I am sure that you have seen this
954 study or at least the summaries of it, Doctor?

955 Dr. {Shuren.} Yes, I have seen it.

956 Mr. {Barton.} Now, the proposal that the industry and
957 your department have agreed to doubles the user fees per year
958 for the next, I think, 4 or 5 years. The current PMA fee
959 right now I believe is \$220,000. Is that correct?

960 Dr. {Shuren.} That is correct, for full fee. If you
961 are a small business, it is \$55,000.

962 Mr. {Barton.} What does it go to in this proposal that
963 we have yet to see?

964 Dr. {Shuren.} So we are finalizing those details but we
965 are thinking at the end of 5 years it would be about
966 \$267,000, \$268,000, so it will go up by about \$48,000, and it
967 was actually a little bit higher last year. We reduced it,
968 because by law, if we collected a little bit more money, we
969 had to reduce the fees so we reduced the fees this year.

970 Mr. {Barton.} And what does the small company fee go up
971 to?

972 Dr. {Shuren.} I think it is about \$67,000.

973 Mr. {Barton.} And what is the level at which you are
974 eligible for the small company fee?

975 Dr. {Shuren.} If your annual sales or receipts are \$100
976 million or less.

977 Mr. {Barton.} And is that what it is in the current?
978 So is that changed or unchanged?

979 Dr. {Shuren.} No, that has remained the same, and you
980 can compare this on the drug side. NDA is the complement on
981 the drug side. That fee is \$1.8 million.

982 Mr. {Barton.} And I am sure, Doctor, that you are aware
983 that in the new health care law that passed several years
984 ago, there is a 2.3 percent tax on medical device companies,
985 and it is expected to raise \$20 billion over the next 10
986 years.

987 Dr. {Shuren.} I am aware of the tax.

988 Mr. {Barton.} Why could we not use some of that money
989 and have no fee increase at all?

990 Dr. {Shuren.} The tax isn't under our purview. That is
991 a question for the Administration. But I will say the
992 concern about dollars, and I recognize, you know, for
993 industry, to ask them to pay more, you know, they are
994 figuring out how to do that. But I will you, \$595 million
995 over 5 years, compared to what you heard the other week on

1996 the Generic Drug User Fee Act, over 5 years, they are going
1997 to collect about \$1.5 billion, and the Prescription Drug User
1998 Fee Act over 5 years is going to collect almost \$3.5 billion.
1999 So I appreciate the industry paying more and they made
1000 compromises, we made compromises to get to where we are, but
1001 to look at us and say that we are asking for way too much,
1002 the drug program is going to get six times the amount in user
1003 fees over 5 years than us. Even generic drugs, a smaller
1004 program, is going to get 3 times the amount.

1005 Mr. {Barton.} I appreciate that, but your current
1006 medical fee is \$287 million, and under this proposal, it
1007 doubles.

1008 Dr. {Shuren.} Well, not the individual fees to
1009 companies, the collections. You know, things like--most of
1010 the small companies make the 510(k) devices, and the fee
1011 right now is about \$2,000, and under the changes being made
1012 over 5 years it would go up to about \$2,600. They also pay a
1013 registration fee, and many of them have one facility. That
1014 right now is about \$2,300, and it might go up to \$3,800. If
1015 you look at the drug side, a registration fee for a facility
1016 is a little over a half a million dollars.

1017 Mr. {Barton.} My time is expired, Mr. Chairman, but put
1018 me down as very skeptical. I will look at this with an open
1019 mind, but if I had to vote today, I would vote no and I would

1020 really ask the committee staff on both sides that once we get
1021 the proposal to really scrub it and let us make sure that we
1022 protect our device user companies and the consumers who are
1023 going to have ultimately pay the increase in these fees.

1024 With that, I yield back.

1025 Mr. {Pitts.} The chair thanks the gentleman, and if you
1026 will provide a copy of that study for the minority, they
1027 would like to see it before we enter it into the record.

1028 Mr. {Barton.} Sure.

1029 Mr. {Pitts.} The chair recognizes the ranking member
1030 emeritus, Mr. Dingell, for 5 minutes for questions.

1031 Mr. {Dingell.} Thank you, Mr. Chairman.

1032 Dr. Shuren, nowhere in the legislation is any money
1033 being diverted from the clearance of devices or
1034 pharmaceuticals. Is there any diversion of the fees to be
1035 collected under this legislation from the actual clearance in
1036 any of the programs at FDA?

1037 Dr. {Shuren.} No.

1038 Mr. {Dingell.} Now, do the agreed-upon user fees give
1039 FDA resources necessary to ensure safety and efficacy of
1040 medical devices? Yes or no.

1041 Dr. {Shuren.} Yes.

1042 Mr. {Dingell.} Insufficient staffing at FDA and high
1043 employee turnover rates were mentioned by you, and they are a

1044 matter of concern. Will the agreed-upon user fees allow FDA
1045 to hire staff to carry out functions necessary to protect
1046 patient safety and improve new innovative devices? Yes or
1047 no.

1048 Dr. {Shuren.} Yes.

1049 Mr. {Dingell.} Will the agreement allow FDA to improve
1050 training and staff to ensure consistency in the review
1051 process? Yes or no.

1052 Dr. {Shuren.} Yes.

1053 Mr. {Dingell.} Do you believe the additional staff and
1054 professional development will help lead to reduced employee
1055 turnover? Yes or no.

1056 Dr. {Shuren.} Yes.

1057 Mr. {Dingell.} This authorization of medical device
1058 user fees includes several accountability provisions. The
1059 independent assessment of the review process is one of these
1060 provisions. Do you believe that this independent evaluation
1061 of the device review process and the recommendations from
1062 this evaluation will help FDA to identify needed areas of
1063 improvement? Yes or no.

1064 Dr. {Shuren.} Yes.

1065 Mr. {Dingell.} And will you put effort into seeing to
1066 it that that transpires?

1067 Dr. {Shuren.} Yes.

1068 Mr. {Dingell.} Now, will the independent assessment
1069 help industry and FDA to evaluate how FDA is using these
1070 resources from the user fee program? Yes or no.

1071 Dr. {Shuren.} Yes.

1072 Mr. {Dingell.} Dr. Shuren, would you agree that user
1073 fees are necessary to supplement the rather miserable level
1074 of appropriations provided by Congress to FDA for the
1075 purposes in the legislation?

1076 Dr. {Shuren.} Yes.

1077 Mr. {Dingell.} Now, Doctor, I have a concern here. If
1078 a high-risk device was put on the market with no trials for
1079 efficacy whatsoever, let us say a pacemaker or a heart valve,
1080 do you believe that a provider would reasonably know when or
1081 under what conditions to prescribe the particular pacemaker
1082 to an individual?

1083 Dr. {Shuren.} No.

1084 Mr. {Dingell.} So we have a real problem. If we don't
1085 assure that these things are safe, we might be putting in a
1086 hip or a knee or a heart valve or a pacemaker that wouldn't
1087 work and then we would have a fine mess on our hands, would
1088 we not?

1089 Dr. {Shuren.} Yes.

1090 Mr. {Dingell.} All right. Now, again, if a high-risk
1091 device was put on the market with no trials for efficacy, do

1092 you believe a patient would be sure of the efficacy of the
1093 particular or specific pacemaker for their particular heart
1094 condition? Yes or no.

1095 Dr. {Shuren.} No.

1096 Mr. {Dingell.} If a high-risk device was put on the
1097 market with no trials for efficacy, can a patient or provider
1098 know that the device is efficacious for the heart conditions
1099 you are trying to treat? Yes or no.

1100 Dr. {Shuren.} No.

1101 Mr. {Dingell.} In my opinion, demonstrating efficiency
1102 and efficacy in postmarket trials as opposed to premarket
1103 approval would weaken the high standard that patients have
1104 come to expect. Do you agree, yes or no?

1105 Dr. {Shuren.} Yes.

1106 Mr. {Dingell.} Now, even industry associations have
1107 made it clear that they support the regulatory framework
1108 currently in effect at FDA. Do you agree that maintaining
1109 this framework will preserve America's leadership in medical
1110 device innovation? Yes or no.

1111 Dr. {Shuren.} Yes.

1112 Mr. {Dingell.} We are not going to be benefited by
1113 approving devices that are not efficacious and that don't
1114 help the patient, are we?

1115 Dr. {Shuren.} No.

1116 Mr. {Dingell.} That is going to have a bad effect on
1117 our sales of devices, is it not?

1118 Dr. {Shuren.} Yes.

1119 Mr. {Dingell.} Now, I want to go back to a little bit
1120 of history on this. This whole business started when I was
1121 chairman of the committee and chairman of Oversight. We
1122 found that there was a massive amount of abuse at FDA, that
1123 there were gratuities taken and all matter of difficulties.
1124 We found that a lot of this was judgments that were being
1125 abused by FDA because it didn't have the money to do the job,
1126 and we found that industry had this awful problem of not
1127 being able to get clearance. So we found in the case of
1128 pharmaceuticals that pharmaceuticals were laying around and
1129 not getting approved and sometimes on a 17-year patent that
1130 was taking 7 to 10 years to get that done. A major U.S.
1131 pharmaceutical company would lose during that time \$250
1132 million a year. The consequences of that were very serious.
1133 So the Congress was always plagued with legitimate demands by
1134 industry to give them an extension of patent, and I supported
1135 many of these things, simply because it was basic fairness.
1136 But we figured out that the only way to do this was to see to
1137 it that they got their clearance quickly. So with agreement
1138 of industry, the first thing we did was to move this into the
1139 pharmaceuticals, and then the over-the-counters came in and

1140 said it would be a good idea if you did this for us because
1141 it would help us, and then we found that others would agree
1142 to it, although I have to say the device manufacturers had
1143 some difficulty in swallowing it, but they ultimately did,
1144 and they found it worked and they found that they all made
1145 more money because they were getting their patents cleared in
1146 a faster and better fashion.

1147 I hope my colleagues will learn a little bit about that
1148 history. This gives cleaner and better service to the
1149 people. It saves money. It helps innovation and it helps
1150 our manufacturers to make decent money out of their patents
1151 without the delay that was occurring previous to these
1152 events.

1153 Thank you, Mr. Chairman.

1154 Mr. {Pitts.} The chair thanks the gentleman and now
1155 recognizes the gentleman from Illinois, Mr. Shimkus, for 5
1156 minutes for questions.

1157 Mr. {Shimkus.} Thank you, Mr. Chairman.

1158 Thank you, Dr. Shuren, for being here. Do you agree
1159 that the Institute of Medicine study on the 510(k) process
1160 was widely rejected? Yes or no.

1161 Dr. {Shuren.} One of their recommendations was widely
1162 rejected.

1163 Mr. {Shimkus.} So that would be a yes?

1164 Dr. {Shuren.} Partial yes.

1165 Mr. {Shimkus.} I will take partial. I am under Mr.
1166 Dingell's standards here.

1167 How much did you pay for that study?

1168 Dr. {Shuren.} About \$1.3 million.

1169 Mr. {Shimkus.} Did you ask for your money back? I am
1170 glad we got some giggling. The reality is, I was at a
1171 breakfast this morning and someone was asking for additional
1172 federal money, only \$21 million. The reality is, you are
1173 sitting here saying we don't have enough money, but then we
1174 fund a study through the Institute of Medicine that costs
1175 \$1.3 million that is widely rejected, and we don't get our
1176 money back. So these dollars all add up, and we are in a
1177 Congress now that says, you know, this whole saying, if you
1178 worry about the pennies, the dollars take care of themselves.
1179 So as we are talking about Mr. Barton, why is he doubling a
1180 user fee? Well, if we take care of the pennies, the dollars
1181 will take care of themselves, and in this case, I don't think
1182 we got our money's worth out of the Institute of Medicine's
1183 report.

1184 Dr. {Shuren.} And I will say, I appreciate those
1185 concerns. They actually had a number of other
1186 recommendations that we are following up on, and if it is of
1187 interest to the committee--and I don't want to eat up your

1188 time--I would be happy whenever it is convenient, now or set
1189 a separate time, to walk through what we will be doing with
1190 the Institute of Medicine's recommendations in their report
1191 and the ones that we deferred a decision on to give them an
1192 opportunity to weigh in.

1193 Mr. {Shimkus.} And I appreciate that, and obviously we
1194 are not pleased with the response so far.

1195 Tell me again, we will go to the yes or format, is it
1196 important that we require reviewers to prove scientific or
1197 regulatory rationale for major decision-making?

1198 Dr. {Shuren.} There needs to be a scientific rationale.

1199 Mr. {Shimkus.} Is that a yes? Come on. You can do it
1200 for Mr. Dingell. I mean, why can't you say yes or no? Maybe
1201 because he is on the other side of the aisle.

1202 Mr. {Dingell.} I would suggest if the gentleman does
1203 need help, I will be glad to assist him.

1204 Mr. {Shimkus.} Do you want to read these for me?

1205 Dr. {Shuren.} Let me say with a caveat within those
1206 constructs of the question but some of the wording I might
1207 have put differently so the real meaning isn't conveyed to
1208 the committee.

1209 Mr. {Shimkus.} Maybe I should share my questions with
1210 you prior to the hearing as other folks do to get a
1211 clarification of that in the question and answering.

1212 Do you think it is important that we establish an
1213 expedited appeals process for any challenges to those
1214 decisions?

1215 Dr. {Shuren.} Yes.

1216 Mr. {Shimkus.} Thank you. Do you think it is important
1217 to have qualified, trained reviewers handling applications
1218 for submissions?

1219 Dr. {Shuren.} Yes.

1220 Mr. {Shimkus.} Do you think it is important that we
1221 have FDA publish detailed review summaries of 510(k)
1222 clearance of premarket approval and HDE and de novo?

1223 Dr. {Shuren.} Yes, with a caveat. I mean, all of the--

1224 Mr. {Shimkus.} We are getting there.

1225 Dr. {Shuren.} Some of these go to legislation that--

1226 Mr. {Shimkus.} Amen, brother. That is what we are
1227 talking about.

1228 Dr. {Shuren.} --would actually--

1229 Mr. {Shimkus.} You know, and legislation that was
1230 lampooned by the ranking member of the full committee here.
1231 I mean, he specifically took crosshairs on legislation
1232 putting it in its worst light where based upon some of your
1233 answers, maybe some of those have some merit, and that is
1234 what we do. I mean, that is what our hearing is about.

1235 Dr. {Shuren.} I know, and we would like to work through

1236 those, but some of these things in the bills and even things
1237 like detailed decision summaries if you are talking about the
1238 summaries that we are doing as opposed to what we are doing
1239 now, those have costs to them. They will divert and--

1240 Mr. {Shimkus.} Well, we have got Obamacare, million
1241 dollars of tax increases now and fee increases, so we are not
1242 sure it is all about money. We see that the medical device
1243 folks are really ponying up a lot money now. They are doing
1244 it in the Obamacare tax and they are doing it with this
1245 agreement.

1246 Let me go to a final point. FDA leadership--you kind of
1247 mentioned this earlier but I wanted to follow up. FDA
1248 leadership explicitly directed staff in a memo dated November
1249 23, 2008, to remove the ``least burdensome language'' from
1250 guidance documents, and of course, we have pieces of the
1251 legislation here that says the importance of the least-
1252 burdensome provision. What are you doing to make sure
1253 reviewers actually apply to the least-burdensome standard in
1254 practice?

1255 Dr. {Shuren.} So what we did is, we took out--there was
1256 boilerplate that was inconsistently being used. It was
1257 creating more confusion and actually wasn't helping our staff
1258 apply least burdensome, so we are doing the following. First
1259 of all, you should also have--I communicated with my staff

1260 about how important is it to follow the least-burdensome
1261 principle. That went out also as a subsequent email.
1262 Secondly, what we are doing is trying to apply the least-
1263 burdensome principles to specific devices so manufacturers
1264 don't just hear well, you apply least burdensome, to show
1265 them in fact how it can be applied to their device. That is
1266 significantly more meaningful. We put processes in place to
1267 try to assure we have got management input so that we are
1268 applying the least-burdensome principle consistently in our
1269 decision-making. And I think those changes are starting to
1270 kick in in the program. Those are meaningful, important
1271 changes to make.

1272 Mr. {Shimkus.} Thank you, Dr. Shuren. Thank you,
1273 Chairman.

1274 Mr. {Pitts.} The chair thanks the gentleman and
1275 recognize the gentl lady from California, Ms. Capps, for 5
1276 minutes for questions.

1277 Mrs. {Capps.} Thank you so much for your testimony, Dr.
1278 Shuren. I appreciate the work that has been done to reach
1279 the MDUFA deal, and I think this is a very important moment
1280 to balance the needs of the companies for increased
1281 predictability at the agency but also to increase patient
1282 safety. Congress needs to uphold our part of the deal.

1283 As I have mentioned in previous hearings, these user fee

1284 agreements do not supplant Congress's role in ensuring that
1285 FDA has the necessary resources to do its job. I hope we can
1286 work together to ensure adequate appropriations for the
1287 agency.

1288 Before I begin with my questions, I want to quickly
1289 raise the issue of the unique identifier policy for medical
1290 devices that is currently stuck in OMB. No matter what one's
1291 position on the policy itself, everyone is stuck in a holding
1292 pattern until this is released. Getting this policy out of
1293 OMB is important for industry and consumers alike, and I
1294 wanted to put on the record that Representative Schakowsky
1295 and I have sent a letter to OMB urging them to move forward
1296 on releasing the policy on the unique device identifier
1297 system. I appreciate, Dr. Shuren, FDA's work on the policy
1298 and I look forward to its release.

1299 Now, shifting gears with my question, Dr. Shuren,
1300 reports by the Institute of Medicine and the GAO have
1301 expressed that women have been historically underrepresented
1302 in medical research, particularly so for cardiovascular and
1303 other device trials, but due to proprietary data issues, it
1304 is hard to know for sure what is and what is not getting
1305 reported to FDA, and that is why my bill, the Heart for Women
1306 Act, which has passed the House twice with near-unanimous
1307 support, would require the GAO to examine whether clinical

1308 trial and drug and medical device safety and efficacy data
1309 are being reported by sex, by race and by age. Perhaps we
1310 can make some headway here.

1311 I understand that as part of MDUFA's agreement, the FDA
1312 and industry members will conduct an initial meeting to set
1313 goals, timelines and expectations. Is that correct?

1314 Dr. {Shuren.} Yes.

1315 Mrs. {Capps.} Can you discuss to what extent the FDA
1316 will inquire about the devices used in the diverse population
1317 of patients, and if the device is intended to be used in a
1318 diverse patient population, could the FDA use this time to
1319 encourage enrollment of a representative group on clinical
1320 trials so that the trials fully represent and reflect the
1321 usage of the product and prevalence of the disease?

1322 Dr. {Shuren.} So we have been stepping up our efforts
1323 to have better representation in medical device clinical
1324 trials, and that has been through guidance, that has been
1325 through workshops and that has been through one-on-one
1326 engagement with companies. So we believe it is important and
1327 it is something we are pursuing.

1328 Mrs. {Capps.} And it is something you can give
1329 measurable results on?

1330 Dr. {Shuren.} To look at what may be changing in terms
1331 of representation in clinical trials, yes, that kind of data

1332 we could be able to provide.

1333 Mrs. {Capps.} Would it be transparent enough for us to
1334 be able to see the data, or at least to get the assurances
1335 that you are giving us that there is a level of understanding
1336 and that it is fully representative sample?

1337 Dr. {Shuren.} Yes. We will go back, because we have
1338 been trying to be more transparent about information that we
1339 are using in our decisions, and we actually have a tool
1340 starting to put up information on the clinical trials that
1341 are used in support of device approvals, and I think that is
1342 one of the components in there, but we can double-check and
1343 get back to you.

1344 Mrs. {Capps.} I would appreciate that we have some
1345 follow-up on this particular question and look forward to
1346 working with you on.

1347 I want to bring up another topic in my remaining time.
1348 Several weeks ago, I asked your colleague, Dr. Hamburg, about
1349 the Sentinel system for postmarket surveillance. The PDUFA
1350 agreement will allow user fees to go towards using Sentinel
1351 for postmarket surveillance of prescription drugs, thereby
1352 protecting the public health, saving money on research and
1353 staying ahead of the curve on drug recalls, and from reports,
1354 most of the work Sentinel has done to date has been in the
1355 drug space. Now, let me ask you, can Sentinel be used in the

1356 medical device space?

1357 Dr. {Shuren.} It can be used. We have been a part of
1358 the discussions. The holdbacks right now is, one, we need
1359 unique device identifiers. Until we have that, we can't do
1360 it. The second is, I will say when Congress put the mandate
1361 to have a program for drugs, that got a lot of people to step
1362 up to the plate to participate, and it is a very non-
1363 regulatory program. But because it is not mentioned
1364 specifically for devices, it has not had that same level of
1365 enthusiasm.

1366 Mrs. {Capps.} I wanted to ask you to expand upon the
1367 barriers that might exist to expanding it to the device side,
1368 and you kind of hinted. Would you go further in the
1369 remaining few seconds to talk about some ways that you see as
1370 barriers that perhaps then we could--somehow there could be a
1371 pathway through to making it be effective there?

1372 Dr. {Shuren.} Well, the unique device identifiers, we
1373 need to have that system in place, and I think the fact that
1374 the legislation that passed just mentioned drugs put a lot of
1375 attention and for the folks who have data, the focus went to
1376 drugs because devices wasn't--

1377 Mrs. {Capps.} Are you saying the legislation needs to
1378 be revisited that includes devices?

1379 Dr. {Shuren.} I think if the legislation mentioned

1380 devices, we would get more interest in having such a program
1381 for medical devices.

1382 Mrs. {Capps.} I yield back. Thank you.

1383 Mr. {Pitts.} The chair thanks the gentlelady and
1384 recognizes the gentleman, Mr. Rogers, for 5 minutes for
1385 questions.

1386 Mr. {Rogers.} Thank you, Mr. Chairman.

1387 Thank you, Dr. Shuren, for being here. I can see how it
1388 gets confusing. This committee asked the FDA just a very
1389 short number of years ago to regulate tobacco, and they are
1390 going to generate some \$2 billion over 5 years on a product
1391 that if you use as directed will kill you. That is a fairly
1392 confusing message to the FDA, so for that, I am going to
1393 apologize for what Congress did to you, and I certainly could
1394 find lots of places for that \$2 billion when it comes to
1395 medical research to do something pretty spectacular that is
1396 not going to find its way there.

1397 But I guess what confuses me, and I too have been
1398 looking at the National Venture Capital Association, mainly
1399 because they are the canary in the coalmine. If they are the
1400 first ones to give an indication if in fact they are going to
1401 change their investment habits to companies who are
1402 innovating when it comes to medical devices and the survey
1403 results are a bit frightening. So you believe that medical

1404 devices that are approved by the FDA, they advance American
1405 public health. Would you agree with that?

1406 Dr. {Shuren.} Yes.

1407 Mr. {Rogers.} And would you agree with Commissioner
1408 Hamburg that the FDA has a role to play in ensuring that
1409 medical device companies stay in the United States and want
1410 to bring their products to the market here first? There is
1411 some advantage to that, is there not?

1412 Dr. {Shuren.} Yes.

1413 Mr. {Rogers.} And I know we are saying to some degree
1414 nothing to say here, we are moving on, we are trying to get
1415 through this, and I hope that you do, but would you find it
1416 concerning that according to this survey, that 44 percent of
1417 American venture capital firms are now going to invest in
1418 life science companies in Europe and Asia? I mean, it is
1419 clearly a shift. Is that concerning to you?

1420 Dr. {Shuren.} Well, it does concern me to see
1421 investments not going into development of products here for
1422 the United States, and I have to tell you, I have been on the
1423 record with that beforehand, and one of the drivers for some
1424 of the policies we have in place, we have been out meeting
1425 with the venture capital community. Ross Jaffe is going to
1426 be up here testifying. Ross and I have spoken on many
1427 occasions, and Ross can tell me if I am not telling the

1428 truth, but, you know, some of the top things of their
1429 concerns was I mentioned that benefit-risk determination,
1430 taking into account patient tolerance for risk, recognizing
1431 that when you have truly novel first-time technology that you
1432 can't expect it to be a home run, you have to view that a
1433 little bit differently. All of that is baked into this
1434 framework, a common framework between us and industry that is
1435 explicit, that will be a part of the record.

1436 A second is incentivizing getting the early clinical
1437 studies to start here in the United States, and those
1438 policies were developed in part directly out of those
1439 concerns, the innovation pathway. Features of that were
1440 things that the venture capital community had raised as could
1441 be helpful to them to help some of these breakthrough
1442 products get to market. We have taken that--

1443 Mr. {Rogers.} Reclaiming my time. I appreciate those
1444 efforts, but what they are also saying is that the reason
1445 that investment shift is because ``the unpredictability at
1446 the FDA.'' So I understand you tried to make some changes.
1447 Did you hear that from those venture capital firms about the
1448 unpredictability of the FDA?

1449 Dr. {Shuren.} Yes, and that is why a number of the
1450 actions we are taking are meant to address predictability in
1451 terms of better guidance, better decision-making in terms of

1452 better oversight on the decision-making that we put in place.

1453 For folks who may be interested, we did put out an
1454 overview that covers all the actions that we are taking and
1455 it puts a list of everything we are doing and if we achieved
1456 it, a link to all that information. I will make sure that
1457 our Office of Legislation--I think that has been passed out.
1458 We will make sure that is sent to everyone, and that is
1459 updated every time we take--

1460 Mr. {Rogers.} The one thing that worried me is a little
1461 bit is, you said you sent out an email to your staff on the
1462 less-burdensome approach. Sorry, but that doesn't sound like
1463 a great plan to me.

1464 Dr. {Shuren.} Well, that is why we follow that up in
1465 terms of specifically addressing--

1466 Mr. {Rogers.} Okay, but my point being here, Dr.
1467 Shuren, I appreciate it. I hope you understand the gravity
1468 of it. And just putting out a report certainly hasn't
1469 deterred the long list of folks who come into Congress every
1470 day and saying they are having these huge problems.
1471 Investment is shifting overseas. The smaller folks are
1472 losing investment as we speak. And so we need a little fire
1473 in the belly here. If you are truly trying to change that
1474 equation, it has to happen now. We don't have time for
1475 reports and lighthearted emails about how we ought to change

1476 for the future. I appreciate you having to defend this, but
1477 at the same time, if we don't change it, we jeopardize having
1478 to have our devices manufactured and innovated in Asia and
1479 Europe. I don't think that is good for U.S. consumers. Oh,
1480 and by the way, we made it more difficult because we also
1481 applied a tax to the companies who were successful enough to
1482 get through what is a very unpredictable FDA process, which
1483 means they are also hiring less and innovating less. I mean,
1484 the policies here don't work together, and that is why I
1485 think people like me are very, very frustrated with the FDA,
1486 knowing that we have asked you to do really dumb things in
1487 the past, but this stuff is so crucially important for our
1488 consumers and the folks who need these medical devices. We
1489 have to have a little urgency in our approach here, and I
1490 just don't see it.

1491 Dr. {Shuren.} Well, I would say actually we have had
1492 the urgency. You know, in 2010, we went out and we went
1493 across the country to get input from industry, from others.
1494 We pushed very quickly to get out reports and
1495 recommendations. I will tell you, I got letters from some of
1496 your colleagues telling me to slow down. I heard from
1497 industry folks, slow down, more time for conversation, and
1498 our feeling was, we can't wait. We know there are these
1499 issues and that is why we moved forward, we put in our plan

1500 in the beginning of 2010 and we have been marching
1501 relentlessly forward. I keep hearing from people, industry
1502 has even said, can you slow down, you are putting too much
1503 stuff, and it is sort of, there is a lot of things that if we
1504 don't work them together and fix, rather than just a few
1505 little things, we won't have the impact we want to have. And
1506 that email I sent out is not fluff. Quite frankly,
1507 leadership starts at the top, and to do that and communicate
1508 with my staff, I have to be out there, I have to be out in
1509 front. I have to put my name on it, and that is what that
1510 email did.

1511 Mr. {Pitts.} The chair thanks the gentleman and
1512 recognizes the gentleman, Mr. Engel, for 5 minutes for
1513 questions.

1514 Mr. {Engel.} Thank you, Mr. Chairman.

1515 Thank you, Doctor. Talking about medical devices, the
1516 2011 Institute of Medicine's report on the FDA's 510(k)
1517 processes raised significant concerns about the current
1518 premarket approval and postmarket monitoring processes for
1519 these medical devices. We would all agree, I don't think
1520 there would be any disagreement on this, that there is a
1521 necessary balance between premarket and postmarket FDA
1522 processes. No matter how stringent the premarket
1523 requirements, it is obviously not possible to know everything

1524 about the safety and effectiveness of new products until they
1525 have been in use for some significant period of time, and as
1526 we improve the processes for getting products to patients
1527 more quickly, I believe we need to improve FDA's ability to
1528 detect problems that occur once products are on the market.

1529 So let me ask you this. Can you please describe the
1530 role that postmarket data collection and surveillance play in
1531 the current FDA device approval framework, and secondly, what
1532 additional authorities or resources does FDA need to address
1533 the problems highlighted in the IOM report?

1534 Dr. {Shuren.} Well, we do use information from the
1535 postmarket setting to help inform on the premarket side.
1536 Many of the devices that are made, they constantly come back
1537 in the door through incremental innovation. So having real-
1538 world experience on those devices is critically important.
1539 Our systems in the United States are pretty good. It is not
1540 really the system the Nation deserves. We have adverse-event
1541 reporting that gives us some information, but we don't have a
1542 truly robust data collection that we really need. The
1543 Institute of Medicine highlighted that point, and we agree
1544 with them. We need to pursue that at a national level, and
1545 that is why as a strategic priority we put out last month, we
1546 said we will go forward and put out a draft national strategy
1547 for postmarket surveillance in the spring. We will have a

1548 public meeting. We will have a public dialog how to do this
1549 because ultimately this will help companies, can help
1550 companies keep products on the market, can help companies get
1551 products on the market, can also help protect patients. It
1552 is a win-win, we need to work together, and I think things
1553 like Sentinel, unique device identifier are all critical
1554 aspects, having more registries. We have been stepping up
1555 our efforts on registries.

1556 I will tell you, Europe has a lot of issues with the
1557 postmarket side. One thing they sometimes will do a little
1558 bit better than us is having a national registry for certain
1559 devices. I will give you an example. Just very recently we
1560 worked with the American College of Cardiology, the Society
1561 of Thoracic Surgeons and with a company, Edwards Life
1562 Sciences, on a registry for heart valves that are being
1563 inserted through blood vessels, revolutionary technology, and
1564 this now will be a national registry, not only getting
1565 information on that device but subsequent devices that come
1566 forward and you can actually do postmarket studies buried
1567 within that registry, can reduce future costs for doing those
1568 kinds of examinations.

1569 Mr. {Engel.} Thank you, Doctor. Let me ask you a
1570 question about the regulation of laboratory-developed tests.
1571 The FDA's oversight of medical tests, the LDTs, have become

1572 controversial of late. As I understand it, there are several
1573 issues in play here. First, there are a wide variety of
1574 tests, everything from blood tests to genetic tests that can
1575 predict whether a patient would benefit from a particular
1576 therapy. Secondly, the FDA regulates the actual tests
1577 themselves while CMS oversees the administration of these
1578 tests called CLIA, the Clinical Laboratory Improvement
1579 Amendments. It is clear that the FDA has jurisdiction over
1580 these tests but the agency has historically exercised
1581 enforcement discretion with respect to so many of them but
1582 there are recent signs that the agency is going to begin
1583 regulating a subset of these tests again.

1584 The reason I ask that is because one of the Republican
1585 medical device bills, the Modernizing Laboratory Test
1586 Standards for Patients Act, which is H.R. 3207, I believe
1587 would make radical changes in its regulatory scheme. The
1588 bill would remove FDA from the picture entirely and give
1589 complete control of these tests to CMS. My understanding is
1590 that CMS does not believe this is a good approach.

1591 So let me say this. I am very concerned about the
1592 direction of this bill, and by all accounts, these tests are
1593 at the cutting edge of new medical therapies, and to take the
1594 responsibility of ensuring that these tests are clinically
1595 effective away from the FDA, our premier scientific

1596 regulatory body, and give it to one that lacks entirely the
1597 scientific expertise to me makes absolutely no sense. Do you
1598 have concerns about the approach to laboratory-developed
1599 tests laid out in H.R. 3207?

1600 Dr. {Shuren.} We do have concerns about it, and we
1601 appreciate the fact that the bill recognizes the fact that
1602 finally laboratory-developed tests need to be regulated. The
1603 days of the Wild West need to stop, that CLIA is not adequate
1604 for the oversight of that. The law as it currently stands is
1605 not good enough, and the standard of analytical validity and
1606 clinical validity, the standard that FDA uses, that it is the
1607 right standard. The problem is, it creates a duplicative
1608 federal bureaucracy at a much higher cost, grows government
1609 unnecessarily and it maintains an unlevel playing field
1610 between traditional manufacturers and labs who make the exact
1611 same kind of test, and as a result, just continues to stifle
1612 innovation and can actually kill jobs on the flip side, and
1613 then it allows those tests to come out on the market and then
1614 for CMS to make a decision after it goes on the market. So
1615 you can have a bad test that is out there, and we have seen
1616 plenty of laboratory-developed tests, ones for diagnosing
1617 ovarian cancer that have been inaccurate, so women are having
1618 their ovaries out and didn't need to, making decisions about
1619 treatment for breast cancer, treatment on chronic Lyme

1620 disease, I mean tests for autism that are just wrong and they
1621 need to be regulated but they need to be regulated right, and
1622 CMS did say they are not the right place for it, they don't
1623 have the expertise, and the cost would be at least \$50
1624 million to \$100 million a year plus \$20 million startup. For
1625 our framework in the first few years, we are talking about a
1626 cost that is probably less than \$3 million in fees to
1627 industry, so I don't know why we want a more costly, less
1628 effective kind of approach and this duplicative oversight
1629 that actually would not help.

1630 Mr. {Engel.} Thank you. I agree.

1631 Thank you, Mr. Chairman.

1632 Mr. {Pitts.} The chair thanks the gentleman and
1633 recognizes the gentleman from Kentucky, Mr. Guthrie, for 5
1634 minutes for questions.

1635 Mr. {Guthrie.} Thanks, Dr. Shuren. We had a meeting in
1636 your office about this important issue. I am from a
1637 manufacturing background and a big believer in making in the
1638 USA and remaking it in the USA and have been concerned about
1639 some companies making them in the Europe because of the
1640 regulatory environment. We talked about that.

1641 I actually have a bill on guidance documents, and a lot
1642 of companies like guidance documents because it gives them
1643 regulatory predictability, but some of the problems--your

1644 process for reviewing internal guidance documents because
1645 some companies have said that they have submitted a guidance
1646 document--that guidance document no longer reflects FDA
1647 thinking, and so what process do you review those and because
1648 how they can submit to you or to a dated guidance document?
1649 Just kind of talk about what you are doing with the guidance
1650 process to improve it.

1651 Dr. {Shuren.} Yes. So with guidance documents, you can
1652 actually continue to submit comments about it after the
1653 comment period has closed. It is different from rulemaking.
1654 So that docket remains open and we will look to see if new
1655 comments come in. We made a concerted effort to improve our
1656 guidance development process. In fact, in 2011, our
1657 production of guidance documents improved by about 22 percent
1658 over 2010, and 2010 was better than 2009, but we sort of
1659 squeezed, you know, the fruit and gotten maybe about as much
1660 juice as we can from the internal processes improvements, and
1661 it is one of the reasons as a part of the MDUFA III
1662 reauthorization agreement we are getting a little bit of
1663 extra dollars, about five additional people to help us for
1664 the oversight of guidances. What is critical is, we need
1665 people who are more technical writers on guidances so our
1666 experts who are doing reviews can provide their expertise but
1667 not write the documents themselves. That is what is going on

1668 now. And so they get diverted away from doing premarket
1669 reviews. The little bit extra help will help us take some of
1670 that tension off. It will also help us do a better job at
1671 looking at guidances that have already been put out to see if
1672 changes need to be made and also to try to make sure that we
1673 are finalizing draft guidances more quickly.

1674 Mr. {Guthrie.} And one other point I wanted to bring
1675 up. On page 7 in your testimony, there is a chart that says
1676 about from 2000 to 2011 has been increasing additional
1677 request additional information from 510(k) requests whereas
1678 now it says in 2011 three-fourths of all 510(k)'s had
1679 additional information requests coming back. And I think the
1680 implication is that companies aren't submitting the
1681 information that you need, therefore, you haven't asked for
1682 more, and I am a manufacturing person, quality engineer, so I
1683 used to be responsible for submitting our tool and dies once
1684 they came in and we got paid based on them being approved,
1685 and let me tell you, they were only wrong if I didn't have
1686 the right information because I had to answer to somebody
1687 because literally once our customers signed off on that, they
1688 were by contract supposed to cut a check. So sometimes I
1689 felt delayed because the other parts of the project weren't
1690 ready.

1691 So the question is, you see the trend. Are three-

1692 fourths of the applications really inadequate or are you not
1693 letting them know what you need? I mean, that is the
1694 question that I have. Because it does seem like a disturbing
1695 trend to go from a third to three-fourths.

1696 Dr. {Shuren.} Yes, and actually because it was a
1697 disturbing trend, we did an analysis of 510(k) decisions, the
1698 first 130 we had done, or 110 in 2010. We put that analysis
1699 on our website, and it is a mixed bag. I mean, there are
1700 times--

1701 Mr. {Guthrie.} You have been willing to show that. I
1702 appreciate these charts because it does show the issues, and
1703 I appreciate that.

1704 Dr. {Shuren.} Yes, but it also shows the problems have
1705 been longstanding, like a decade, and this was a canary in
1706 the coalmine that then led to increased total times for
1707 review. The data just marches up starting around 2002. But
1708 when we looked at it, so a number of different reasons behind
1709 it. There are companies who we have put out very clear
1710 guidance on what to do and they opted not to follow it, and
1711 they could do something different but they didn't even
1712 justify doing something different. I mean, even where for
1713 years you provide a little bit of clinical data. If you want
1714 to measure oxygen through the skin, you take a blood sample
1715 and compare it. A company comes in and never even did the

1716 blood samples. We go back, do the blood samples.

1717 Mr. {Guthrie.} That is legitimate. That is absolutely
1718 legitimate. It is hard to believe companies whose products
1719 are based on that.

1720 Dr. {Shuren.} Believe it or not, it happens, but then
1721 we have companies where if we had better clarity on what to
1722 do, that would help, and the last is, there are times where
1723 we ask for things that we shouldn't be asking for, and that
1724 was one of the drivers behind our changing our decision-
1725 making within the center, making sure we have that level of
1726 oversight that the staff can't suddenly decide to ask for
1727 something extra until you have the proper level of sign-off.
1728 In fact, if you want to ask for a new kind of clinical study
1729 across a type of device, that is made at the highest levels
1730 in the center by the Center Science Council where those kinds
1731 of decisions in fact should be made. I just need enough
1732 managers to provide that oversight.

1733 Mr. {Guthrie.} I have a chart here from the venture
1734 capitalists, like 38 percent of their decisions, FDA
1735 regulations are about 38 percent of their decision whether to
1736 invest, and about two flights down there is a meeting now,
1737 and I am going to run back to it, on manufacturing and so we
1738 have talked about that. That is a concern. That is why we
1739 are here and why we are real concerned about it because we

1740 want it made in America and made safety and securely and
1741 efficiently. I appreciate your efforts. Thanks.

1742 Mr. {Pitts.} The chair thanks the gentleman and
1743 recognizes the gentlelady from Illinois, Ms. Schakowsky, for
1744 5 minutes for questions.

1745 Ms. {Schakowsky.} Thank you, Mr. Chairman.

1746 You have heard a lot today from many that the FDA has
1747 become too risk-averse in terms of what the agency requires
1748 device manufacturers to do in order to obtain FDA clearance
1749 or approval, and we have heard that the FDA is insisting on
1750 too much clinical data prior to approval and that this has
1751 resulted in a decrease in venture capital investment as well
1752 as an export in innovation and jobs abroad, and to help
1753 address the situation, some have suggested that the FDA's
1754 mission statement should be changed to include things like
1755 job creation and innovation, and a bill has been introduced
1756 that would accomplish this. But even if we assume there is
1757 some truth to these reports, and I think there is a lot of
1758 evidence to suggest that in fact there is not, revising FDA's
1759 mission statement seems drastic to me. So I wanted you to
1760 comment on the implications of revising the FDA's mission
1761 statement to include things like job creation.

1762 Dr. {Shuren.} Well, we are concerned about a change to
1763 mission statement that would include job creation, economic

1764 growth, competitiveness because we read that, so are we
1765 looking at job growth in the context of product approvals?
1766 Are we now going to--I mean, to do that, then we are asking
1767 for financial data on the companies, we are looking at
1768 reimbursement opportunities, market analyses become part of
1769 approval decisions, and then whose jobs? Jobs in the United
1770 States or jobs overseas? What about jobs of the competitors?
1771 I mean, the devices most at risk will actually be the most
1772 disruptive technologies because they are more likely to
1773 adversely affect the competitors in the short term and could
1774 hurt job growth in that direction.

1775 So those are the kinds of, I really think, unintended
1776 consequences happen with those changes, and there are a
1777 number of other things in this bill as you march down the
1778 list that would lead to, we think, very troublesome changes
1779 in what we do. It can change the standard for evidence for
1780 our product approval decisions. I mean, one of them is on
1781 public participation. So we then say okay, so we are talking
1782 now about public participation in product approval decisions.
1783 That means, so should we revisit what information we have
1784 considered confidential and start making more of that
1785 information public and some people may think it is a good
1786 thing. We hear from industry, please don't do that, but that
1787 is where this bill is actually directing us. It talks about

1788 using the most, you know, innovative tools. Well, innovative
1789 doesn't mean it is the best tool. So we start using bad
1790 tools and we talk about, well, make sure you are using modern
1791 tools. Well, sometimes the newest tools aren't the best
1792 ones. Old ones are just as good but why we should change the
1793 goalpost on industry every time there is some modern tool?
1794 It may not be necessary to do that.

1795 Ms. {Schakowsky.} So you think that this could slow
1796 down, complicate and actually make less efficient the
1797 process?

1798 Dr. {Shuren.} Oh, yes. I think it could lead to some
1799 fairly dramatic changes in how we make product approval
1800 decisions and I think it would adversely affect industry and
1801 adversely affect patients.

1802 Ms. {Schakowsky.} If you look at the language of the
1803 bill, and that is called the Food and Drug Administration
1804 Mission Reform Act, there is some language that may on its
1805 face seem less controversial like changing the mission to
1806 require FDA to take into account the risks that certain
1807 patients are willing to take. Am I correct in saying that
1808 these are things the FDA is already doing, and if so,
1809 proponents of the bill would argue that there should be no
1810 harm in revising the mission statement to encompass things
1811 that the FDA is already doing, and I wondered if you could

1812 comment on that.

1813 Dr. {Shuren.} Yes, this is something we already are
1814 doing as part of the benefit-risk determination framework we
1815 put out. That is already out there publicly, and it will go
1816 final and begin implementation at the end of March. That is
1817 going to happen.

1818 But this is an activity. It is not really a mission.
1819 And so this isn't exactly the right way of sending a message
1820 about having a benefit-risk determination framework because
1821 it is really an activity. It is an action.

1822 Ms. {Schakowsky.} Well, I am concerned about revising
1823 FDA's mission statement. I think it is a pretty drastic step
1824 and it doesn't seem that there is a record for why such a
1825 dramatic change would in fact be necessary.

1826 So I thank you for your comments, and I yield back.
1827 Thank you.

1828 Mr. {Pitts.} The chair thanks the gentlelady and
1829 recognizes the gentleman from Louisiana, Dr. Cassidy, for 5
1830 minutes for questions.

1831 Dr. {Cassidy.} Dr. Shuren, a friend of mine, an
1832 orthopedist, went to--I am a doctor--went to a conference in
1833 San Francisco and said he was struck that there was, relative
1834 to previous years, a paucity of new equipment being
1835 displayed. So what I am speaking of is somewhat influenced

1836 by the conversation I had with him. I assume there must be
1837 some difference in terms of how you regard the bigger
1838 manufacturer or the bigger innovative company versus the
1839 smaller. Fair statement?

1840 Dr. {Shuren.} Yes. Actually, we try to do a lot more
1841 hand-holding with the smaller companies.

1842 Dr. {Cassidy.} What in this bill--I mean, if I were to
1843 go and say to those smaller companies, first, how do you
1844 define a small company, and secondly, if I were to go to
1845 those innovators and say these are the specific provisions
1846 that pertain to you, what would be your summary?

1847 Dr. {Shuren.} So small businesses for purposes of the
1848 user fee act is \$100 million or less in annual sales or
1849 receipts.

1850 Dr. {Cassidy.} I want to have such a small business, by
1851 the way, but continue.

1852 Dr. {Shuren.} And what we will do is actually work with
1853 them in terms of what they may need to do to bring a product
1854 to market. We are very used to dealing with small companies
1855 because they make up the largest segment of the device
1856 industry, although most of the devices on the market are made
1857 by big companies. But I will tell you, one of the challenges
1858 we are seeing is some of the data suggesting we are seeing an
1859 uptick of some of the first-time sponsor companies coming to

1860 us, and because they are small companies, they oftentimes
1861 don't have a good understanding of what they need to do to
1862 come to market. I quite frankly think--

1863 Dr. {Cassidy.} But that suggests a regulatory
1864 complexity as much as anything, correct?

1865 Dr. {Shuren.} No. You come to it with what you know,
1866 and for people who understand that system, can work a lot
1867 better. I think you don't suddenly--you need to have
1868 efficient systems, you need to have clear systems. They need
1869 to be predictable and consistent. But you don't just
1870 suddenly lower the bar simply because someone says--

1871 Dr. {Cassidy.} That is a fair statement. Are your fees
1872 the same for larger and smaller companies?

1873 Dr. {Shuren.} No, they are smaller for smaller
1874 companies.

1875 Dr. {Cassidy.} And do they remain constant relative to
1876 the previous authorization or do they increase or decrease
1877 for smaller companies in this regard?

1878 Dr. {Shuren.} So in MDUFA III, they will go up, and
1879 what we are talking about now is for PMA going from about
1880 \$55,000 now to \$67,000 by 2017, and the first PMA for a small
1881 business is free. It is on the house.

1882 Dr. {Cassidy.} Now, I presume that if you have a small
1883 company, you would still be required for the double blind

1884 control trial insofar as that is practical to test your
1885 invasive device. I assume that is the case?

1886 Dr. {Shuren.} The evidence you have to provide wouldn't
1887 change. I mean, the device is the device. It shouldn't
1888 change based upon who made it. That has been one of the
1889 issues with laboratory-developed tests.

1890 Dr. {Cassidy.} That is a fair statement.

1891 Dr. {Shuren.} But by the same token, we are trying to
1892 apply least burdensome, so actually most of our clinical
1893 trials are not placebo-controlled double blind clinical
1894 trials. They are either not practical or they may not be
1895 necessary.

1896 Dr. {Cassidy.} Now, let me ask you as regards the
1897 increased revenue you all are requesting, I have again seen
1898 stuff and I have learned to say what I have been told, not
1899 what I know. Let me first say that. But you in your
1900 testimony can see that there is an increased time for
1901 approval over the last several years. You are working to
1902 address that.

1903 Dr. {Shuren.} Yes.

1904 Dr. {Cassidy.} But I have also seen that your revenue
1905 increased under the last MDUFA authorization. Your revenue
1906 significantly increased, and I think I know that your number
1907 of employees similarly increased. And so it seems like the

1908 lack of resources was not there. I mean, you have the
1909 resources. You had more money, you had more people, and yet
1910 the time to approval increased. So since we are being asked
1911 to give you more resources, why did more resources not work
1912 last time but they are going to work this time?

1913 Dr. {Shuren.} So two parts to that. One, there are
1914 program issues that need to get fixed, and those are things
1915 we have identified and we are fixing, and that is separate
1916 from resources if you are going to make it work.

1917 But the second is the resources we got weren't
1918 sufficient for the work we had to do, and one of the things
1919 in MDUFA II was we didn't take into account the increase in
1920 workload that would occur. So we got more people to try to
1921 meet the goals but then the workload was also going up and
1922 sort of outpaced the resources we got, and we never addressed
1923 the fundamental issue of having enough people to do the work
1924 and enough managers to provide oversight, and so we
1925 constantly have this high turnover rate, which industry has
1926 complained about because it disrupts the review of the
1927 device.

1928 Dr. {Cassidy.} I see you have a high turnover rate, but
1929 you did increase your number of employees. So what you are
1930 saying is, you just needed to increase them even more?

1931 Dr. {Shuren.} That is correct, and we have the same

1932 problem, by the way, in the drug program. About a decade
1933 ago, they had the same high turnover rate, same issues. The
1934 drug industry said--and they were not concerned about--they
1935 were very concerned about performance. And so what happened
1936 was, there were process improvements in the drug program and
1937 they got more money. They were able to get over that hump
1938 and they were able to put the drug program on the right
1939 track.

1940 Dr. {Cassidy.} So you feel like your process
1941 improvements are not enough, just to use your existing
1942 employees with existing revenue more efficiently, but rather
1943 you need both efficiency and much more money?

1944 Dr. {Shuren.} That is correct.

1945 Dr. {Cassidy.} I yield back.

1946 Mr. {Pitts.} The chair thanks the gentleman and
1947 recognizes the gentleman, Mr. Matheson, for 5 minutes for
1948 questions.

1949 Mr. {Matheson.} Thank you, Mr. Chairman.

1950 Thank you, Dr. Shuren, for being here today. I am glad
1951 that Mr. Barton and Mr. Rogers both made reference to the
1952 Venture Capital Association study. I was going to note that,
1953 but I think they covered what the substance is, is the
1954 troubling trend of investment going offshore. I have grave
1955 concern for a couple of reasons. One is, of course, I want

1956 folks in the United States to have access to the best devices
1957 possible to maintain their health and safety, number one, and
1958 secondly, the medical device industry is the great U.S.
1959 success story over time and it has tremendous presence
1960 throughout the country including in my home State of Utah,
1961 and I am worried about investment shifting offshore.

1962 I do applaud your goal that you stated of bringing
1963 greater consistency and efficiency and transparency at the
1964 device center, and I want to ask you about your proposed
1965 guidance document on when device modification requires a
1966 510(k). Last year, as you know, FDA released its draft
1967 guidance to industry detailing when a manufacturer needs to
1968 submit a new 510(k) for a change to an existing device.
1969 Obviously, FDA has had a policy on the books for many years
1970 that industry understood and was well accepted, but the new
1971 policy could, from what I have been told, dramatically
1972 increase FDA's workload, by estimates of 200 to 500 percent,
1973 I mean, that many more applications coming to the FDA for
1974 510(k). Is it your interpretation of the guidance document
1975 that it would require manufacturers to file 510(k)'s in that
1976 much of an increased magnitude in terms of workload within
1977 the FDA?

1978 Dr. {Shuren.} It is not, and we had put out the
1979 guidance actually to clarify when to submit a modification,

1980 predominantly in areas that were gray where we didn't provide
1981 clarity in the past, and we were not intending to raise the
1982 bar but to clarify to make it easier. We recognized, though,
1983 the concerns that had been raised by industry. We take them
1984 seriously. And I will tell you, we have got companies in, we
1985 have had trade associations in, and we are actually working
1986 very closely with them, sort of marching through to see what
1987 would be the real impact, did we get some things wrong, did
1988 we not clarify properly and we are going through that. We
1989 are doing that very methodically.

1990 You know, one of the downsides is, one of the bills on
1991 guidance document development would actually limit the time
1992 frame to get a final guidance out, and if that was in effect
1993 and we had just the one year to do it, I would be in a
1994 position to take that guidance and rush to finish it whereas
1995 I would rather take the time and work with industry to get it
1996 right. I think that is ultimately the right thing to do and
1997 that is what we are trying to do now.

1998 Mr. {Matheson.} Let me ask you a specific component of
1999 the guidance. Is it your interpretation that the new
2000 guidance would require manufacturers to file a 510(k) when a
2001 manufacturer would need to change suppliers due to a supplier
2002 goes bankrupt or there is a fire or some other emergency?
2003 Would they need to file a new 510(k) with the agency?

2004 Dr. {Shuren.} Just to change suppliers, no. They would
2005 have to document it as part of their design controls. That
2006 is just internal records. But they don't have to submit a
2007 510(k).

2008 Mr. {Matheson.} It is my understanding that the
2009 guidance proposed last year would require manufacturers to
2010 file 510(k)'s for likely uses. Can you comment as to how or
2011 why the FDA would require manufacturers to anticipate likely
2012 off-label uses of their devices and file a 510(k)?

2013 Dr. {Shuren.} They would not have to file a 510(k) for
2014 off-label uses. They don't have to go and say well, it could
2015 be used this way so I have to file a 510(k) then. That is
2016 the guidance.

2017 Mr. {Matheson.} But there is something in the guidance
2018 about likely uses. Is that correct?

2019 Dr. {Shuren.} There is something in there about if the
2020 manufacturer on their own puts a contraindication in their
2021 labeling about a particular likely use, then there is
2022 something called a changes being affected manifestation that
2023 they would submit to us. So it just that one circumstance
2024 where they are actually making this change in the labeling
2025 and it is just a certain kind of update to 510(k).

2026 Mr. {Matheson.} So absent the manufacturer listing on
2027 their labels another likely use, you are suggesting that if

2028 there some off-label use, the manufacturer is not going to be
2029 compelled to file a 510(k)?

2030 Dr. {Shuren.} That is correct.

2031 Mr. {Matheson.} Okay. Thank you, Mr. Chairman. I
2032 yield back.

2033 Mr. {Pitts.} The chair thanks the gentleman and
2034 recognizes Ms. McMorris-Rodgers for 5 minutes for questions.

2035 Mrs. {McMorris Rodgers.} Thank you, Mr. Chairman, and
2036 thank you, Dr. Shuren, for being here. This is a very
2037 important discussion, and when it comes to new cutting-edge
2038 medical research, exciting new medical devices, the FDA can
2039 either help make it happen or the FDA can close the doors to
2040 an entire industry, and as Mr. Matheson just said, the
2041 medical device industry in America is a great success story
2042 over the last 50 years, and we have been the world leader.
2043 Americans have benefited and lives have been saved. And yet
2044 today we hear because of the FDA, we hear about delays, we
2045 hear about increased cost, increased user fees. We hear
2046 about regulatory unpredictability. And it is not just--it is
2047 not the regulations themselves, it is the fact that the
2048 goalpost changes so often. And then along with that, we know
2049 that this industry is also facing huge tax increases because
2050 of the President's health care bill. We also know that it
2051 takes on average now 4 years longer in America to bring a new

2052 device to market than in Europe, and I don't believe that
2053 Europe is using bad tools and I don't believe it means that
2054 we have to lower the bar, but we do need to address what is
2055 happening.

2056 And so my first question is, do you believe that the
2057 current regulatory environment at FDA is negatively impacting
2058 the development of new medical devices here in America and
2059 sending jobs overseas?

2060 Dr. {Shuren.} I think the program that we have here
2061 needs to be improved so that we are actually having devices,
2062 more devices developed over here and that we are keeping and
2063 actually creating more jobs over here in the United States,
2064 and I take it seriously very much from a public health
2065 standpoint. I am a physician myself. I would like to see
2066 more treatments and diagnostics for patients. I am a
2067 neurologist. That space, if there is ever a space that could
2068 use more help, that is the one. But I don't think Europe is
2069 the answer. Europe actually does have a lower standard. You
2070 don't show effectiveness over there. You don't show that
2071 there is any benefit to patients, and as a result, you do
2072 have products--we are finding more products that have been
2073 approved over there later shown through subsequent studies,
2074 often through the United States, that it is unsafe or it is
2075 ineffective, but they don't have a centralized database of

2076 their approvals so it is very hard to follow much of this.

2077 And there has been a growing chorus in Europe for
2078 change, particularly for high-risk devices. Like the
2079 European Society of Cardiology, the British Medical Journal
2080 are all coming out to say high-risk devices should be treated
2081 more like the United States: demonstrate effectiveness, more
2082 robust clinical trials over there, putting out guidance to
2083 clarify what to do. Believe it or not, for the need for more
2084 guidance, we put more guidance than Europe does. So I don't
2085 think the answer is that the United States should become
2086 Europe. I think we should keep the American standard but the
2087 program behind it needs to be predictable, consistent,
2088 transparent and timely. I don't know what--

2089 Mrs. {McMorris Rodgers.} Do you believe that that
2090 program currently is predictable?

2091 Dr. {Shuren.} Well, I don't think it is sufficiently
2092 predictable, consistent, transparent, and we have said that,
2093 and I wouldn't be making these changes, I wouldn't have my
2094 staff spending the time to make those changes if we didn't
2095 believe it, and I will tell you, in spite of their working
2096 hard to try to get products out and the added effort to make
2097 these changes in the program, we are actually now starting to
2098 see early signs of improvement in performance. It is going
2099 to take a little time to really show bigger impact but it

2100 goes to show you, making those investments on our part can
2101 pay off dividends, but what we really need is, we need the
2102 support to go ahead and do it and then ultimately between our
2103 changes and the extra dollars with the user fee program, we
2104 can get ourselves back on track and we can keep the American
2105 standard.

2106 Mrs. {McMorris Rodgers.} Well, at the current rate, we
2107 are going to run out of time, and I have introduced
2108 legislation regarding harmonization, and I wanted to ask you
2109 what role you believe harmonization with other countries
2110 could play in terms of getting devices to market more
2111 quickly.

2112 Dr. {Shuren.} I actually consider harmonization
2113 critically important. We had what is called a global
2114 harmonization task force, which was us, European Union,
2115 Canada, Australia, Japan working on harmonization. I will
2116 tell that most of the members of that group had felt that
2117 that group had kind of run its course. We put out--

2118 Mrs. {McMorris Rodgers.} Now, when was this?

2119 Dr. {Shuren.} This is the global harmonization task
2120 force, and it put out many high-level documents that were
2121 more helpful to developing countries who didn't have a
2122 regulatory program in place or just developing but didn't
2123 lead to a lot of true harmonization. We, the United States,

2124 I will tell you I personally felt we needed to do better and
2125 so we put a new proposal on the table for an international
2126 medical device regulators forum to broaden the participation.
2127 It can't just be those few countries because the rest of the
2128 world was at risk of moving in different directions. We had
2129 to broaden our scope and we had to focus on real
2130 implementation on harmonization, and that group, I will tell
2131 you, to the credit of the members of GHTF, they agreed to do
2132 it and the very first meeting of that new forum is at the end
2133 of this month.

2134 Mrs. {McMorris Rodgers.} So are you seeing products
2135 being brought to market any quicker because of these efforts?

2136 Dr. {Shuren.} No, this effort is going underway. That
2137 was the problem with GHTF. We actually weren't focusing on
2138 critical questions about could we actually be relying on data
2139 submitted or in some cases decisions being made by other
2140 regulatory bodies in support of bringing the product here to
2141 the United States.

2142 Mrs. {McMorris Rodgers.} Thank you. I have run out of
2143 time. Bottom line, we are running out of time and we have to
2144 start making it happen. Thank you.

2145 Mr. {Pitts.} The chair thanks the gentlelady and
2146 recognizes Ms. Blackburn for 5 minutes for questions.

2147 Mrs. {Blackburn.} Thank you, Mr. Chairman, and I thank

2148 you all for being here.

2149 And Dr. Shuren, I hope that you realize and appreciate
2150 that we would like to see a sense of urgency coming from you
2151 to do more than just talk about issues but actually have some
2152 demonstrable actions, and when you talk about a global task
2153 force, when you talk about, you know, time, as Ms. McMorris-
2154 Rodgers said, we are running out of time with a lot of our
2155 constituents and their companies who complain about the way
2156 they are dealt with by the FDA, and in their mind, time is
2157 money.

2158 Now, you all in government have an additional, a
2159 continuing appropriation but I think it is important that you
2160 realize what we see from you is that you may not get
2161 additional money. The federal government doesn't have
2162 additional money to give. Taxpayers are saying we want to
2163 see them show some successes and some changes in behavior,
2164 and right now, perception is reality, and the reality is, the
2165 FDA is a very difficult agency with which to deal. You can
2166 look at the Jobs Council. You can look at the ODE annual
2167 report, the GAO, the Venture Capital Alliance. You can look
2168 at all of these, and there are problems dealing with you and
2169 the regulatory burden that you impose and the method in which
2170 you impose that.

2171 Now, let me ask you a question. You may have seen this

2172 article about mobile devices. This is something that is
2173 important to my constituents in Tennessee. And this is from
2174 February 7th Washington Times. So I want to ask you about
2175 mobile devices, and how do you plan to move forward with
2176 regulation of mobile devices? Do you think you have got
2177 enough on your plate with that? And if you do move forward
2178 with mobile devices, do you intend to subject them to the
2179 device tax? If somebody goes out and buys their iPad and
2180 places a mobile device on that, some monitoring device on
2181 this, are they going to be subject to the device tax? So
2182 please speak specifically to the mobile device.

2183 Dr. {Shuren.} So specifically for mobile devices, we
2184 actually took a very unique approach for FDA. Normally if
2185 something is a device, you regulate it like a device, and we
2186 said wait a minute, why do we need to do that. Quite
2187 frankly, if there is not sufficient value added to do that,
2188 and keeping in mind the value of having certain technologies
2189 out there and recognizing the more rapid innovation cycles we
2190 see, then we shouldn't do it. So the policy we put out--and
2191 that article is dead wrong. They got it wrong, and you
2192 should see the commentary in other publications on that
2193 article saying what was this person thinking. No, what we
2194 actually said is, while the world of mobile apps is maybe
2195 this big for devices, we are only interested in this, and in

2196 reality, what we are interested in is, it is the same thing
2197 as devices we already regulate. It shouldn't matter if the
2198 device is on a desktop versus on a mobile application. It is
2199 still a device. It is something we already regulate. That
2200 doesn't change it. And that is really the very narrow
2201 universe that we focused our attention on. That is
2202 essentially it. That makes a lot of sense.

2203 What we got back from comments is, can you provide more
2204 clarity on the boundaries, give us more examples about it,
2205 but for the most part, the read we have been getting from
2206 people is that very narrow look makes a lot of sense, and for
2207 the rest we have said even if you are a device--

2208 Mrs. {Blackburn.} What about expediency? Because right
2209 now it is taking about 3 years and about \$75 million to get
2210 something through your process, and I have to tell you, some
2211 of the innovators that I am talking with, they don't think
2212 this was completely wrong. They saw a lot of commonalities
2213 in the article, and so I would just highlight with you, when
2214 you look at the speed of innovation that is taking place in
2215 the medical mobile applications that you can't spend 3 years
2216 trying to get through all of your filings and reviews and the
2217 repetitiveness and switching reviewers. Sir, there is a
2218 tremendous amount of frustration with the FDA by our
2219 innovative community. So talk with me about expediency.

2220 Dr. {Shuren.} Sure, and again, when we are talking
2221 about the mobile apps that we are looking at, it is things
2222 like you have technology that is pulling down X-rays and
2223 reading the X-rays, I mean, the stuff we normally regulate,
2224 or EKG machines to measure heart rhythm. We have been
2225 regulating those for years. But when we deal with just
2226 software, we recognize too that the paradigm we have, the
2227 framework we have in place for devices does not work well.
2228 Actually, that was one of the recommendations from the
2229 Institute of Medicine to look at software because it was so
2230 challenging. So maybe we don't have to get the \$1.3 million
2231 fully backed. We can let them keep a few dollars. But we
2232 are actually underway to sort of revisit our entire framework
2233 as regard software, recognizing exactly the point that you
2234 make, that you have these rapid changes, and you need to
2235 allow for that kind of business model and constant updates.
2236 By the same token, there may be other ways to assure you have
2237 a good product that we might be able to avoid even looking at
2238 it premarket, and the other is, there is a whole bunch of
2239 things for clinical decision support, things to help you make
2240 decisions that while they could be medical devices, we are
2241 going through it and saying leave it alone, just leave it
2242 alone completely, and that is what we are working on by way
2243 of policy. Because we agree, we have to have a rationale

2244 approach.

2245 Mrs. {Blackburn.} When do you think that your policy
2246 will--when are you going to have some guidance? And my time
2247 has expired. I will ask you to answer, and yield back.

2248 Dr. {Shuren.} Okay. Our goal is on mobile medical apps
2249 to close out that one this year and also to put out the draft
2250 policy on the clinical decision support software this year as
2251 well.

2252 Mr. {Pitts.} The chair thanks the gentlelady. That
2253 concludes the questions by the members of the subcommittee.
2254 Without objection, we will go to members of the committee for
2255 questions. Dr. Christensen, you have been very patient, you
2256 were here the whole hearing. We will recognize you first for
2257 5 minutes for questions.

2258 Dr. {Christensen.} Thank you, Mr. Chairman and Ranking
2259 Member. It has been very informative to sit here and listen
2260 to the questions and the answers.

2261 I wanted to follow up on Mr. Waxman's questions about
2262 the Premarket Predictability Act of 2011. The bill would
2263 make changes in two areas in addition to the least-burdensome
2264 provisions, one, to the investigational device exemption, and
2265 then second, to the procedures for appealing decisions
2266 through CDRH.

2267 On the first, the bill would change the investigational

2268 device exemption process in ways that appear designed to
2269 permit companies to conduct studies that are not necessarily
2270 geared towards an approval or clearance decision. That seems
2271 to run counter to the company's interest, so can you explain
2272 where this is coming from, if you know, and whether you
2273 believe a change like this is necessary?

2274 Dr. {Shuren.} Well, we actually find problematic the
2275 change that is put in there because that change in standard
2276 for approving a clinical trial will mean that we will approve
2277 a clinical trial that is supposed to be the pivotal trial to
2278 show it is safe and effective and we will approve a trial
2279 that isn't going to be good enough so it will go forward, and
2280 then when the product comes back in the door with the
2281 results, we want to approve the product. And we suffered in
2282 that circumstance previously and so we were watching our
2283 approval of products going bad. It wasn't working well.

2284 Now, on the flip side, we sort of changed that but
2285 didn't change it well enough so that we said look, let us
2286 stop doing it, but what we didn't allow is, there may be
2287 extra questions we don't need an answer to right now, and
2288 they are nice to know but we shouldn't worry about them, and
2289 so we put out new policy in November of 2011 to actually set
2290 that balance right on approving clinical trials, and we think
2291 that is the smart approach. That will get us to actually

2292 approving clinical trials more quickly but appropriately.
2293 This change in the standard will actually adversely affect
2294 products coming on the market.

2295 Dr. {Christensen.} That was my impression as well.

2296 And the Premarket Predictability Act would also make
2297 changes to CDRH's appeals process to make it easier to have
2298 you as the center director be directly involved in appeals.
2299 In fact, it appears that under that bill, you would not be
2300 doing much else other than just dealing with appeals. So can
2301 you comment on that section of the bill and what impact those
2302 changes to the appeal process would have on the center?

2303 Dr. {Shuren.} Well, if folks would prefer that I just
2304 work on appeals and not improving the premarket program and
2305 making the changes necessary to do, this is a good way to do
2306 it. I would actually prefer just being sent on vacation, but
2307 that is a problem with this bill. And I will tell you, most
2308 appeals actually get resolved at the office level. In fact,
2309 of the appeals filed in the past 2 years, 26 to 28 percent
2310 wind up getting changed in whole or in part. So it goes to
2311 show you, the appeal process can actually work.

2312 Dr. {Christensen.} Thank you. I just wanted to get
2313 that on the record.

2314 And on the guidance issue that was raised, H.R. 3204,
2315 the Guidance Accountability and Transparency Act of 2011,

2316 appears aimed at making FDA guidance development a more
2317 public process and ensuring that they remain up to date. I
2318 think we all agree that government procedures should be as
2319 transparent as possible and that the ability of government to
2320 make informed and sensible decisions is dependent on
2321 receiving and making use of information stakeholders, and we
2322 certainly agree that guidance should be finalized in a timely
2323 manner and kept up to date.

2324 At the same time, though, I think we all understand that
2325 the principal purpose of FDA guidance is to enable the agency
2326 to provide advice in a more timely and flexible manner than
2327 it can through regulations. For instance, when FDA learns of
2328 new information relevant to certain product approvals, the
2329 agency needs to be able to communicate this information to
2330 the regulated industry as quickly as possible. Otherwise the
2331 industry could waste valuable time and money doing clinical
2332 trials on other work that won't necessarily help with
2333 approval of clearance of their product. So we need a
2334 workable process that balances the need.

2335 But I am concerned that the processes that would be
2336 required would actually make the guidance more onerous and
2337 more time consuming. So as my time is getting short, I know
2338 that the legislation would apply to all FDA guidances but
2339 could you tell me how it would affect CDRH and are there any

2340 aspects of that legislation that you agree with that might be
2341 helpful?

2342 Dr. {Shuren.} The bottom line is, we will issue fewer
2343 guidance and there will be less predictability in our
2344 programs. I mean, there are all these additional hoops and
2345 hurdles. You have to announce that you are going to do this
2346 particular guidance 3 months in advance. We already put out
2347 a list. Then we have to meet both before and after putting
2348 out the draft so the cost just dramatically increases, and
2349 where we have been trying to improve our productivity,
2350 productivity is going to go into the toilet and we know that
2351 is not good for industry.

2352 Dr. {Christensen.} And if you have to issue your final
2353 guidance in 12 months, that just makes you say no, I can't do
2354 it, so--

2355 Dr. {Shuren.} Well, that is one of the problems, and
2356 industry sometimes asks for longer comment periods because
2357 they want more time to look at it. I can't grant the longer
2358 comment period. Modifications guidance, we couldn't be
2359 working through those issues. And if I have HHS or OMB who
2360 are reviewing it, that just adds on a lot of additional time.
2361 We understand the need to kind of try to move quickly and
2362 rapidly but this actually would have unintended consequences.
2363 And the other part about expanding what is under a guidance

2364 document actually can have adverse consequences for patient
2365 safety because it includes notices that involve a complex
2366 scientific issue. Those are public health notices that we
2367 have to get out quickly to tell the public about a big public
2368 health concern would not be subject to this good-guidance
2369 practice more onerous. So we would have to say there is
2370 something coming up on this device, we will announce it in 3
2371 months, stay tuned. That doesn't help patients.

2372 Dr. {Christensen.} Thank you for clarifying those
2373 issues for us. Thank you.

2374 Mr. {Pitts.} The chair thanks the gentlelady and
2375 recognizes Mr. Bass for 5 minutes for questions.

2376 Mr. {Bass.} Thank you very much, Mr. Chairman, and I
2377 appreciate your accommodation. I am also not a member of
2378 this subcommittee.

2379 Dr. Shuren, I represent a State, New Hampshire, with a
2380 number of important medical device manufacturers as well as
2381 laboratories that are at the forefront of developing new
2382 medical devices, some of which are very common now and in use
2383 not only in America and around the world, and to say that
2384 some of them at least are very frustrated with the length of
2385 time and the quality of the decisions that are coming out of
2386 the FDA on the medical device side would be an understatement
2387 and perhaps in some cases we can work together on some of

2388 these issues.

2389 But I am here to ask you a question about a bill that I
2390 have introduced as part of, I think there are 10 altogether,
2391 on MDUFA having to do with humanitarian-device reform. As
2392 you know, we haven't had nearly as much success since the
2393 1990s in developing humanitarian devices for rare diseases as
2394 we have had with the orphan drug program, just 55 devices
2395 compared to 350 orphan drugs. But that isn't FDA's fault or
2396 the industry's fault. There are flaws in the law that chill
2397 investigator and sponsor interest in demand targeted reforms.
2398 The bill that I have agreed to introduce, H.R. 3211, the
2399 Humanitarian-Device Reform Act of 2011, would lift the profit
2400 restriction on current law but maintain FDA's current
2401 oversight of humanitarian devices. The act would simply do
2402 it for adult HDEs what the 2007 pediatric device law has
2403 already done for pediatric HDEs. Today, there is evidence
2404 that this has already led to more interest in pediatric HDEs.

2405 My question to you is, do you agree that lifting the no-
2406 profit restriction on adult HDEs while maintaining FDA
2407 oversight is a win-win reform that would encourage more
2408 innovation, ensure safety and result in more treatment for
2409 rare-disease patients?

2410 Dr. {Shuren.} So the honest answer is, I don't know
2411 what the ultimate impact would be on the flip side for

2412 pediatric devices. We happen to agree with you that there is
2413 a need for more incentives to develop devices for these rare
2414 conditions. I know the National Organization for Rare
2415 Disorders has said look, lift the cap on adult products.
2416 That makes a lot of sense. The American Academy of
2417 Pediatrics has a concern that if you broaden it, then
2418 manufacturers won't make devices for the pediatric
2419 population, and we have seen a fivefold increase in companies
2420 coming forward to actually get a fivefold increase in
2421 designations for humanitarian-device exemption for pediatric
2422 indications.

2423 So this is exactly the kind of topic quite frankly that
2424 we agree Congress should be tackling. We would like to be a
2425 part of that conversation. We suggest get all the players in
2426 there, because I don't think we have enough information to
2427 make a firm decision but we fully support this is an area
2428 that it is critical that we take a closer look at.

2429 Mr. {Bass.} I appreciate that, and I appreciate the
2430 fact that you are willing to work with me and other members
2431 of the subcommittee. I would point out that there are other
2432 patient groups that disagree with AAP, and the reality is
2433 that we could really benefit significantly if we had an
2434 honest debate and could work out some sort of a legislative
2435 remedy for this.

2436 And with that, Mr. Chairman, I will yield back. Thank
2437 you, Doctor.

2438 Mr. {Pitts.} The chair thanks the gentleman. That
2439 concludes the first round of questioning. We will now take
2440 one follow-up per side. I recognize Dr. Burgess for 5
2441 minutes.

2442 Dr. {Burgess.} Thank you, Mr. Chairman.

2443 I vowed to be good today, but someone on the other side
2444 took the first shot, so let us talk about laboratory-
2445 developed tests for just a moment and the reason why H.R.
2446 3207 was in fact necessary because of draft guidance coming
2447 out of your shop, the Center for Devices and Radiological
2448 Health, appeared to be overstepping the boundaries. In fact,
2449 there appeared to be a basic change in the standard
2450 regulatory paradigm that had been established, and if one
2451 even wanted to draw it to its further conclusion, there
2452 appeared to be violations of the Administrative Procedures
2453 Act coming out of your office by issuing this draft guidance.
2454 You are going to require people to do things that had never
2455 previously been required, and this was all happening without
2456 any legislative authority. It was simply happening upon the
2457 will and the whim of the Center for Devices and Radiological
2458 Health.

2459 So I have got several letters from laboratories across

2460 the country that are in support of keeping this jurisdiction
2461 within CMS, within the purview of CLIA. Laboratory tests
2462 must be accurate, they must have clinical utility, and that
2463 is the correct place. To ask these companies to literally be
2464 sucked into the maelstrom of the regulations of the devices,
2465 you can't do what you are already supposed to be doing and
2466 you are asking for more jurisdiction. How is this helpful?
2467 How does this move anything in the proper direction?

2468 So Mr. Chairman, I did want to submit these letters on
2469 the laboratory-developed tests for the record, because again,
2470 I think this is an important part of the discussion. Maybe
2471 this legislation is not the correct final product but this
2472 discussion needs to be part of the reauthorization of the
2473 user fee agreements. I will certainly allow you time to
2474 respond.

2475 Mr. {Pallone.} Mr. Chairman, I would have to review
2476 those before I could agree to unanimous consent to put them
2477 in the record.

2478 Mr. {Pitts.} Okay. We will provide copies to you.

2479 Dr. {Shuren.} So laboratory-developed tests, we have
2480 been clear for years, they are medical devices. I mean, it
2481 is the test. It doesn't matter who makes the test and that
2482 is how the law is, but we have exercised enforcement
2483 discretion but the world changed, and we have more-complex

2484 tests that are actually putting patients at significant risk.
2485 I would be very interested to see the framework you are
2486 talking about because we actually never issued draft
2487 guidance, so maybe it is another group that put it out there,
2488 but we have yet to put anything out there for people to react
2489 to. But it makes absolutely no sense to have the same kind
2490 of test that is regulated by two different government
2491 agencies, depending upon who makes it.

2492 And CMS has been clear when they looked at the
2493 legislation, this is not the right place for doing it. In
2494 fact, one of the changes under CLIA was about where you make
2495 determinations in terms of the risk on the test, and it moved
2496 from CDC to FDA, specifically to reduce duplication and try
2497 to have more of one-stop shopping, and this actually goes the
2498 opposite direction of--

2499 Dr. {Burgess.} No, sir. The indications of the draft
2500 guidance you were going to put out, that would be the
2501 duplication that this legislation is seeking to avoid. And
2502 CLIA, remember, in its inception in the late 1980s, I was
2503 never a big fan of CLIA as a practicing physician but their
2504 whole purpose, the purpose that Senator Kennedy and others
2505 worked on this was so that laboratory tests could be
2506 certified as accurate and have clinical utility. That is
2507 their job. Don't tell me they don't want to do their job.

2508 If a federal agency doesn't want to do its job, then perhaps
2509 we will have that discussion, but this is their job. This is
2510 what they were required to do under the amendments in 1988.

2511 Dr. {Shuren.} No, the amendments actually don't address
2512 these issues on analytical and clinical validity. In fact,
2513 your bill now changes that so you have to provide the data to
2514 actually show that. The problem is, it is not set up in a
2515 good way to get there and it creates duplicative government.

2516 This is actually a problem for personalized medicine.
2517 We have heard this from companies who are making drugs and
2518 then devices to actually have the devices diagnose who is the
2519 right population to get the drug, and you now have companies,
2520 they make the device, they make the drug, they do the data.
2521 Everything works out and moves forward. In fact, one of
2522 them, two of them that just came out, we and our Center for
2523 Drugs, we approved it, both the drugs and the diagnostic, in
2524 less than 5 months. But then the day that they go out with
2525 their test and with their drugs, labs come out and say oh, I
2526 have got the exact same thing and in fact we are better.
2527 Really? And so now people can go use those other tests. Who
2528 knows if they are actually any good. Because none of the
2529 studies was even done with the drug. It is not even out
2530 there. And so what do you have now? Now you have tests that
2531 actually may be directing patients to get treatment they

2532 shouldn't get or not get a treatment they should get, and
2533 that is a disaster.

2534 Dr. {Burgess.} Well, I would submit that the
2535 duplication actually exists within your center, and albeit
2536 there is work to be done here but to simply ignore that there
2537 is a problem is to do no service to anyone at all.

2538 Thank you, Mr. Chairman, for your indulgence and I will
2539 yield back.

2540 Mr. {Pitts.} The chair thanks the gentleman and
2541 recognizes the ranking member for 5 minutes for follow-up.

2542 Mr. {Pallone.} Thank you, Mr. Chairman.

2543 Dr. Shuren, H.R. 3202, the Novel Device Regulatory
2544 Relief Act, appears to be intended to streamline the de novo
2545 process for FDA approval of medical devices. Although it is
2546 important to ensure that FDA review processes are efficient,
2547 I am sure we would all agree that the fundamental goal of the
2548 FDA is to ensure the safety of the public and to protect
2549 Americans from unsafe and ineffective medications and
2550 devices.

2551 The proposed new language in this bill would allow
2552 device companies to require that their new device be
2553 evaluated under the de novo process without first submitting
2554 a 510(k) application demonstrating a substantial equivalence
2555 to another device already on the market, which is what is

2556 currently required under the de novo procedures, and it
2557 changes the timelines under which a de novo application must
2558 be submitted.

2559 So my question is, do you think this change under this
2560 proposed legislation would add to the efficiency of your
2561 clearance process? Does it give you enough time to do the
2562 reviews for products that presumably will be more novel than
2563 most 510(k) submissions?

2564 Dr. {Shuren.} We do think that the change of not having
2565 to be required to submit a 510(k) before going down the de
2566 novo pathway makes sense. So taking that requirement out of
2567 the law makes sense. Giving us only 60 days to do it,
2568 however, isn't enough time. I mean, even a 510(k), which is
2569 less complicated, is 90 days by law, and even that, we all
2570 know that that is not enough time for many of these as well.
2571 So not enough time but it is the right thing to do to take
2572 out the 510(k) if they don't want to submit it. Some
2573 companies, you actually don't know and they don't know, and
2574 they submit a 510(k) and then we will look at it. They
2575 actually never the requirements for a 510(k).

2576 Mr. {Pallone.} All right. Then I wanted to ask you a
2577 second question. As you know, the Safe Medical Devices Act
2578 of 1990 mandated that FDA evaluate pre-amendment class III
2579 devices and on a case-by-case basis either reclassify them to

2580 class I or II or require them to go through premarket
2581 approval as most post-amendment class III devices. What I
2582 would like to know is why FDA hasn't completed its mandated
2583 task of reclassifying pre-amendment class III devices or
2584 requiring them to go through premarket approval. Can you
2585 tell us how far you have gotten in this activity and how many
2586 devices remain, and are there unnecessary procedural hurdles
2587 in the law that keep you from finishing this activity?

2588 Dr. {Shuren.} So when I came on board, we put a new
2589 refocused energy into trying to get these done, and we have
2590 on our website each of the devices that we have to go through
2591 and where they are in the process. There are five steps.
2592 Four of them, we have wrapped up on. Another six we have
2593 proposals out and we will be issuing some actually final rule
2594 coming up and another proposed rule. So we are marching down
2595 the list. The challenge for us are the statutory
2596 requirements to go through this process, advisory committee
2597 meetings and doing rulemaking. In fact, this challenge--I
2598 mean, you all in legislation are telling us do this faster.
2599 This is a challenge when we have to change classification on
2600 a product. It is by rulemaking, and it cuts both ways. On
2601 the one hand, it is a weakness with 510(k). If you have a
2602 device that is in the 510(k) pathway and we have new data to
2603 say there are concerns, it should not be under 510(k), it

2604 should have been under PMA, a higher classification. It will
2605 take us several years to go there and puts a terrible
2606 quandary on doctors and patients who are out there and have
2607 the technology and they don't have the data behind it, or we
2608 take it completely off the market and that doesn't make sense
2609 in a lot of cases. We want to leave it there. That process
2610 is too burdensome.

2611 On the flip side--and that is a safety issue. On the
2612 flip side, though, when we want to down-classify so we have
2613 something at a high risk or moderate risk and we want to make
2614 it lower risk and reduce regulatory burdens, we have so many
2615 statutory burdens on us, it is hard to do that. So it is
2616 hard for us to be deregulatory and it is hard for us to set
2617 the bar in the right place. And if that were fixed, that
2618 would solve a big challenge. It would actually buttress
2619 things like the 510(k) program where the attention goes on
2620 these few devices where there are a lot of issues but it will
2621 also allow us to free up resources by down-classifying
2622 devices that should be subject to a lower standard.

2623 Mr. {Pallone.} You know, just an editorial comment. I
2624 don't envy you your job because it is a constant problem
2625 which is on the one hand, we want innovation, we want
2626 approvals to move more quickly, but we also have to balance
2627 that with public safety, and we get it at both ends. I mean,

2628 I as a politician get that from both ends, you know, why
2629 aren't you moving quickly. On the other hand, everything has
2630 to be safe. You know, it is tough. I mean, I know a lot of
2631 my colleagues particularly on the other side of the aisle
2632 have been saying there are too many hurdles but you can't
2633 sacrifice public safety, either, so it is a difficult
2634 quandary. Thank you.

2635 Dr. {Shuren.} I appreciate that. Actually, not even my
2636 dog is talking to me these days.

2637 Mr. {Pitts.} The chair thanks the gentleman.

2638 The chair has two unanimous consent requests. One, the
2639 report by the National Venture Capital Association entitled
2640 ``Vital Signs.'' You have seen that?

2641 Mr. {Pallone.} That is fine.

2642 Mr. {Pitts.} Without objection.

2643 Mr. {Pallone.} And the other being from--

2644 Mr. {Pitts.} Mr. Burgess's letter?

2645 Mr. {Pallone.} --my colleague is fine too, yes.

2646 Mr. {Pitts.} Without objection, those will be entered
2647 in the record.

2648 [The information follows:]

2649 ***** COMMITTEE INSERT *****

|
2650 Mr. {Pitts.} That completes panel one. Thank you very
2651 much, Dr. Shuren. We look forward to sitting down with you
2652 and working with you as the process goes forward.

2653 At this point we will take a 5-minute recess while panel
2654 two sets up on the table, and we will reconvene in 5 minutes.

2655 [Recess.]

2656 Mr. {Pitts.} I will ask all of our guests and witnesses
2657 to please take their seats, and I will introduce the second
2658 panel. First of all, thank you all for agreeing to testify
2659 before the subcommittee today. Let me quickly introduce each
2660 one of you, and you can present your testimony, summarize
2661 your statements in this order. Mr. David Perez, the
2662 President and CEO of Terumo BCT; Ms. Elisabeth George, Vice
2663 President of Global Government Affairs, Regulations and
2664 Standards for Philips Healthcare; Mr. Ralph Hall, Professor
2665 at the University of Minnesota Law School; Dr. Ross Jaffe,
2666 Managing Director of Versant Ventures; Dr. Aaron Kesselheim,
2667 an Internal Medicine Physician at Brigham and Women's
2668 Hospital; Dr. Art Sedrakyan, an Associate Professor at Weill
2669 Cornell Medical College; Ms. Lisa Swirsky, Senior Health
2670 Policy Analyst at Consumers Union; and Mr. Jim Shull from the
2671 State of New Jersey.

2672 Again, thank you all for coming. We have your prepared

2673 statements, which will be entered into the record. Mr.
2674 Perez, we will begin with you. You are recognized for 5
2675 minutes to summarize your testimony.

|
2676 ^STATEMENTS OF DAVID PEREZ, PRESIDENT AND CEO, TERUMO BCT;
2677 ELISABETH M. GEORGE, VICE PRESIDENT, GLOBAL GOVERNMENT
2678 AFFAIRS, REGULATIONS AND STANDARDS, PHILIPS HEALTHCARE; RALPH
2679 HALL, J.D., DISTINGUISHED PROFESSOR AND PRACTITIONER,
2680 UNIVERSITY OF MINNESOTA LAW SCHOOL; ROSS JAFFE, M.D.,
2681 MANAGING DIRECTOR, VERSANT VENTURES; AARON S. KESSELHEIM,
2682 M.D., J.D., M.P.H., ASSISTANT PROFESSOR OF MEDICINE AT
2683 HARVARD MEDICAL SCHOOL, DIVISION OF PHARMACOEPIDEMOLOGY AND
2684 PHARMACOECONOMICS, BRIGHAM AND WOMEN'S HOSPITAL; ART
2685 SEDRAKYAN, M.D., PH.D., ASSOCIATE PROFESSOR AND DIRECTOR,
2686 PATIENT-CENTERED COMPARATIVE EFFECTIVENESS PROGRAM, WEILL
2687 CORNELL MEDICAL COLLEGE AND NEW YORK PRESBYTERIAN HOSPITAL;
2688 LISA SWIRSKY, SENIOR HEALTH POLICY ANALYST, CONSUMERS UNION;
2689 AND JIM SHULL, BROWNS MILLS, NEW JERSEY

|
2690 ^STATEMENT OF DAVID PEREZ

2691 } Mr. {Perez.} Thank you, Chairman Pitts, Ranking Member
2692 Pallone and members of the committee for this opportunity to
2693 testify today.
2694 My name is David Perez and I am the President and Chief
2695 Executive Officer of Terumo BCT and Chairman of Terumo
2696 Corporation's Blood Management Business board, and I am

2697 responsible for leading the strategic direction, the growth
2698 and the execution of this global organization.

2699 At Terumo BCT, we believe in the potential of blood to
2700 do even more for the world than it does today. This belief
2701 unites our organization, inspires our innovation and
2702 strengthens our collaboration with customers, which
2703 ultimately benefits the patients that we all serve. Working
2704 with the American Red Cross, community blood centers
2705 throughout the United States as well as hospitals, we unlock
2706 the potential of blood as we strive to make even safer high-
2707 quality transfusions available to people. We help our
2708 customers bring even more treatment options to patients with
2709 advanced blood therapies, and we support researchers in
2710 developing cell therapies that may fundamentally improve
2711 health care.

2712 I want to thank you for convening today's hearing and
2713 for your interest in improving medical device regulation for
2714 patients in our industry.

2715 Over the course of the last year, members of this
2716 committee have demonstrated their focus on improving the
2717 efficiency and effectiveness of FDA regulation in your
2718 outreach to the agency and to the policy proposals that show
2719 your commitment to this important issue.

2720 The medical technology industry is an American success

2721 story. Our industry directly employs more than 400,000
2722 workers nationwide including 22,000 in the State of
2723 Pennsylvania, 20,000 in New Jersey and over 11,000 in my home
2724 State of Colorado, making these among the States with the
2725 largest med tech employment. In 2011, our company alone
2726 added 297 jobs, 224 of which were in manufacturing.

2727 Whether the firm is large or small, success in our
2728 industry comes only from innovation, the creation of
2729 diagnostics, treatments and cures that extend and enhance
2730 lives. While we are very proud of our contribution to the
2731 U.S. economy, we are even more proud of our contributions to
2732 improving patient care.

2733 Even though we are making progress in improving patient
2734 care and see immense future opportunities, we are also very
2735 worried. Today, America is the world leader in medical
2736 technology but there are warning signs that our lead is
2737 slipping, and a key factor in our loss of competitiveness has
2738 been the decline in the FDA's performance. Put simply, FDA
2739 is a crucial partner to our company's efforts to bring safe
2740 and effective medical devices to patients. Without a strong,
2741 effective and efficient FDA, we cannot have a strong and
2742 competitive industry.

2743 While the FDA has consistently maintained an excellent
2744 record of assuring the safety and effectiveness of the

2745 products it reviews, delays in product approval,
2746 inconsistency in the review process and the resulting
2747 downstream effects on investment and innovation have
2748 undermined the competitiveness of our industry and harm
2749 patient access to new treatments, diagnostics and cures.

2750 I am pleased to be able to report that after extensive
2751 negotiations, industry and FDA recently reached an agreement
2752 in principle for a new user fee package, which we believe has
2753 the potential to help achieve meaningful change in FDA
2754 performance through groundbreaking accountability and
2755 transparency measures.

2756 The FDA leadership and Dr. Shuren in particular have
2757 recognized the need to vigorously address the issues
2758 affecting the device center, and I want to applaud them for
2759 this commitment. The user fee agreement is a huge step in
2760 the right direction. It is good for industry, it is good for
2761 the FDA, and most of all, it is good for patients.

2762 The user fee agreement builds the conditions for success
2763 in a number of major ways. For the first time ever, this
2764 user agreement establishes average total time goals for FDA
2765 product review. All previous agreements have set goals in
2766 terms of time on the FDA clock. What matters to companies
2767 like my own and patients is the time it actually takes to get
2768 the product to patients. By setting in place this new goal,

2769 we will helping the FDA focus on the metric that is truly the
2770 most important to all concerned.

2771 The agreement also includes process standards that we
2772 anticipate will improve the consistency and timeliness of the
2773 review process independent of the specific time goals, and
2774 the agreement provides for meaningful pre-submissions
2775 interactions where agreements reached will not change so that
2776 companies know what the FDA expects and the FDA is bound by
2777 its commitments. And a new procedure, what we call No
2778 Submission Left Behind, will be instituted so that if the FDA
2779 time target is missed, the company and the FDA will meet to
2780 work out a schedule to resolve the remaining issues so that
2781 the submission doesn't go to the bottom of the pile.

2782 The agreement also provides for greater accountability
2783 so that FDA's success will be transparent to FDA management,
2784 to industry, to patients and to Congress so that any problems
2785 that arise can be corrected promptly. There will be
2786 quarterly and annual reporting on key metrics both the FDA
2787 and the industry have agreed are very important. In
2788 addition, this agreement requires analysis of FDA's
2789 management of the review process by an independent consulting
2790 organization coupled with an FDA corrective plan to address
2791 opportunities for change and improvement.

2792 Finally, to give FDA additional tools to meet these

2793 goals, the agreement provides \$595 million in user fees,
2794 additional reviewers, lower management-to-reviewer ratios,
2795 enhanced training, and other resources provided by the
2796 agreement will give FDA what it needs to improve performance.

2797 I appreciate the committee's work and its focus on
2798 enactment of this reauthorization package as soon as
2799 possible, and once again, I thank you for the opportunity to
2800 testify.

2801 [The prepared statement of Mr. Perez follows:]

2802 ***** INSERT 2 *****

|
2803 Mr. {Pitts.} The chair thanks the gentleman and now
2804 recognizes Ms. George for 5 minutes for an opening statement.

|
2805 ^STATEMENT OF ELISABETH GEORGE

2806 } Ms. {George.} My name is Elisabeth George and I
2807 represent Philips Healthcare as their Vice President of
2808 Global Government Affairs, Regulations and Standards. I want
2809 to start by thanking Chairman Pitts and Ranking Member
2810 Pallone for holding today's hearing. I also want to thank
2811 you for your particular interest in medical innovation and
2812 for leading a policy discussion on how we can work together
2813 to collectively improve the medical device user fee program.

2814 It is clear to me that we all share the goal of getting
2815 safe and innovative products to U.S. patients in a timely and
2816 predictable manner. Philips Healthcare employs over 15,000
2817 hardworking Americans in cities and towns across the country.
2818 We are just one in a global industry. Philips Healthcare's
2819 current activities are organized across four businesses:
2820 imaging systems, patient care and clinical informatics, home
2821 health care solutions, and customer services. We have
2822 appreciated your steadfast support in ensuring the access to
2823 medical technology and particularly imaging and its important
2824 appropriate use for patients.

2825 I have worked for Philips Healthcare for more than 15
2826 years. I have managed strategic planning and technical

2827 aspects for global affairs, regulations and standards. I
2828 have also served on multiple FDA advisory panels through the
2829 years and have most recently represented the medical imaging
2830 industry during the MDUFA negotiations with the FDA. As an
2831 industry negotiator, I am pleased to talk with Congress today
2832 about the agreement in principle between the medical device
2833 industry and FDA. We believe that this agreement will
2834 facilitate improved transparency and consistency leading to
2835 better predictability and more timely access for patients.

2836 After negotiating for more than a year, we believe that
2837 this agreement is balanced and is fair to all stakeholders.
2838 We hope this package will lead to a timely reauthorization of
2839 the medical device user fee program. The goal of this
2840 agreement is to ensure timely patient access to safe,
2841 effective treatments and diagnostics. Although it is not
2842 formerly proposed to Congress until it receives full
2843 administrative approval and the FDA completes its public
2844 commenting period, the package as negotiated includes
2845 commitments from the agency that will improve the device
2846 review program through additional predictability,
2847 transparency and accountability. In a time of tremendous
2848 advances in medical technology, the agreement enables the
2849 industry to bring innovative, lifesaving technologies to
2850 market faster so that patients receive the highest quality

2851 care.

2852 The explicit goal of the device user fee program has
2853 been to achieve more timely clearance of safe and effective
2854 devices by providing the FDA with supplemental funds to
2855 independently evaluate applications. However, despite clear
2856 Congressional intent, FDA performance has declined steadily
2857 over the past several years. For example, fiscal year 2006,
2858 it took an average of 105 calendar days to make a final
2859 decision on a submission. The number increased to 154 days
2860 in 2009 despite the fact that the user fees had increased by
2861 over 50 percent over the same period. The decline in
2862 timeliness has been an overarching concern for industry. Our
2863 goal in this agreement was to reverse this downward trend and
2864 to ensure value for our user fee investment for both patients
2865 and innovators. The increase in resources to the agency
2866 under this agreement corresponds to more timely approval
2867 process, which will benefit patients and the manufacturers
2868 who develop these innovative technologies.

2869 The agreement includes several new quantitative goals to
2870 hold the FDA accountable. These goals include total time for
2871 decision as well as improved annual targets for 510(k)
2872 applications. The agreement also works to ensure an improved
2873 review process that is more predictable and transparent for
2874 manufacturers, patients and other stakeholders such as

2875 through enhanced clarity in the pre-submission process,
2876 enhanced guidance development and an independent assessment
2877 of the FDA's performance. These improvements are important
2878 for patients, innovation and jobs in America.

2879 I believe it is important that Congress do everything
2880 possible to encourage high-tech 21st century industries like
2881 the medical device manufacturing that will continue to create
2882 jobs and necessary to grow the U.S. economy. We are very
2883 appreciative of members of this committee who have held a
2884 series of hearings and introduced a number of bills in an
2885 effort to respond to these concerns and improve the FDA
2886 review process for medical devices. I believe that our
2887 collective efforts will lead to constructive improvements.

2888 Thank you for your consideration of these important
2889 issues. As the legislative process moves forward, we look
2890 forward to continuing to work with Congress and the
2891 Administration to ensure patients are guaranteed timely
2892 access to medical technologies.

2893 I again thank you for this invitation.

2894 [The prepared statement of Ms. George follows:]

2895 ***** INSERT 3 *****

|
2896 Mr. {Pitts.} The chair thanks the gentlelady and
2897 recognizes Mr. Hall for 5 minutes for an opening statement.

|
2898 ^STATEMENT OF RALPH HALL

2899 } Mr. {Hall.} Chairman Pitts, Ranking Member Pallone,
2900 members of the committee, I appreciate the opportunity to
2901 address you on these important issues of medical device
2902 regulation. I serve on the faculty of the University of
2903 Minnesota Law School. I am also part-time counsel with
2904 Faegre Baker Daniels and am CEO of a four-person startup
2905 company.

2906 I am here to focus on two matters: the agency's
2907 authority in the area of medical device regulation and the
2908 safety performance of FDA in its actual review. I believe it
2909 is important to differentiate between questions of authority
2910 from questions of implementation. Authority is whether the
2911 agency can act or has the power to compel action, while
2912 implementation goes to issues such as resources, skill sets,
2913 timing, processes, etc. The user fees that are under
2914 discussion specifically today primarily address
2915 implementation challenges and are intended to address those.

2916 On the authority front, the agency has extensive
2917 authority for the entire lifecycle or, as we call it, total
2918 product lifecycle, of a device from initial design to final
2919 obsolescence. There are of course improvements, some of them

2920 which have been discussed in the de novo process or HDEs, for
2921 example, but fundamentally, the agency has the current
2922 authority to require products to meet the statutory standard
2923 of a reasonable assurance of safeness and effectiveness.
2924 This is true under both the 510(k) system and the PMA system.
2925 There are differences in how we achieve that objective or
2926 that test but that same statutory standard applies to all
2927 products.

2928 Along the same lines, the agency has extensive
2929 postmarket authority. Examples include the MDR system, the
2930 522 orders, MedSun, registries, and there have been
2931 discussions about registries. It is important to note again
2932 on the authority front that the agency currently has the
2933 authority under the 510(k) system to mandate patient
2934 registries for products for which it believes such registries
2935 are appropriate and valuable. The agency likewise has
2936 extensive authority in the areas of recall and dealing with
2937 product issues including the authority to ban products where
2938 that is necessary and the authority to mandate recalls.

2939 The major question then is, how is the agency performing
2940 on the safety aspects. I leave to others the issues of
2941 impact on innovation, timeliness, predictability, etc. We
2942 have performed a study looking at medical device recalls. We
2943 have analyzed 5 years of data. We are actually in the

2944 process right now of analyzing another year's worth of data.
2945 That is not yet completed. The conclusion of this study is
2946 that the agency is doing a very good job on the safety
2947 aspect. The vast majority of products that get through their
2948 system do not have significant safety issues. It is obvious
2949 and critical to remember that all medical devices have risks
2950 and the statutory standard is a balance between the benefit
2951 and the risk of the product. So one of the key aspects and
2952 requirements of the system is to identify the risks so that a
2953 knowing balance can be made between the risks and the
2954 benefits, and when you look at the data, you can see that
2955 greater than 99.5 percent of all product approvals do not
2956 result in a class I recall, that the majority of recall
2957 safety issues that do occur are postmarket issues:
2958 manufacturing mistakes, labeling errors, etc. And changes to
2959 a premarket system obviously can impact events that take
2960 place after product approval.

2961 Quality systems are the key to improving product safety.
2962 Of all recalls, as we have looked at the data, approximately
2963 90 percent of all of those have some relationship to quality
2964 systems and improvements in quality systems therefore provide
2965 the greatest leverage. Very preliminarily, we have looked at
2966 2010 data, as I mentioned. That data seems consistent with
2967 what we have seen to date with the other data, with a slight

2968 increase in manufacturing issues. We are not clear if that
2969 is statistical or not. We have also taken a look at class II
2970 recalls, and preliminarily, the reasons for recall appear to
2971 be consistent between class I and class II recalls.

2972 So in conclusion, the agency has multiple control points
2973 to ensure product safety and effectiveness, not just one:
2974 quality systems, premarket approval, postmarket approval.
2975 The agency has authority, extensive authority both pre- and
2976 postmarket, and the agency's safety record has been very good
2977 over the past years.

2978 Thank you very much.

2979 [The prepared statement of Mr. Hall follows:]

2980 ***** INSERT 4 *****

|
2981 Mr. {Pitts.} The chair thanks the gentleman and
2982 recognizes Dr. Jaffe for 5 minutes for an opening statement.

|
2983 ^STATEMENT OF ROSS JAFFE

2984 } Dr. {Jaffe.} Chairman Pitts, Ranking Member Pallone,
2985 members of the subcommittee, thank you for the opportunity to
2986 testify today. My name is Ross Jaffe. I am a physician
2987 trained in internal medicine who for the last 21 years has
2988 had the privilege of working to help develop innovative
2989 medical technologies.

2990 In my role as a physician and venture capitalist, over
2991 the last few years I more and more frequently face a
2992 frustrating paradox. On the one hand, we live in a time of
2993 incredible innovation in science and medicine that I see
2994 embodied in fascinating technologies every day. On the other
2995 hand, more and more often I am forced to turn down many of
2996 these important medical innovations because our unpredictable
2997 regulatory system here in the United States has stretched
2998 development time frames and increased capital requirements
2999 needed to fund these technologies, precluding adequate
3000 investment return for my investors.

3001 It is important to note that our investors are primary
3002 university endowments, foundations and pension funds, which
3003 rely on us to generate a positive return on their capital.
3004 If we do our jobs well, not only do patients benefit and

3005 physicians have access to more innovative medical
3006 technologies, high-quality jobs are created, universities can
3007 educate more students, foundations can do more good works,
3008 and people can retire in greater comfort, a real win-win-win
3009 system that supports medical innovation and the U.S. economy.

3010 Colleagues of mine who have testified during previous
3011 hearings have described how most medical innovation comes
3012 from small venture-backed companies. However, the growing
3013 uncertainty with the FDA has dramatically reduced the amount
3014 of investment available to fund innovative medical companies.
3015 According to data from PriceWaterhouseCoopers, in 2007, 116
3016 early-stage companies raised approximately \$720 million in
3017 initial financing. In just 4 short years, that investment
3018 amount has dropped by more than 70 percent to just 55
3019 companies raising only \$200 million. To put this in
3020 perspective, 2011 saw the lowest level of venture capital
3021 investment in medical startups in the last 16 years.

3022 In a recent survey by the National Venture Capital
3023 Association, which has been referenced this morning, 42
3024 percent of health care venture firms expect to decrease
3025 investment in medical device companies over the next 3 years.
3026 In addition, 31 percent of firms expect to shift health care
3027 investment and operational focus away from the United States
3028 towards Europe and Asia. In both cases, regulatory

3029 challenges here in the United States were cited as the
3030 primary factor for declining investment and driving
3031 investment overseas. Indeed, it is now common for many
3032 innovative lifesaving technologies, for example, percutaneous
3033 heart valves, to be available for patients in Europe years
3034 before they are available to patients here in the United
3035 States.

3036 Fortunately, within the last year or so, the FDA
3037 leadership including Dr. Shuren has acknowledged how
3038 regulation is slowing innovation and driving product
3039 development overseas. They have begun internal efforts to
3040 improve FDA processes as illustrated by a series of draft
3041 guidance documents released over the past few months.

3042 One notable efforts seeks to make explicit FDA
3043 considerations and risk-benefit determinations for premarket
3044 approval. Under the law, FDA is supposed to assess medical
3045 technologies to assure that the probable benefits are greater
3046 than the probable risks. Unfortunately, over the past few
3047 years, many FDA reviewers appear to be applying a different
3048 standard, weighing the probable benefit against any possible
3049 risk, which is not the standard in the law. If implemented
3050 appropriately, this guidance should make risk-benefit
3051 determinations more patient-centric and evidence-based and
3052 therefore improve the transparency, consistency and

3053 accountability of FDA decision-making, and I was pleased to
3054 hear today that that should be moving forward very quickly in
3055 the next few months.

3056 Beyond administrative changes under consideration by the
3057 FDA, the MDUFA reauthorization being discussed at this
3058 hearing will include additional process enhancements as well
3059 as needed resources to increase the predictability of the
3060 process. However, resources alone are not enough. We also
3061 need meaningful operational improvements, not only through
3062 MDUFA but also through additional legislation that leads to
3063 better application of the least-burdensome principle,
3064 streamlining the de novo process and revision of conflict of
3065 interest policies to allow more leading experts to sit on FDA
3066 advisory panels.

3067 In closing, let me be clear about one thing. We are not
3068 asking for increased regulatory predictability, consistency
3069 or efficiency at the expense of public safety. Innovation
3070 and safety are not a tradeoff. It is not an either-or. We
3071 absolutely need both. As investors, my colleagues and I
3072 pursue medical innovations precisely because they are safer
3073 and more effective for patients, preferably when they also
3074 can reduce health care costs. We need to work together to
3075 assure a regulatory system that supports the timely
3076 development of innovative products and therefore enables

3077 safer and more effective patient care.

3078 Thank you.

3079 [The prepared statement of Dr. Jaffe follows:]

3080 ***** INSERT 5 *****

|
3081 Mr. {Pitts.} The chair thanks the gentleman, and Dr.
3082 Kesselheim, you are recognized for 5 minutes for an opening
3083 statement.

|
3084 ^STATEMENT OF AARON KESSELHEIM

3085 } Dr. {Kesselheim.} Chairman Pitts, Ranking Member
3086 Pallone and members of the Subcommittee on Health, thank you
3087 very much for the chance to share my thoughts with you today
3088 about the regulation of medical devices. I am Assistant
3089 Professor of Medicine at Brigham and Women's Hospital and
3090 Harvard Medical School in the Division of
3091 Pharmacoepidemiology and Pharmacoeconomics.

3092 One essential question being addressed in today's
3093 hearing is whether requiring the FDA to loosen its standards
3094 for medical device regulation would encourage innovation and
3095 help patients. Some offer the European Union as a model
3096 because high-risk devices generally make it to market sooner
3097 and more easily there. The main reason is that E.U. device
3098 approval usually only requires studies in small numbers of
3099 patients showing the device appears to be safe and performs
3100 as expected. Such evidence could include demonstrating that
3101 a new stent expands appropriately in the coronary artery.
3102 There are no requirements in the E.U. that companies
3103 demonstrate that their devices benefit patients. By
3104 contrast, the FDA requires more robust evidence of safety and
3105 effectiveness for many of these implantable or high-risk

3106 devices. Thus, approval for the same coronary stent might
3107 require showing fewer cardiac events or the need for another
3108 invasive procedure.

3109 The current E.U. system for approving medical devices
3110 recalls the U.S. prescription drug market before 1962 when
3111 the FDA only required limited studies of purity or safety
3112 before a drug could be marketed, but after the thalidomide
3113 public health crisis, legislation gave the FDA authority to
3114 compel reasonable safety and efficacy data before a new drug
3115 could be sold. This reform was almost derailed by
3116 accusations that it would threaten the viability of the
3117 pharmaceutical industry, but what happened instead was that
3118 the U.S. pharmaceutical industry grew into one of the most
3119 profitable in the world. Why? FDA validation meant that
3120 physicians could prescribe drugs confident that a neutral
3121 expert body had certified their efficacy and safety.
3122 Requiring companies to demonstrate that their products were
3123 effective also created incentives for manufacturers to impose
3124 a higher standard on their product evaluation, leading to
3125 their developing some of the most important medications we
3126 have, and today, nobody seriously advocates returning to a
3127 time when we essentially let any drug on the market and then
3128 figure out afterwards which ones were useful or dangerous
3129 based on haphazard patient experience.

3130 But this is indeed what is happening in the E.U. for
3131 approval of even the highest-risk medical devices. For
3132 example, the French company PIP is now under criminal
3133 investigation for using non-medical-grade silicone in breast
3134 implants. PIP's silicone implants were never submitted for
3135 marketing in the United States. Or take the case of the
3136 PleuraSeal lung sealant system, which was approved in the
3137 E.U. in 2007 to treat air leaks after pulmonary resection
3138 surgery. A clinical study conducted as part of an FDA
3139 premarket approval application showed in 2011 that it had
3140 triple the rate of adverse events compared to standard
3141 techniques. As a result, the device was rejected by the FDA
3142 and a worldwide recall was initiated. Or the CorCap cardiac
3143 support device, a harness for patients with heart failure to
3144 improve their cardiac output. The device was granted E.U.
3145 approval in 2000 but a pivotal U.S. premarket trial conducted
3146 by 2004 showed no change in mortality, had numerous
3147 irregularities including missing data for about 40 percent of
3148 patients, and it was not approved by the FDA. Thus, the FDA
3149 requirement for premarket testing helped identify unsafe or
3150 ineffective devices or prevented companies from introducing
3151 substandard products, sparing U.S. patients from being
3152 exposed to them.

3153 But the FDA approval process is not perfect. Rigorous

3154 premarket testing cannot identify all safety concerns, and
3155 the FDA must use a least-burdensome approach in working with
3156 manufacturers to decide what clinical data will be required.
3157 In addition, experts have identified the clearance of high-
3158 risk devices through pathways designed for low-risk devices
3159 as an important inconsistency between the FDA's mandate and
3160 practice. Thus, patient safety also requires enhanced
3161 postmarket testing of new devices.

3162 In the drug world, one of the lessons from the Vioxx
3163 episode was that safety surveillance cannot be dependent on
3164 the receipt of adverse-event reports alone. More active
3165 postmarket device surveillance would include development of
3166 national registries with mandatory reporting of all implanted
3167 devices along with automatic review of clinical experiences
3168 for certain devices after a period of years to ensure that
3169 they are producing the expected benefits. With today's
3170 advances in informatics and epidemiological surveillance
3171 techniques, this would not be problematic in terms of either
3172 cost or regulatory burden.

3173 In summary, patients and physicians do not want access
3174 to any latest drug or device. Rather, they want access to
3175 products that have meaningful clinical benefits with
3176 reasonable assurance of safety. The Medical Device User Fee
3177 Act should bolster this essential role of the FDA by

3178 increasing funding for inspections of manufacturers, hiring
3179 of more reviewers or safety experts, and by providing for
3180 more rigorous postmarket surveillance so that devices proven
3181 to be effective and safe can be used confidently by
3182 physicians for the benefit of their patients.

3183 Thank you very much.

3184 [The prepared statement of Dr. Kesselheim follows:]

3185 ***** INSERT 6 *****

|
3186 Mr. {Pitts.} The chair thanks the gentleman, and Dr.
3187 Sedrakyan, you are recognized for 5 minutes for an opening
3188 statement.

|
3189 ^STATEMENT OF ART SEDRAKYAN

3190 } Dr. {Sedrakyan.} Thank you very much, Chairman Pitts
3191 and Ranking Member Pallone and members of the subcommittee.
3192 It is a pleasure to talk today. I am Art Sedrakyan. I am an
3193 Associate Professor at Weill Cornell Medical College, and I
3194 am directing the Patient-Centered Comparative Effectiveness
3195 Research Program that is focusing on safety and effectiveness
3196 of devices. In my career, I have been exposed to regulatory,
3197 academic and manufacturing perspectives.

3198 In the past decade, we have seen a lot of groundbreaking
3199 devices that will change the practice of medicine. However,
3200 at the same time, we have seen a number of high-profile
3201 failures of approved medical devices. Many of these failures
3202 occurred through these pathways which was called substantial
3203 equivalency pathway, which was 510(k) pathway.

3204 The mere presence of this pathway creates an environment
3205 that is making people prone to committing errors. The
3206 absence of funding for robust postmarket surveillance is an
3207 even more important issue that we need to consider. The
3208 Centers for Devices and Radiological Health recognized the
3209 limitations of postmarket surveillance infrastructure today
3210 and they set up a program called Medical Device Epidemiology

3211 Network, and it also created a new entity that will look for
3212 a specific example, an orthopedic device. It is called
3213 International Consortium of Orthopedic Registries that is
3214 planning to bring together 15-plus nations and registries
3215 from around the world to create an infrastructure that will
3216 enhance postmarket surveillance in the area of orthopedic
3217 devices. However, there is limited funding to sustain and
3218 replicate this effort in many other areas.

3219 The absence of robust postmarket infrastructure system,
3220 in the absence of that, we need to make only gradual
3221 adjustment to the balance of pre- and postmarket evaluation.
3222 It is important for us to build these large comprehensive
3223 registries and registry consortia and also advance the
3224 registry science. The process will be through evidence-based
3225 innovation and will protect manufacturers as well. Only
3226 after we build this strong postmarket surveillance
3227 infrastructure will we accumulate evidence of device
3228 performance in a variety of device performance in a real-
3229 world setting. We can make those adjustments at the
3230 premarket threshold.

3231 Let me discuss the issue that shows the limitations for
3232 both premarket and postmarket infrastructure and the
3233 investment we have to make to ensure that we don't get
3234 disasters in the future. There are over 270,000 hip

3235 replacement devices used in the country, and this is a very
3236 safe operation. There are some devices that are very
3237 successful and have 95 percent success rate over a 10-year
3238 period. Even in this environment where there are very
3239 successful devices on the market, through the 510(k) pathway
3240 new devices were introduced, so-called metal-on-metal
3241 devices, and a specific example is the ASR device. The
3242 device has been approved through the path of substantial
3243 equivalency and used a predicate device of the same company
3244 that if you look closely does not really resemble the
3245 original predicate device. It has undergone substantial
3246 transformation. Over the iterative cycle, I was able to--
3247 these products entered the market because you could--that if
3248 you use one predicate as a predicate for another device and
3249 then so forth encourages vicious cycle for bringing device
3250 that might be dissimilar to the previous device that has been
3251 approved.

3252 Without any evidence, these metal-on-metal devices were
3253 quickly adopted by surgeons and registries around the world
3254 reported really disastrous outcomes with this particular
3255 implant. DePuy recalled 93,000 of these devices out of the
3256 market, and the evidence has been summarized in our paper and
3257 also well covered by Barry Meyer at New York Times.
3258 Interestingly, there would be more than 50,000 patients that

3259 will undergo this serious revision surgery in the next 10
3260 years, and this is going to cost American taxpayers billions
3261 of dollars of additional costs, and this has--I am not aware
3262 of any discussion between CMS and manufacturers to cover side
3263 effects related to faulty medical products.

3264 So I have some graphic pictures in my testimony that
3265 show that these revision surgeries that are happening are not
3266 really trivial problems. People have substantial suffering
3267 related to these procedures.

3268 I have to also note that even though European registries
3269 were the first and Australian registries were the first to
3270 see these problems, they are not necessarily the best
3271 registries that we have today in the world and we should
3272 build much more robust infrastructure system in this country
3273 and sometimes multinational infrastructure to be able to
3274 prevent this happening in the future, and one of the most
3275 important ways that we can do that is through public-private
3276 partnership, and a public-private partnership that can be led
3277 by FDA and involve stakeholders in partnership with
3278 manufacturers and insurers.

3279 Thank you very much.

3280 [The prepared statement of Dr. Sedrakyan follows:]

3281 ***** INSERT 7 *****

|
3282 Mr. {Pitts.} The chair thanks the gentleman and
3283 recognizes Ms. Swirsky for 5 minutes for an opening
3284 statement.

|
3285 ^STATEMENT OF LISA SWIRSKY

3286 } Ms. {Swirsky.} Good afternoon. My name is Lisa Swirsky
3287 and I am a Senior Health Policy Analyst at Consumers Union.
3288 Consumers Union is the publisher of Consumer Reports magazine
3289 and Best Buy Drugs. We also have a Safe Patient Project,
3290 which is a campaign to improve the safety and efficacy of
3291 devices. We are also member of the Patient Consumer and
3292 Public Health Coalition, which is a broad coalition of public
3293 interest groups interested in the safety and efficacy of
3294 drugs and devices, and some of our comments today reflect the
3295 broader interest of that community.

3296 Consumers Union urges Congress to take a balanced
3297 approach to reauthorizing MDUFA, focusing both on the real
3298 need to keep deficient devices off the market while also
3299 providing timely access to safe and effective devices.
3300 Safety failures such as those that occurred with metal-on-
3301 metal hips and surgical mesh resulted from failures in the
3302 device regulatory system, particularly the problem 510(k)
3303 process. But we would also urge Congress to understand that
3304 behind those failures, there are real people. Lana Keaton is
3305 one such consumer. She was a previously healthy woman who
3306 was treated for what was a pretty routine condition for a

3307 middle-aged woman, incontinence. She went on for surgery for
3308 insertion of a synthetic mesh bladder sling, which is a
3309 product that was cleared through the 510(k) system. She
3310 awoke from surgery in extreme pain due to complications from
3311 the mesh, and she has had to undergo 17 surgeries, and she
3312 has another one upcoming.

3313 CU urges Congress to remember the experiences of
3314 hundreds of thousands of people like Lana who have been
3315 injured by defect devices as it considers reauthorization of
3316 the medical device user fee program. Our priority is that
3317 these devices work and that they don't hurt people, and we
3318 believe that with proper resources, we can have a streamlined
3319 timely system without sacrificing safety.

3320 To this end, we would ask Congress to strengthen the
3321 premarket approval process for devices. In particular,
3322 Congress should pass legislation ensuring that recalled
3323 devices cannot be used as a predicate for subsequent devices.
3324 Congress should also shore up the system for monitoring
3325 devices once they are already on the market by providing FDA
3326 with the authority to require postmarket studies when it
3327 deems necessary to ensure the safety of devices and also to
3328 improve postmarket surveillance tools such as Sentinel and
3329 the adverse event reporting system.

3330 CU has reviewed provisions of the agreement as described

3331 in the minutes from the FDA's January 31st meeting with
3332 industry, and we offer the following comments and concerns on
3333 the outlines of the agreement in principle.

3334 Overall, we feel that the user fee amount is inadequate.
3335 During the course of negotiations with industry, the FDA
3336 indicated it would need somewhere between \$770 million to up
3337 to \$1 billion to implement the program enhancements that it
3338 was asking for. Now, while we understand that FDA has since
3339 scaled back those proposals in light of the lower-than-
3340 expected user fee, nonetheless, a lot of those program
3341 enhancements still remain in the agreement and we are
3342 concerned that as long as they remain in the agreement
3343 without dedicated funding, they will become an unfunded
3344 mandate on an agency that is already struggling to meet
3345 current requirements. And we would ask that if Congress
3346 thinks that these enhancements are beneficial, that they
3347 appropriate adequate funding.

3348 We also are concerned that the agreement overemphasizes
3349 the achievement of performance goals when device applications
3350 are reviewed and processed within a reasonable time frame
3351 because the application is sound and the device is safe and
3352 effective. This is obviously a win-win for consumers and
3353 industry. However, there is no mention in the agreement that
3354 these goals are conditioned on the overall quality of the

3355 products, the complexity of the products, the benefit of the
3356 products to consumers or really any factors that may be
3357 relevant to protecting the public health. Notably, the word
3358 ``safety'' does not appear once in the minutes from the
3359 meeting where industry and FDA came to agreement. We
3360 consider this a striking omission, given recent notable
3361 safety lapses by the device industry.

3362 Even more worrisome, the agreement in principle
3363 references total time to decision, goals based on calendar
3364 years in addition to the goals based on FDA days. Current
3365 performance goals stop the clock when the FDA sends an
3366 application back to a device manufacturer when the agency
3367 needs additional information. Under the agreement, the FDA
3368 is kept on the clock even when it needs to get further
3369 information. CU opposes any kind of binding of the FDA to
3370 get the information that it needs to ensure the safety and
3371 adequacy of devices.

3372 We have further concerns about provisions in the
3373 agreement that call for incorporating the patient perspective
3374 and risk-benefit considerations. The industry has requested
3375 that groups that represent patients with a specific disease
3376 represent the patient perspective. However, in our
3377 experience, many of these patient groups are heavily funded
3378 by industry. Patient representatives used for these purposes

3379 should be held to conflict of interest standards and should
3380 be required to disclose any financial ties with industry.

3381 Finally, as Congress considers MDUFA, we urge it to
3382 provide a direct seat at the table for consumers in future
3383 reauthorization negotiations. While the stakeholder meetings
3384 that FDA conducted with consumer groups was an advancement
3385 over prior authorization processes, they still kept consumers
3386 at arm's length from negotiations that have significant
3387 implications for the public health.

3388 Thank you.

3389 [The prepared statement of Ms. Swirsky follows:]

3390 ***** INSERT 8 *****

|
3391 Mr. {Pitts.} The chair thanks the gentlelady and now
3392 recognizes Mr. Shull for 5 minutes for an opening statement.

|
3393 ^STATEMENT OF JIM SHULL

3394 } Mr. {Shull.} My name is Jim Shull. I am from Browns
3395 Mills, New Jersey. I would like to thank the committee for
3396 allowing me to speak here today.

3397 My story goes back to 2005 when I was told I had a
3398 hernia. I woke in the recovery room from the surgery in
3399 excruciating pain. Two days later, I was in such pain that I
3400 couldn't stand up straight or barely walk. I called my
3401 surgeon's office and he told me to meet him at the emergency
3402 room. He took me into an examination room, looked at the
3403 surgical site and told me that it was very infected. He
3404 prescribed an antibiotic, and morphine for the pain, but
3405 nothing seemed to help. The infection was so bad that I had
3406 streaks running down my groin.

3407 I continued to call the surgeon over the next 2 weeks
3408 only for him to tell me that I am a slow healer. At my 6-
3409 week follow-up I explained again to my surgeon that I was in
3410 unbearable pain, so, he decided to inject my groin with
3411 Novocain right through the incision and sent me back to work.

3412 The pain I was feeling was as if there was a sharp
3413 object left inside of me. After continuously going back to
3414 the surgeon he decided to send me to pain management, where

3415 over the course of 6 weeks the pain doctor injected my groin
3416 upwards of 70 times.

3417 Nothing would help the pain so I decided to investigate
3418 myself. I went back to the surgeon and explained to him what
3419 I had found. Only then did he tell me that he had put a
3420 synthetic mesh inside of me and told me that it was not the
3421 mesh, because the mesh is inert and my problem has to do with
3422 the nerves in my groin. I tried to go back to work because I
3423 couldn't afford not getting a paycheck, but the pain was so
3424 unbearable that I ended up in the ER. The doctor in the ER
3425 did a CT scan only to find nothing. That is because the mesh
3426 is transparent and cannot be seen on X-rays. The doctor in
3427 the ER told me that I probably had diverticulitis and that I
3428 needed to follow up with a GI specialist. Those tests came
3429 back negative also.

3430 I decided to get a second opinion from another surgeon
3431 and asked if he could remove the mesh from inside of me. He
3432 told me that he couldn't remove the mesh but could do an
3433 exploratory surgery to see if the nerves were stitched up.
3434 This surgeon did cut and tie off one of the nerves in my
3435 groin and thought that it would ease my suffering. After
3436 returning to him for 6 weeks in unbearable pain, he told me
3437 that there was nothing else he could do for me. So I was on
3438 my own.

3439 I finally did find a surgeon in another State and he
3440 agreed to see me. When he examined me he told me that he
3441 knew exactly what was wrong with me but to be sure he sent me
3442 to have an MRI. I went back to this surgeon and he showed me
3443 the problem. There it was: a hardened piece of synthetic
3444 mesh inside of me. So finally after almost 2 years of
3445 unbearable pain, I found someone who could give me some
3446 answers. The surgery to remove the mesh took 3-1/2 hours.
3447 When I awoke in the recovery room, the surgeon was at my
3448 bedside. He told me that he was sorry and that I would be in
3449 pain for the rest of my life. The surgeon explained to me
3450 that he had removed a balled-up piece of concrete from my
3451 groin, that the mesh had hardened and balled up, and had
3452 encapsulated the other two main nerves in my groin. In order
3453 to get the mesh out, the nerves had to be severed. He
3454 explained to me that the mesh was so hard, that when I moved
3455 it was acting like a saw and cutting into the surrounding
3456 tissue. I had a 3-inch gash in my pelvic floor along with
3457 hundreds of smaller cuts and tears.

3458 In 2008 I was diagnosed with a degenerative nerve
3459 condition. The pain that I suffer through on a daily basis
3460 consists of constant burning and sharp pains in my groin and
3461 upper thigh. My groin and upper thigh are purple and brown
3462 color because of the nerve condition I now have. I must take

3463 three strong medications--OxyContin, Percocet and Tramadol--
3464 just for the pain alone. Every 6 months I have to have radio
3465 frequency ablation done at the spinal level where the nerve
3466 roots are located. It is very uncomfortable for me to sleep
3467 at night without the help of medication. Because of this
3468 product I am no longer able to work as a printer.

3469 When I was a teenager, I had a hernia. That hernia was
3470 not repaired with mesh, but was stitched back together.
3471 Thirty-four years later and I still have no problems with
3472 that repair. The mesh that was put inside of me caused so
3473 much damage that none of the nerves will ever be able to be
3474 repaired and will never grow back. I live a life of pain
3475 because of a product that never had any kind of clinical
3476 testing and slipped through the back door of what you know as
3477 the 510(k) process based on the use of predicate devices. I
3478 am left disabled because the FDA considered surgical mesh
3479 equivalent to that of sutures and allowed it to be implanted
3480 in patients like me.

3481 After years of people reporting problems and
3482 investigations into synthetic mesh, the FDA published a
3483 public health warning. Unfortunately, the warning was only
3484 for synthetic transvaginal meshes that are used in woman.
3485 There was no public health notification for hernia meshes,
3486 which are just as tragic and cause horrible complications for

3487 men and women alike. Failing to address the hernia mesh
3488 issue puts too many people in danger. I think synthetic mesh
3489 should not be on the market because it is unsafe and I have
3490 proudly taken the challenge to work to prevent this from
3491 continuing to happen to others.

3492 In closing, I would like to say that I am only one face
3493 in thousands of people that this has happened to, and the sad
3494 part of it all is that I feel that I may be one of the lucky
3495 ones. This committee can change the laws to improve the
3496 safety of medical devices and put patients first. Surgical
3497 mesh and other medical devices should be tested for safety
3498 before they are allowed to be implanted into people like
3499 myself. We also need a national system to track what happens
3500 to patients like me after devices are implanted, to catch
3501 these problems as soon as possible.

3502 Thank you.

3503 [The prepared statement of Mr. Shull follows:]

3504 ***** INSERT 9 *****

|
3505 Mr. {Pitts.} The chair thanks the gentleman and thanks
3506 to all the panel for your testimony, and we will now begin
3507 questioning, and I will recognize myself for 5 minutes for
3508 that purpose.

3509 Dr. Jaffe, you presented some very compelling data in
3510 your testimony, and it reiterates what we have been hearing
3511 from medical device innovators who have testified before this
3512 committee and those we speak with back in our home districts.
3513 PWC reports show that in 2007, 116 medical device startups
3514 had \$720 million in funding, and that last year, 55 companies
3515 received under \$200 million. This reflects more than a half-
3516 billion-drop in funding of medical device startups. Can you
3517 explain the impact of this alarming drop in funding, the
3518 impact on patients and jobs?

3519 Dr. {Jaffe.} Thank you, Chairman Pitts. Let me start
3520 with the jobs issues first. Clearly, each of these companies
3521 may only have five to ten employees who start up funding, but
3522 if they are successful, they will grow, and many successful
3523 medical device companies we are involved with have hundreds
3524 of employees. We also know from data that for every one job
3525 we create in a company, there are three or four created in
3526 the community to support to those jobs, so clearly there is
3527 an economic impact.

3528 The more important issue, though, is really the impact
3529 on patients and potential technologies for those patients. I
3530 have an unusual job in the sense that I invest in things I
3531 hope I never have to use personally and I hope none of you or
3532 your loved ones ever need any one of the products we develop.
3533 But if you are someone with the issue that our technologies
3534 address, you will be very grateful they were developed. And
3535 the sad part of all this is that there are many technologies
3536 that I mentioned earlier that I see every day that deserve
3537 development but I can't pursue because the time and capital
3538 requirements would be too great to allow me to make returns I
3539 need to satisfy my investors' requirements, and it is the
3540 challenge of the system we all need to work on.

3541 Mr. {Pitts.} Thank you.

3542 Mr. Perez, can you give us an example of difficulties
3543 your company has had with the FDA? Have you experienced an
3544 increase in how long it takes to get through the FDA process,
3545 and why do you believe that doubling the amount you pay in
3546 user fees is going to solve what is partly a management
3547 issue?

3548 Mr. {Perez.} Well, I think the performance metrics that
3549 are specifically addressed in the MDUFA agreement go back to
3550 some of the issues that we have had with the FDA. I will
3551 give you an example. We had a pre-submission hearing with

3552 the FDA on a technology, and then we went almost 14 months
3553 before we heard back from the FDA, and a lot of that had to
3554 do with the fact that there was not agreement within the FDA
3555 on how to go forward with the approval process of a product
3556 like this, and this specific MDUFA agreement addresses that
3557 where we have a pre-submission meeting, there has to be
3558 agreements and those agreements can't be changed. We had
3559 another example where we had an agreement with the FDA on a
3560 clinical trial. We moved forward on the clinical trial. We
3561 got about halfway through the clinical trial and the
3562 requirements of that trial were changed.

3563 So once again, I think some of the things that we are
3564 trying to address regarding predictability and accountability
3565 are specifically addressed in this MDUFA agreement, and I
3566 think some of the challenges that we have, I am not saying
3567 they are all going to go away but I think some of the
3568 specific challenges that we have had will be addressed with
3569 this new agreement.

3570 Mr. {Pitts.} Ms. George, how does the proposed user fee
3571 agreement improve predictability and consistency with respect
3572 to FDA's review of medical devices, if you can be specific?

3573 Ms. {George.} I believe that there are a couple of
3574 areas that it does that. First off, that through the pre-
3575 submissions process, as was stated by Mr. Perez, there would

3576 be agreement as to what the requirements are ahead of time
3577 early prior to submission so that the manufacturer when they
3578 submit their 510(k) it includes the requirements up front so
3579 that it can flow through the process more quickly. I also
3580 think that the interaction requirement that we have put into
3581 the agreement of having earlier interaction with the FDA so
3582 that we know what the questions might be if they are going to
3583 have them, that will support it, and then the added
3584 management as through the resources that are going to be
3585 added, that will ensure consistency in how they make those
3586 determinations so that a reviewer by themselves doesn't have
3587 to make that decision.

3588 Mr. {Pitts.} Professor Hall, from what I understand,
3589 FDA has extensive postmarket authority for medical devices.
3590 Would you walk us through that authority, please?

3591 Mr. {Hall.} There are a number of authorities the
3592 agency currently has. They include obtaining information
3593 through medical device reports, so-called MDRs, the MedSun
3594 process, which is an active postmarket surveillance system
3595 linking about 350 hospitals. There is a 522 order process.
3596 You have special controls that specifically include the
3597 statutory authority for postmarket surveillance obligations,
3598 patient registries and other tools. In the PMA world, you
3599 have conditions of approval. The QSR systems include

3600 postmarket surveillance. We call them CAPA, corrective and
3601 preventive action, processes that, for example, require
3602 product trending, root-cause analysis, etc. So those are
3603 just a number of the statutory systems that are currently in
3604 place.

3605 Mr. {Pitts.} Thank you. My time is expired. The chair
3606 recognizes the ranking member, Mr. Pallone, for 5 minutes for
3607 questions.

3608 Mr. {Pallone.} Thank you, Mr. Chairman.

3609 I wanted to ask Ms. Swirsky and Ms. George, only because
3610 of time limitations, because of these advisory committees and
3611 conflict of interest. As you know, industry and some patient
3612 groups have focused on removing limits on how many experts
3613 with financial conflicts of interest may serve on the
3614 committees. Many consumer groups are concerned that for FDA
3615 and the public to be confident in the objectivity of the
3616 advice FDA receives, every effort must be made to minimize
3617 the number of conflicted experts that serve on these
3618 committees. I would like to ask Ms. Swirsky, if you could
3619 suggest ways that FDA could broaden its pool of experts. Let
3620 me start with that and then I will go to Ms. George. How
3621 would you suggest the FDA could broaden its pool of experts?

3622 Ms. {Swirsky.} I want to say first off, I think the FDA
3623 has already suggested that those caps on the waivers, which I

3624 think are the subject of many of the bills in the House and
3625 some in the Senate, haven't really been at issue. They are
3626 not using the existing caps.

3627 Mr. {Pallone.} Right. She mentioned that when we had
3628 the Commissioner here last week.

3629 Ms. {Swirsky.} So that suggests to us that there is
3630 some broader problems.

3631 Mr. {Pallone.} Right. Just give me your suggestions,
3632 because I don't have a lot of time.

3633 Ms. {Swirsky.} I am sorry. So some of our suggestions,
3634 we would hope that the FDA would be ripe for a task force to
3635 bring in stakeholders, various stakeholders, consumer groups
3636 and industry to sort of come together to look at some of the
3637 barriers and identify some solutions. But some of the
3638 solutions I think we and other consumer groups have thought
3639 about is first of all, creating better awareness of advisory
3640 panels. I think right now there isn't great awareness of it,
3641 and so what you have now are self-selected folks who sign up
3642 for these advisory panels, and some ideas include trying to
3643 work with medical schools to make this a part of their
3644 curriculum so we can create more prestige around the advisory
3645 panels. Obviously we can pay them more, which is probably
3646 not in the cards for the short term. But also I think there
3647 is a lot of evidence that about 50 percent of academic

3648 researchers aren't conflicted at all so we need to tap into
3649 that pool, and research suggests that academic medical
3650 centers have fewer conflicted members, and so bringing them
3651 into the process and getting their input in how we can make
3652 it more attractive to them.

3653 Mr. {Pallone.} Thank you.

3654 Ms. George, first I wanted to thank you for coming to
3655 that FDA roundtable we had at Rutgers with the Commissioner,
3656 but would explain why elimination of the caps on waivers
3657 would be helpful, given as Ms. Swirsky said, that the FDA
3658 hasn't come anywhere near reaching its cap to date? Do you
3659 think it would be helpful? And if you want to comment on
3660 broadening the pools also but--

3661 Ms. {George.} One of the challenges--

3662 Mr. {Pallone.} --quickly because I have one more
3663 question.

3664 Ms. {George.} One of the challenges I think that does
3665 occur with the panels is, anything that goes to panels is
3666 innovative. It is new technology. It is new clinical
3667 science and there are not a lot of available people out there
3668 to actually come in to be those experts, to come in and
3669 answer the questions, to be able to ask industry the
3670 questions. So one of the challenges that we have as a
3671 manufacturer if we bring something to panel is, we probably

3672 already tapped a lot of those people to help us in the
3673 development and in the creation of the technology or science
3674 and so the FDA has limited people available that they could
3675 use, so that does cause some aspect of conflict.

3676 Mr. {Pallone.} Let me ask Mr. Perez, I have one more
3677 question. I have about a minute left. You know, I
3678 understand the negotiation over the medical device agreement
3679 wasn't easy, but we have heard from the drugs and biologics
3680 trade associations that they are committed to a clean PDUFA,
3681 and while they may have some additional legislation they
3682 would be happy to see enacted as part of the UFA legislation
3683 package, they don't want anything that would slow down or
3684 jeopardize the passage of that package. So I just wanted to
3685 ask you, are you committed to seeing that nothing slows down
3686 or stands in the way of passage of MDUFA as part of the
3687 package of FDA legislation? I am asking you to take the same
3688 pledge.

3689 Mr. {Perez.} I think we share a common goal here, that
3690 we want to get this done in a very timely manner. We know
3691 many members have already introduced some legislation all in
3692 an effort to improve and help the FDA be more successful but
3693 I think right now we need to make sure that we balance those
3694 efforts with trying to get the MDUFA passed in a very timely
3695 manner. So we would like to work with the members of the

3696 committee, to listen to them, and I think it is very, very
3697 important to get this done. Dr. Shuren outlined a timetable
3698 and I hope we can stick to it.

3699 Mr. {Pallone.} All right. Thank you so much.

3700 Mr. {Pitts.} The chair thanks the gentleman and
3701 recognizes the vice chairman of the committee, Dr. Burgess,
3702 for 5 minutes for questioning.

3703 Dr. {Burgess.} Thank you, Mr. Chairman.

3704 Mr. Perez, a valid point, what a lot of people don't
3705 realize about the user fee agreements is when they expire on
3706 September 30, this is not like the typical Congressional
3707 action where we can say the dog ate my homework so I am going
3708 to give myself an IOU for the next couple of months. These
3709 are voluntary funds that are provided by the industry, and
3710 without the user fee agreement and in force, those monies
3711 simply stop on October 1st. Is that correct?

3712 Mr. {Perez.} That is correct.

3713 Dr. {Burgess.} So this timeline that we are looking at
3714 now is one with a great deal more severity than the usual
3715 Congressional timelines. I mean, I forget, we had, what, 35
3716 different temporary patches to the FAA reauthorization in the
3717 last 10 years. We can't do this.

3718 Mr. {Perez.} We have to get it done.

3719 Dr. {Burgess.} We have to get it done, and so I

3720 appreciate all of you being here and Dr. Shuren being here
3721 because I think this is--you know, we may disagree about some
3722 parts of this but we all understand how important it is to
3723 get this done.

3724 Dr. Jaffe and Dr. Kesselheim, let me just take advantage
3725 of the fact that you two are sitting next to each other and
3726 you seem to have vastly different views of the world. You
3727 both heard each other's testimony. Is there any common
3728 ground between you or are we left with this rather stark
3729 definition on either side of what an ideal user fee agreement
3730 would look like?

3731 Dr. {Jaffe.} Well, I don't know where the differences
3732 are between us on the user fee agreement. I certainly didn't
3733 hear any concerns about the need for more resources for the
3734 FDA and for process improvements.

3735 Dr. {Kesselheim.} I would agree with that. I mean, I
3736 think that the need for greater funding for a lot of the
3737 essential work that the FDA does is essential and it would be
3738 my preference to see that money come directly from Congress,
3739 but since that is not going to happen, I think that the user
3740 fee agreement is essential and a lot of the issues we will
3741 deal with by improving the--

3742 Dr. {Burgess.} Let me interrupt you in the interest of
3743 time because they just called a vote. Dr. Jaffe, you

3744 describe a world in which the risk-averse nature of the
3745 agency charged with protecting the public interest, the risk-
3746 averse nature has damaged your business model. Is that
3747 correct? Did I misinterpret that?

3748 Dr. {Jaffe.} Yes, Dr. Burgess.

3749 Dr. {Burgess.} And Dr. Kesselheim, your view seemed to
3750 be that it doesn't matter about the damage because these
3751 companies are out there trying to push products out on the
3752 American public, the unsuspecting American public that are
3753 bad products and the FDA has to stand as the last bastion of
3754 defense against the industry and these bad products. Did I
3755 miss something in the testimony of two individuals?

3756 Dr. {Kesselheim.} Well, so I would first say that for
3757 many products in the 510(k) clearance process, for 95 percent
3758 of products the time to market in the United States and the
3759 European Union is not different, that what we are talking
3760 about are the highest risk products that arrive at the E.U.
3761 market sooner, and I think as I said before, the essential
3762 reason for that is that they are just not being tested for
3763 efficacy and for--

3764 Dr. {Burgess.} Dr. Jaffe, do you agree with that?

3765 Dr. {Jaffe.} I don't fully agree with that, I must say.
3766 You know, we do go to Europe early because there is a more
3767 straightforward path but we do test products in Europe. They

3768 do have to have data to get approved. We have a company
3769 selling in Europe a leadless cardiac defibrillator which
3770 could be a major improvement over the problems we have had
3771 with leads here in the United States. That product has been
3772 on the market for 3 years in Europe and it will probably be
3773 several more years before it is approved here.

3774 Dr. {Burgess.} Now, let me ask you something. Do they
3775 have a postmarket surveillance program in Europe?

3776 Dr. {Jaffe.} The company has continued to do studies
3777 but I am not sure--I am not directly involved in it. I don't
3778 know if they are required to but the company has continued to
3779 do studies of that product both in Europe and it has
3780 completed a clinical trial here in the United States which is
3781 submitted.

3782 Dr. {Burgess.} Now, will that company be able to use
3783 any of that data when it goes to the FDA to present its case?

3784 Dr. {Jaffe.} I do not know the answer to that question.
3785 I am not directly involved.

3786 Dr. {Burgess.} Mr. Hall, do you know?

3787 Mr. {Hall.} It is possible, assuming that it meets the
3788 U.S. criteria for informed consent, data, validity, etc., but
3789 there are many situations where data can be used.

3790 Dr. {Burgess.} Now, I have got a list of a number of
3791 things where the postmarketing authority exists in the device

3792 world and is missing from the drug world. Now, there are
3793 some things where drugs and devices share some postmarketing
3794 authority, things like adulteration, misbranding,
3795 manufacturer changes both drugs and devices are required to
3796 report but you look at things like classification based on
3797 risk, devices have it, drugs don't; user reporting, devices
3798 have it, drugs don't; reports of removals or corrections,
3799 devices have it, drugs don't; tracking, devices have it,
3800 drugs don't. I mean, it looks like the Food and Drug
3801 Administration is already applying many of these standards in
3802 the device world maybe even a little bit more stringently
3803 than the drug world. Do you agree with that, Mr. Hall?

3804 Mr. {Hall.} There are obviously a number of differences
3805 between drugs and devices. The agency has a plethora of
3806 postmarket authorities in the device world. Some of them do
3807 not exist in the drug world. In part, that is because of the
3808 differences between drugs and devices. You don't have an
3809 implantable drug, you know, as a general rule.

3810 Dr. {Burgess.} You do for some hormonal agents.

3811 Mr. {Hall.} As a general rule, is what I am trying to
3812 say.

3813 Mr. {Pitts.} The chair thanks the gentleman and
3814 recognizes the ranking member emeritus--I mean ranking member
3815 of the full committee, Mr. Waxman, for 5 minutes.

3816 Mr. {Waxman.} Thank you. I will be emeritus when we
3817 get the control back and then I will be chairman, but thank
3818 you very much for calling on me and I thank this panel for
3819 their testimony. I had a chance to review some of the
3820 testimony, and I have had my staff here throughout your
3821 presentation.

3822 Dr. Kesselheim, I must express alarm over your article
3823 describing the harms caused by the devices approved in Europe
3824 first and then later found to be ineffective or, worse,
3825 harmful to patients. This is important information for us to
3826 have given that so many in the device industry have
3827 complained that FDA is depriving Americans of the innovative
3828 devices patients in the E.U. get so early. Obviously as you
3829 have shown, this is not always such a good thing. Your New
3830 England Journal article also describes what are some critical
3831 fundamental differences between the E.U. and the U.S.
3832 systems. You say that the E.U. system is a part of a
3833 framework for commerce which originated as a means of
3834 streamlining trade and coordinating manufacturing safety and
3835 environmental standards in the E.U. Your article also states
3836 that so-called notified bodies, which are for-profit
3837 independent companies that specialize in evaluating many
3838 products, not just medical devices, are not ``designed to
3839 work as public health agencies'' and the approval standards

3840 in the E.U. are quite different from ours. Device
3841 manufacturers have only to prove that the device works as
3842 intended, not that it is effective at treating or curing the
3843 particular indicated condition.

3844 So yet in recent months, many have argued that we should
3845 reformulate our device regulatory system so that it more
3846 closely resembles the E.U. Let me ask you, based on what you
3847 have learned from your study, do you agree that we should
3848 look to the European system as a model for how we regulate
3849 devices in the United States?

3850 Dr. {Kesselheim.} Absolutely not. You know, there is
3851 no evidence that I have found in all the places that I have
3852 looked that suggests that the model for device approval in
3853 the E.U. in any way benefits patients overall as compared to
3854 the U.S. system, and indeed these notified bodies have major
3855 problems with conflicts of interest and their independence,
3856 and in fact, they only evaluate devices for approval whereas
3857 the competent authorities in the E.U. are the ones charged
3858 with safety evaluations. So the safety and the approval
3859 evaluations in the E.U. are separate and that is just not the
3860 way to effectively protect the public health.

3861 Mr. {Waxman.} Some of the bills that are being proposed
3862 change FDA device regulation to make our system look a lot
3863 more like the E.U. system. Let me ask you about one of them

3864 that would expand the device center's so-called third-party
3865 review program. Currently, that program permits third
3866 parties to review certain 510(k) applications and provide
3867 recommendations to FDA on whether the agency should clear a
3868 particular device. FDA has 30 days in which to make a final
3869 decision but it is has FDA that has the final say. That is
3870 existing law. One bill has an alteration of the scheme to
3871 make the third party's recommendation binding on FDA if FDA
3872 fails to respond in 30 days. The bill would also expand the
3873 types of devices that these third parties are permitted to
3874 review to include ``permanently implantable or life-
3875 sustaining or supporting devices.'' These outside reviewers
3876 are not currently allowed to review these devices.

3877 Dr. Kesselheim, as an expert on the U.S. and E.U.
3878 systems of medical device oversight, do you believe this
3879 legislation is a move in the right direction? Would you be
3880 concerned about these kinds of changes to the program?

3881 Dr. {Kesselheim.} Yes, I believe this is definitely a
3882 move in the wrong direction, and I would be concerned about
3883 these types of changes. First of all, there is plenty of
3884 peer-reviewed evidence showing in the drug realm that
3885 decisions made at the end of a fixed regulatory period end up
3886 more likely leading to drugs that have safety problems later
3887 on down the road, so imposing this 30-day fixed time limit on

3888 the FDA in terms of devices is bad policy, and I also think
3889 that increasing the role of these independent agents into the
3890 evaluation of the most highest-risk devices would again move
3891 us more towards the E.U. equivalent, notified bodies, and it
3892 would be bad policy, and there is very little oversight of
3893 what these notified bodies are able to do. Manufacturers are
3894 able to game the system in a way and select which notified
3895 bodies they want to based on which are known to provide a
3896 faster path to approval, and I just think it would be a bad
3897 idea.

3898 Mr. {Waxman.} It is ironic that Governor Romney is
3899 attacking President Obama saying he wants us to be more like
3900 the Europeans. That may or may not be right, but in this
3901 case, we don't want to be more like the Europeans. The FDA
3902 gives a seal of approval that is respected all around the
3903 world for our drugs and devices and we are better able to
3904 protect the public health with our present system.

3905 Dr. {Kesselheim.} Indeed, I do, and in fact, a lot of
3906 the European authorities rely on the studies done for FDA
3907 approval in order to make decisions about payments and use of
3908 the devices there. So indeed, you know, authorities around
3909 the world rely on the FDA system.

3910 Mr. {Waxman.} Thank you, Mr. Chairman.

3911 Mr. {Pitts.} The chair thanks the gentleman. We are

3912 going to try to wrap this up. We are in the middle of a
3913 vote. Dr. Cassidy, 5 minutes for questions.

3914 Dr. {Cassidy.} So Mr. Hall and Dr. Jaffe, just to be on
3915 record, are you all in favor of this bill, the number three,
3916 if you will?

3917 Dr. {Jaffe.} The MDUFA reauthorization? Yes.

3918 Dr. {Cassidy.} And Mr. Hall, are you?

3919 Mr. {Hall.} The agency needs adequate resources. I am
3920 Don Quixote on this. I prefer the funding to be from public
3921 sources. I recognize the practical aspects and problems with
3922 that right now.

3923 Dr. {Cassidy.} Okay. That sounds good.

3924 Now, Dr. Kesselheim, I think William Moser said let us
3925 use our drugs while they still work, and that was obviously
3926 way back when, when there was poor regulation. You suggest
3927 it still may be true in Europe of medical devices. And Dr.
3928 Jaffe, obviously there is tension there that was earlier
3929 alluded to. I am way out of field. I am a
3930 gastroenterologist. But don't I recall something--I was
3931 looking at but I couldn't find it--that there was an
3932 artificial disc that was being used by maybe orthopods or
3933 spine surgeons that had been implanted in lots of folks and
3934 turned out not to be efficacious?

3935 Dr. {Kesselheim.} As far as I am concerned, yes, there

3936 have been examples of those sorts of orthopedic spine devices
3937 that turn out later to have been unsafe or not work, yes.

3938 Dr. {Cassidy.} Now, Dr. Jaffe, how would you--
3939 understanding there has to be a kind of movement towards
3940 innovation but understanding that there are these instances
3941 where things are not efficacious, that they are approved and
3942 they are put in a lot of people and they cost a lot of money.
3943 How would you balance that tension?

3944 Dr. {Jaffe.} Congressman, I just wanted to say clearly
3945 that we have not advocated for any type of European system
3946 here in the United States, and we still believe in the
3947 importance of good clinical safety and efficacy studies. The
3948 challenges we have with the FDA are less around those
3949 standards than they are about the unpredictability and the
3950 delays and the difficulty in getting decisions made that cost
3951 our companies millions that stretch time frames in a great
3952 distance.

3953 Dr. {Cassidy.} So you are not so concerned with the
3954 paradigm that they use, rather how they implement it, if you
3955 will?

3956 Dr. {Jaffe.} Exactly. It is more their internal
3957 management. That is why these guidance documents that Dr.
3958 Shuren referred to are so important, making the clinical
3959 risk-benefit determination much more transparent and clear

3960 and accountable so we can review over time, make sure that we
3961 are in agreement to start and we are in agreement at the end
3962 of the process using the same standards because we have seen
3963 standards change as reviewers change. We have seen delays in
3964 getting to decisions. We see--

3965 Dr. {Cassidy.} I have limited time, so Dr. Kesselheim,
3966 again, I am just kind of curious about this, and again, I am
3967 trying to dig from the recesses of my memory, so if I say
3968 something stupid, it won't be the first time. Somebody has
3969 pointed out to me that some of the things that are approved,
3970 maybe certain types of stents for cardiac disease, turn out
3971 not to be efficacious but there is no vested interest in
3972 terms of learning efficacy in terms of your outcome data is--
3973 if your outcome data is mortality, it is a long study, very
3974 expensive, etc. Surrogates may not be adequate markers for
3975 the ultimate outcome. And Dr. Sedrakyan, I think I saw you
3976 nodding your head. Would you all comment on that? Because
3977 again, I am trying to understand this issue. I am not
3978 challenging anybody. I am just trying to understand.

3979 Dr. {Sedrakyan.} I can answer that. In many
3980 situations, it is possible that a device will take time until
3981 side effects will develop, and a large number of products
3982 will be already on the market with consequences for public
3983 health. Now, the best answer to that kind of problem is to

3984 have a worldwide network that will help us determine the side
3985 effects early.

3986 Dr. {Cassidy.} But side effects is lack of clinical
3987 efficacy. It may decrease angina, for example, but it may
3988 not prolong life. Do we need 10,000 people and 5,000 get a
3989 stent and 5,000 don't? Do you see what I am saying? Can we
3990 use surrogate markers?

3991 Dr. {Kesselheim.} I mean, I think that there are
3992 surrogate markers that have been validated as relatively well
3993 predicting final outcomes, and in those cases, surrogate
3994 markers are useful. There are also, you know, new techniques
3995 for doing randomized trials in detecting efficacy so that
3996 they can be done in a more expedited way, and I am also more
3997 in favor of promoting an efficient and predictable FDA
3998 regulatory process as well, but I think that at the end of
3999 the day--

4000 Dr. {Cassidy.} Let me cut you off because I told my
4001 colleague I would give him the remainder of my time, because
4002 I think I got your point.

4003 Dr. {Burgess.} I thank the gentleman for yielding.

4004 Dr. Kesselheim, if I could just ask you very quickly,
4005 are you currently involved either with the plaintiff or
4006 defense in any of the product liability lawsuits involving,
4007 say, the artificial hip?

4008 Dr. {Kesselheim.} No.

4009 Dr. {Burgess.} And the same question to you, Dr.

4010 Sedrakyan?

4011 Dr. {Sedrakyan.} No.

4012 Dr. {Burgess.} Mr. Shull, let me just ask you, your
4013 story is very compelling. Certainly at some point there has
4014 been a lawsuit involved, I would assume.

4015 Mr. {Shull.} Yes.

4016 Dr. {Burgess.} And currently your lawsuit is against
4017 whom?

4018 Mr. {Shull.} It is settled.

4019 Dr. {Burgess.} With whom did you settle?

4020 Mr. {Shull.} That would be the doctor.

4021 Dr. {Burgess.} Was the product you referenced in your
4022 case, was that product ultimately recalled from the market?

4023 Mr. {Shull.} No, it was never recalled.

4024 Dr. {Burgess.} Did you file suit against the company?

4025 Mr. {Shull.} I did, but the product was deemed used off
4026 label and--

4027 Dr. {Burgess.} So it was the physician involved, not
4028 the company?

4029 Mr. {Shull.} The company exchanged testimony for me to
4030 drop the suit against them.

4031 Dr. {Burgess.} All right. I thank you for that.

4032 I will yield back, Mr. Chairman.

4033 Mr. {Pitts.} The chair thanks the gentleman. We have a
4034 unanimous consent request.

4035 Mr. {Pallone.} Mr. Chairman, I would ask unanimous
4036 consent to enter into the record first the testimony from
4037 Public Citizen; second, testimony from American Congress of
4038 Obstetricians and Gynecologists; and third, two New England
4039 Journal of Medicine articles, one, postmarketing surveillance
4040 of medical devices, filling in the gaps, and second,
4041 regulation of medical devices in the United States and
4042 European Union.

4043 Mr. {Pitts.} Have you shared that with us?

4044 Mr. {Pallone.} Yes.

4045 Mr. {Pitts.} Without objection, so ordered.

4046 [The information follows:]

4047 ***** COMMITTEE INSERT *****

|
4048 Mr. {Pitts.} That concludes the second panel. I would
4049 like to thank the witnesses and members for participating in
4050 today's hearing. I remind the members that they have 10
4051 business days to submit questions for the record, and I ask
4052 the witnesses to respond promptly to the questions. Members
4053 should submit their questions by the close of business on
4054 Thursday, March 1. Without objection, the subcommittee is
4055 adjourned.

4056 [Whereupon, at 1:58 p.m., the Subcommittee was
4057 adjourned.]