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4 HEARING ON ``REGULATORY REFORM SERIES #5 - FDA MEDICAL DEVICE

5 REGULATION: IMPACT ON AMERICAN PATIENTS, INNOVATION, AND

6 JOBS''

7 WEDNESDAY, JULY 20, 2011

8 House of Representatives,

9 Subcommittee on Oversight and Investigation

10 Committee on Energy and Commerce

11 Washington, D.C.

12 The subcommittee met, pursuant to call, at 10:02 a.m.,
13 in Room 2322 of the Rayburn House Office Building, Hon. Cliff
14 Stearns [Chairman of the Subcommittee] presiding.

15 Members present: Representatives Stearns, Terry,
16 Sullivan, Burgess, Blackburn, Myrick, Bilbray, Gingrey,
17 Scalise, Gardner, Griffith, Lance, Barton, DeGette,
18 Schakowsky, Green, Christensen, Dingell and Waxman (ex

19 officio).

20 Staff present: Clay Alspach, Counsel, Health; Carl
21 Anderson, Counsel, Oversight; Karen Christian, Counsel,
22 Oversight; Todd Harrison, Chief Counsel, Oversight and
23 Investigations; Sean Hayes, Counsel, Oversight and
24 Investigations; Sean Hayes, Counsel, Oversight and
25 Investigations; Kirby Howard, Legislative Clerk; Debbie
26 Keller, Press Secretary; Ryan Long, Chief Counsel, Health;
27 Carly McWilliams, Legislative Clerk; Alan Slobodin, Deputy
28 Chief Counsel, Oversight; Sam Spector, Counsel, Oversight;
29 John Stone, Associate Counsel; Tim Torres, Deputy IT
30 Director; Kristin Amerling, Democratic Chief Counsel and
31 Oversight Staff Director; Phil Barnett, Democratic Staff
32 Director; Stacia Cardille, Democratic Counsel; Stephen Cha,
33 Democratic Senior Professional Staff Member; Brian Cohen,
34 Democratic Investigations Staff Director and Senior Policy
35 Advisor; Eric Flamm, FDA Detailee; Karen Lightfoot,
36 Democratic Communications Director, and Senior Policy
37 Advisor; Ali Neubauer, Democratic Investigator; and Mitch
38 Smiley, Democratic Assistant Clerk.

|
39 Mr. {Stearns.} Good morning, everybody, and the
40 subcommittee will come to order and I will open with my
41 opening statement.

42 We convene this hearing of the Subcommittee on Oversight
43 and Investigations to examine FDA's medical device
44 regulations and their impact on American patients, innovation
45 and jobs. The medical device industry has brought hundreds
46 of thousands of high-paying jobs to our country and life-
47 saving, life-improving devices to our Nation's patients in a
48 safe and efficient manner.

49 Unfortunately, it appears that regulatory inconsistency
50 and inefficiency at FDA is causing innovative medical device
51 companies to move offshore and launch their products abroad,
52 oftentimes years before they enter the U.S. market, if at
53 all. These are systemic problems at the Center for Devices
54 and Radiological Health, CDRH, that must be resolved that are
55 not a matter of funding.

56 A Congressional Research Service report issued in April
57 2010 found that medical device review process funding
58 increased from \$275 million in fiscal year 2008 to \$368
59 million in fiscal year 2010. This represents nearly a 35
60 percent increase in funding. Comparing 2010 with the 2003 to
61 2007 time period, the average review time for lower-risk

62 devices approved through the 510(k) process increased by 43
63 percent and the average review time for higher-risk,
64 innovative devices under the premarket approval system
65 increased 75 percent.

66 President Obama himself has acknowledged that he has
67 gotten a lot of commentary about the fact that essentially
68 FDA's model was designed for the kind of medical devices you
69 see in museums. In reference to his Administration's
70 purported commitment to regulatory reform, he noted that this
71 would be an area where they should be ``getting a group to
72 think strategically about how we design these regulatory
73 bodies so that they are up to speed and more responsive in a
74 dynamic economy.'' Unfortunately, in the eyes of the
75 Administration, this group does not appear to include the
76 innovative, job-creating companies or the very patients that
77 these devices are designed to help.

78 For example, FDA commissioned the Institute of Medicine,
79 IOM, to review the current 510(k) process and consider a
80 number of specific issues related to the improvement of
81 device regulations. Not a single company or industry
82 representative that is impacted by these regulations is on
83 the panel. Judging from a letter sent by Senator Al Franken
84 to CDRH Director, Jeffrey Shuren, our witness today, Senator
85 Franken and others share my concerns. In it, he states, ``I

86 believe that the medical device industry contains a wealth of
87 expertise that is too often neglected when considering
88 changes to the device review process. I strongly encourage
89 you to establish a clear process for soliciting and
90 considering the suggestions and concerns of the medical
91 device industry on any and all recommendations made by the
92 IOM before finalizing or implementing any changes to the
93 process.'' In addition to the stunning lack of industry
94 representation, there is not a single patient representative
95 on the panel. This is not acceptable and does not comply
96 with President Obama's call for allowing ``public
97 participation and an open exchange of ideas.''

98 In addition, CDRH is supposed to ``use the least
99 burdensome'' tools for achieving regulatory ends. This is
100 not only a key tenet of the President's Executive Order on
101 Regulatory Reform, but required by the Food and Drug
102 Modernization Act of 1997. Specifically, in order to improve
103 regulatory efficiency of the 510(k) and premarket approval
104 process, Congress mandated that the FDA eliminate unnecessary
105 burdens that may delay the marketing of beneficial new
106 products and only request the least burdensome information
107 necessary to make those determinations. Unfortunately, FDA
108 appears to be actively thwarting the mandates of Congress and
109 fostering regulatory uncertainty by reducing its use of the

110 least burdensome provisions.

111 Now, whether this is a calculated effort or a lack of
112 leadership in promoting such principles, the end result is
113 equally unacceptable: companies closing their doors and
114 moving abroad; patients in the United States waiting for
115 innovative treatments or being forced themselves to go abroad
116 to get them.

117 We will hear today from several of these patients.
118 Hopefully, Dr. Shuren will gain some insight from these
119 experiences and better understand the fact that patient
120 safety and public health are not only jeopardized by
121 approving devices that are unsafe, but also by failing to
122 approve devices that are safe. Such poor processes and
123 decision-making also stifle innovation, cutting-edge American
124 companies that create numerous badly needed jobs here in the
125 United States. As FDA Commissioner Hamburg said just this
126 past week, ``This is a critical time for innovation.''
127 She acknowledged that FDA has played a role in the national
128 decline in medical product innovation, adding that she felt
129 much of the criticism of her agency was deserved. Hopefully
130 we can find some solutions to reverse this alarming trend
131 today and soon. Patients are waiting.

132 [The prepared statement of Mr. Stearns follows:]

133 ***** COMMITTEE INSERT *****

|
134 Mr. {Stearns.} With that, I recognize the ranking
135 member, Ms. DeGette.

136 Ms. {DeGette.} Thank you very much, Mr. Chairman, for
137 holding this hearing.

138 The topic of medical devices hits very close to home
139 with me and I am very, very interested in this topic, because
140 just like Ms. Sagan's daughter, my daughter, Francesca, has
141 type 1 diabetes and has had type 1 diabetes for 13 years, and
142 so I know every day what children living with these diseases,
143 and young adults living with these diseases need to do with
144 devices--blood sugar monitoring, making sure they eat healthy
145 meals and daily exercise. For the generation of kids like
146 our two kids, Ms. Sagan's and mine, the short-term cure is
147 medical devices. My daughter and probably Ms. Sagan's
148 daughter uses an insulin pump and a continuous glucose
149 monitor every day and yet--Ms. Sagan, I read your testimony
150 and it broke my heart because every single parent who has a
151 child living with this disease knows the scary low blood
152 sugars and the scary thought about some of the consequences
153 that can happen with this disease, but for our children, good
154 devices have been the cures and the treatment for them and
155 what will continue to be the treatments for them in their
156 lives.

157 Now, unfortunately, some of the advances in these
158 technologies, not just for diabetics but for other diseases,
159 seem to so many of us to have been so slow over at the FDA,
160 and the perfect example is in Ms. Sagan's testimony where she
161 talks about our efforts to get a continuous glucose monitor
162 approved that would send a message to the pump and would cut
163 off insulin flow if the blood sugar is way too low.

164 Mr. Chairman, I want to thank you and many members of
165 this committee for signing a letter by the Diabetes Caucus
166 urging the FDA to look at this device because it can
167 literally save lives, and we appreciate it, and this is true
168 not just for these devices but for devices that millions of
169 Americans use for countless different diseases. On the one
170 hand, people are relying on devices, and on the other hand,
171 we want to make sure that improvements and advances in those
172 devices and new devices are approved with speed. But on the
173 other hand, we need to make sure that the FDA has the
174 appropriate tools to make sure that medical device approval
175 process helps encourage innovation while at the same time
176 protecting patient safety, and that's the challenge I think
177 that the FDA faces and I think that that's the challenge that
178 we all face on this committee is making sure that while we
179 support the FDA expediting an approval process that we make
180 sure that the reviews are done in a way that is safe for

181 those patients and for those devices. We need to find the
182 right balance and we can't pretend that there aren't
183 sometimes tradeoffs between safety and speed.

184 Now, I am sympathetic to the industry concerns we hear
185 today but I also fear that too often the device industry and
186 also people like me who are eager to see cures and treatments
187 for diseases kind of minimize those tradeoffs between safety
188 and speed. Two studies funded by the medical device
189 industry, one conducted by Dr. Josh Makower and the other by
190 the California Healthcare Institute, that have been heavily
191 cited by many of our colleagues and by proponents of
192 weakening FDA regulations provide a good example of how facts
193 can be twisted. These studies have been heavily cited, and
194 so our committee staff asked a panel of distinguished outside
195 reviewers to analyze the methodology of these studies, and at
196 the staff's request, officials from the FDA also submitted
197 comments on the studies.

198 Mr. Chairman, Democratic committee staff prepared a
199 supplemental memo summarizing the expert reviews of these
200 industry studies, and I would ask unanimous consent to
201 include this memo and the letters from FDA and the
202 independent experts in today's hearing record.

203 Mr. {Stearns.} I thank the gentlelady. Can we just
204 have a copy of it and we will read it and we will look at it.

205 Ms. {DeGette.} You bet.

206 The reviewers found the following problems with these
207 industry-funded studies. First, the existence of ``so many
208 flaws in design and execution that the authors' conclusions
209 are rendered essentially meaningless.'' Second, a ``woefully
210 inadequate'' response rate of only 20 percent, a biased group
211 of respondents that included companies that had never gone
212 through the process of getting a product reviewed by the FDA,
213 a subjective, apples to oranges, and especially troublesome
214 conclusion regarding the difference in approval times between
215 the European Union and the United States, the failure to
216 provide any evidence that a U.S. delay in approval and
217 availability leads to adverse health outcomes. The journal
218 editors concluded that the studies would not be fit for
219 publication in a peer-reviewed journal.

220 And so as we consider the role of the FDA, we have got
221 to rely on the facts. The patients and their families and
222 the industry need to know how can we have the quickest review
223 process possible while at the same time ensuring patient
224 safety and efficacy of the devices.

225 So I thank you for having this hearing. I look forward
226 to both of our panels of testimony, and I yield back.

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

228 ***** COMMITTEE INSERT *****

|
229 Mr. {Stearns.} I thank the gentlelady, and the
230 gentleman from Texas, Mr. Barton, is recognized for 1 minute.

231 Mr. {Barton.} Thank you, Mr. Chairman. Thank you and
232 Ranking Member DeGette for holding this oversight hearing.

233 The issues that we are discussing today have the ability
234 to harm our sick, inhibit innovation and stifle domestic
235 economic jobs and growth. On the other hand, if done
236 properly, they have the ability to bring state-of-the-art
237 medical devices quickly and efficiently to not only the
238 United States citizenry but to people all over the world. I
239 hate to say it, but the medical device review process at the
240 Food and Drug Administration in my opinion has become overly
241 burdensome, unpredictable and inconsistent under its current
242 leadership.

243 I would like to read briefly a paragraph from the
244 document that was prepared for this hearing, which is common
245 themes raised by the device companies seeking FDA approval
246 include unclear guidance, high turnover of review staff,
247 impractical clinical designs, changing the goalpost,
248 reluctance to approval protocols, and duplicative or overly
249 burdensome data requests.

250 Hopefully, this hearing will lead to some soul searching
251 at the FDA, and if necessary, it may lead to some legislative

252 solutions recommended by this subcommittee to the legislative
253 subcommittees.

254 I will put the rest of my statement in the record, Mr.
255 Chairman, but this is an important hearing and it has
256 important implications for the country.

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

258 ***** COMMITTEE INSERT *****

|
259 Mr. {Stearns.} I thank the gentleman.

260 The gentleman from Texas, Dr. Burgess, is recognized for
261 1 minute.

262 Dr. {Burgess.} Thank you, Mr. Chairman, and Dr. Shuren,
263 thank you for being here. Thank you for your willingness to
264 hear from the panel and of course I want to thank our
265 panelists for being here. Ms. Conger, thank you for
266 reminding us if we are not careful, NIH stand in the future
267 for Not Invented Here.

268 Now, the FDA is not interactive, it is unpredictable and
269 discourages innovation, and this ultimately hurts patients.
270 We don't want the FDA to approve anything that will harm
271 people. We don't want you to simply adopt European
272 standards. But we do want you to understand that a little
273 predictability can go a long way. We want you held to your
274 own standards. If you say 30 days, we shouldn't have to ask
275 how long is that in FDA days. If a company is asked to
276 provide proof the device does something it wasn't designed to
277 do and they tell you that, you can't claim that as an example
278 of noncompliance. I know you care about the FDA. You know I
279 care about the FDA. And you do have a critically important
280 job, but don't hide behind a twisted interpretation of
281 benchmarks.

282 The truth, the doctors of tomorrow are going to have
283 tools at their disposal that are unlike anything that you or
284 I imagined during our training. The ability to alleviate
285 human suffering is going to be on a scale never imagined
286 before by any other generation of doctors. It is our job to
287 be certain that the tools get into their hands.

288 Thank you, Mr. Chairman. I will yield back.

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

290 ***** COMMITTEE INSERT *****

|
291 Mr. {Stearns.} I recognize the gentleman from Georgia,
292 Dr. Gingrey, for 1 minute.

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

294 I focused my opening statement during the July 11th
295 prescription drug user fee hearing on my intent to pursue
296 regulatory reform through PDUFA reauthorization building on
297 the steps that the FDA and Dr. Hamburg have already taken.
298 The same is true for medical devices. Patients, industry and
299 the FDA can benefit from a more predictive regulatory
300 framework. With limited financial resources, as outlined by
301 the chairman, both within the FDA and in industry, it appears
302 that an approval approach that is able to maximize effort is
303 one that will benefit all, and I believe that if the FDA is
304 going to be successful and becoming more responsive to new
305 technologies and products, it is going to need the support of
306 industry experts, patient advocates and other agencies.

307 I look forward to working with this committee and Dr.
308 Hamburg to ensure we achieve this worthy goal. I thank both
309 panels of witnesses. We look forward to hearing from you,
310 and I yield back.

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

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

|
313 Mr. {Stearns.} I thank the gentleman.

314 The gentleman from Nebraska, Mr. Terry, is recognized
315 for 1 minute.

316 Mr. {Terry.} Thank you. My statement is going to
317 reference the February 9th article from the New York Times
318 that I would like to submit for the record, unanimous consent
319 to submit.

320 Mr. {Stearns.} Without objection, so ordered.

321 [The information follows:]

322 ***** COMMITTEE INSERT *****

|
323 Mr. {Terry.} Biosensors International, a medical device
324 company, shut its operation in southern California, which had
325 once housed 90 people, 90 lost jobs. The CEO is moving the
326 manufacturing to Europe and says their stent ``is available
327 all over the world including Mexico and Canada but not in the
328 United States. We decided, let's spend our money in China,
329 Brazil, India and Europe.'' It is disappointing to hear the
330 CEO's statement.

331 We hear later in the article a quote from a capital
332 venture company who says, ``Ten years from now, we'll all get
333 on planes and fly somewhere else to get treated.'' That is a
334 true indictment of our FDA's inability to timely approve
335 medical devices, and I would like to see us, the United
336 States, continue to be the world leaders in technology
337 development. Yield back.

338 [The prepared statement of Mr. Terry follows:]

339 ***** COMMITTEE INSERT *****

|
340 Mr. {Stearns.} I thank the gentleman.

341 The gentlelady from Tennessee, Ms. Blackburn, is
342 recognized for 1 minute.

343 Mrs. {Blackburn.} Thank you, Mr. Chairman, and welcome
344 to all of our witnesses. We are grateful that you would take
345 your time and be here with us today.

346 Continuing on the theme of making these innovations,
347 having the innovations here, I think it is important for us
348 to realize that 40 percent of the global medical technology
349 industry is here in the United States, and it represents
350 about 2 million U.S. jobs. Where I am from in Tennessee, we
351 have about 10,000 individuals who are employed in the medical
352 device industry and the wages and earnings are about 40
353 percent higher than the average earnings. So when you look
354 at it from an issue of keeping those jobs here, it is vitally
355 important.

356 When you look at the fact that we are in a 21st century
357 creative economy and innovation, intellectual property and
358 protecting that is vital to jobs retention. We want to make
359 certain that FDA is responsive and responsive in a timely
360 manner.

361 Welcome to the hearing, and I look forward to questions.

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

363 ***** COMMITTEE INSERT *****

|
364 Mr. {Stearns.} I thank the gentle lady.

365 The ranking member from California, Mr. Waxman, is
366 recognized for 5 minutes.

367 Mr. {Waxman.} Thank you, Mr. Chairman, for holding this
368 important hearing today.

369 I think we can all agree it is critically important that
370 innovation in the medical device industry is vibrant and
371 healthy, and that patients have access to the best and newest
372 technological advances. If FDA is unnecessarily impeding
373 technological advances that improve the lives of patients, we
374 should all be united in doing whatever it takes to remove
375 these unnecessary regulatory barriers to public health.

376 But we cannot have a conversation about the impact of
377 regulations and policies at FDA have on patient access and
378 innovation without talking about the importance of ensuring
379 the safety and effectiveness of medical devices. We should
380 not forget that that is the fundamental mission of FDA.

381 Practically every month, there is a new report in the
382 papers about horrific patient suffering from dangerous
383 medical devices. Last year, the New York Times revealed that
384 radiation machines have killed and disfigured patients. The
385 Subcommittee on Health held a hearing on the issue and heard
386 from a father whose son was killed by an overdose from

387 radiation therapy. We learned this year that malfunctioning
388 linear accelerators have left patients nearly comatose and
389 unable to speak, eat or walk.

390 Just last month, the New York Times reported on the
391 suffering caused by faulty metal-on-metal hip implants.
392 According to the Times, patients were promised these hips
393 would last longer and enable more activity. About half a
394 million patients got these devices. Now they are being
395 recalled due to high rates of failure and patients have
396 suffered severe health effects and have been forced to
397 undergo surgery to replace the defective devices.

398 And these are just the most recent examples. We have
399 also heard about problems with implantable heart devices that
400 shocked patients and led to at least 12 deaths. Implantable
401 defibrillators made by another company were failing for years
402 before the manufacturer told anyone.

403 Our focus in this committee should be on how we can
404 strengthen our device laws to protect patients from these
405 grievous harms. Yet I fear that this is not the committee's
406 goal today. Instead of strengthening our device laws,
407 Republican members have proposed radical changes to our
408 device laws that could further imperil patients. That is
409 exactly the wrong direction for us to take.

410 We will hear testimony today that FDA is imposing new

411 restrictions to innovation. Device industry advocates often
412 refer to two industry-funded reports, one conducted by Dr.
413 Josh Makower and one by the California Healthcare Institute,
414 that they say show that FDA is unduly slow, burdensome and
415 unpredictable. Yet neither of these studies, as Ms. DeGette
416 pointed out, was published in a peer-reviewed journal, and
417 both of these studies were funded by and conducted for
418 industry advocates. Because of the lack of independent
419 validation of these reports, I asked my staff to request that
420 the editors of our Nation's top medical journals, one of whom
421 is a witness today, examine the methodology of these two
422 industry papers. All three editors we asked agreed to
423 participate.

424 As our witness will describe today, there are serious
425 methodological flaws in both studies--biased samples, small
426 sample size and botched statistical analysis, just to name a
427 few--rendering them essentially useless as part of any
428 discussion of FDA's regulatory system. None of the editors
429 felt that the methodology of these studies was worthy of
430 publication in a peer-reviewed journal.

431 We will also hear today from six witnesses who will
432 express their concerns that the FDA's device regulatory
433 system is depriving patients of new and potentially life-
434 saving devices, inhibiting innovation, and costing Americans

435 jobs. FDA can and should do better in many of these cases.
436 But we can't legislate by anecdote.

437 We need to ask why unsafe devices have gotten onto the
438 market and harmed so many patients. Then we need to explore
439 how we can strengthen the FDA review process to protect
440 patients from these risks. The soon-to-be-released
441 recommendations from the Institute of Medicine could provide
442 a roadmap for how to improve FDA's regulatory oversight of
443 medical devices.

444 In order to have a flourishing and innovative American
445 device industry that puts safe and effective devices on the
446 market, we need to have a strong and well-resourced FDA.
447 That is in the best interest of American patients. It is
448 also in the interest of the device industry itself. If
449 patients lose confidence in the FDA, they lose confidence in
450 the industries it regulates as well.

451 This is an issue that can and should be bipartisan. I
452 look forward to hearing from our witnesses and to working
453 with my colleagues on this important matter.

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

455 ***** COMMITTEE INSERT *****

|
456 Mr. {Stearns.} I thank the gentleman.

457 Let me say, we have seven witnesses, not six, and we
458 welcome all seven witnesses to our hearing, and I call
459 attention to the bio of each of these witnesses. If members
460 will take the time to read that, I won't have to go through
461 all seven.

462 Let me address all of you. You are aware that the
463 committee is holding an investigative hearing, and when doing
464 so has the practice of taking testimony under oath. Do any
465 of you object to taking testimony under oath? No? The chair
466 then advises you that under the rules of the House and the
467 rules of the committee, you are entitled to be advised by
468 counsel. Do you desire to be advised by counsel during your
469 testimony today? In that case, if you would please rise and
470 raise your right hand, I will swear you in.

471 [Witnesses sworn.]

472 Mr. {Stearns.} You are now under oath and subject to
473 the penalties set forth in Title XVIII, section 1001 of the
474 United States Code. We welcome your 5-minute opening
475 statement, and your written statement will be part of the
476 record.

477 Dr. Fischell, we will start with you. Welcome.

|
478 ^TESTIMONY OF ROBERT FISCHELL, DAYTON, MARYLAND; CAROL
479 MURPHY, FAIRBORN, OHIO; MARTI CONGER, BENICIA, CALIFORNIA;
480 PAM SAGAN, LOS ALTOS, CALIFORNIA; MICHAEL MANDEL, PROGRESSIVE
481 POLICY INSTITUTE, WASHINGTON, D.C.; SEAN IANCHULEV, M.D.,
482 M.P.H., CHIEF MEDICAL OFFICER, TRANSCEND MEDICAL, INC., MENLO
483 PARK, CALIFORNIA; AND GREGORY CURFMAN, M.D., EXECUTIVE
484 EDITOR, NEW ENGLAND JOURNAL OF MEDICINE

|
485 ^TESTIMONY OF ROBERT FISCHELL

486 } Mr. {Fischell.} Chairman Stearns, Ranking Member
487 DeGette, members of the subcommittee. My name is Robert
488 Fischell, and I am pleased to testify today about an issue of
489 great importance to me, to patients, to physicians and to the
490 American public.

491 For more than four decades of my 82 years, I have
492 dedicated my life to inventing and developing novel medical
493 technologies including an implantable insulin pump for
494 diabetics, heart pacemakers, implantable defibrillators, and
495 co-inventing about 10 million of the heart stents that have
496 improved health and saved lives of patients in the United
497 States and throughout the world. I have personally been the
498 inventor or co-inventor on more than 10 medical devices

499 including a new external device that is effective in
500 eliminating the pain of migraine headaches, which device is
501 here in front of me on this table.

502 These technologies have also spurred tens of thousands
503 of jobs in this country and resulted in billions of dollars
504 in U.S. exports to other countries that value our American
505 medical devices. Unfortunately, the environment that exists
506 at FDA's Center for Devices and Radiological Health over the
507 past few years is the worst that I have experienced in my 42-
508 year career involving medical technologies.

509 Given the success I have enjoyed over the years, some
510 might ask why am bothering to testify today. It is certainly
511 not in pursuit of money. I have enough to live pretty well.
512 I am here today because of the millions of patients and
513 physicians who are searching for therapies to improve the
514 human condition. Unfortunately, it is not technology,
515 science, ingenuity or the economy that is standing in the way
516 of success in developing new medical technologies. In my
517 opinion, it is today the FDA. As a strong supporter of
518 President Obama and his policies, that is not easy for me to
519 say.

520 Prior to 2008, CDRH division was demanding safety and
521 efficacy for the many new medical devices that I had
522 invented. At that time, they were reasonable in allowing

523 clearance of devices that showed safety and efficacy. CDRH
524 demonstrated the ability to properly weigh the benefits and
525 risks of new medical devices as part of the premarket review
526 process. CDRH leadership understood that medical devices may
527 have some risks, but corresponding benefits that patients
528 realized with the therapy they provided were worth the risk
529 associated with such devices.

530 Over the past few years, I have personally been aware of
531 many instances where product clearances were denied or
532 significantly delayed by CDRH when the patient benefit
533 clearly outweighed any potential risk to the patient. One
534 example of this is a device that I invented that relieves the
535 pain of migraine headache with no serious side effects, this
536 device right here. That device was not approved by CDRH even
537 after the clinical trial proved safety and efficacy. A
538 somewhat trivial example is a small plastic valve that I have
539 in my hand that could open or close to allow liquid to flow,
540 and had its approval delayed by over a year when it had
541 already been approved for regular use in other equipment.

542 The failure of the current CDRH to efficiently and
543 effectively review medical devices is a serious problem for
544 the citizens of the United States. Many published reports
545 suggest that patients are being forced to travel outside the
546 United States for therapies that were developed here. Even

547 worse, many patients do not have the resources to travel
548 abroad and are forced to suffer, waiting desperately for FDA
549 to clear or approve therapies that in some cases have already
550 been available for years outside the United States.

551 Beyond the adverse impact FDA is having on patient care,
552 it is weakening the U.S. leadership position in medical
553 technology innovation, and as a result, hurting our economy.
554 As someone who has enjoyed success in this industry, I have
555 been proactive in trying to assist the innovators, scientists
556 and engineers of tomorrow to be in this field. I recently
557 established the Fischell Department of Bioengineering and the
558 Fischell Institute for Medical Devices at the University of
559 Maryland. Today, I am truly concerned for those scientists,
560 engineers and innovators who study there who are about to
561 embark on their careers. If I were to be starting out today,
562 I would likely be unable to make the contribution to
563 patients' lives that I have made over the past 40-plus years
564 because I would be unable to raise the funding or endure the
565 delays that exist with the current regulatory environment at
566 CDRH.

567 In dealing with the FDA today, the reviewers appear to
568 be slowing down or totally denying clearances for valuable
569 medical devices that would be of great benefit for patients
570 in the United States. By doing this, they are proud of being

571 so conservative. I mean, look how good I am, I am so
572 conservative, I am not even going to approve it. I am aware
573 of examples where reviewers have changed the requirements for
574 companies during the premarket review process with no
575 credible evidence supporting the moving goalposts.

576 One such example has recently occurred with a device
577 that I co-invented that improves the treatment for epilepsy
578 using a tiny electrical stimulator that I have here.

579 The inability for reviewers to be held accountable for
580 their changing standards and increased risk aversion is
581 something Congress and undoubtedly this committee must
582 address if we are to improve patient care in this country and
583 promote innovation and jumpstart our economy. While it may
584 be difficult to legislate culture and restore the
585 collaborative, reasonable and effective CDRH that existed
586 back in 2008, I urge this committee to try. Patients,
587 physicians, innovators and the American public are counting
588 on you to step up and restore a reasonable and predictable
589 CDRH that appropriately balances risks and benefits, works
590 collaboratively with industry and understands that
591 unnecessarily denying--

592 Mr. {Stearns.} Dr. Fischell, I need you to summarize.

593 Mr. {Fischell.} Two sentences.

594 Mr. {Stearns.} Good. Okay.

595 Mr. {Fischell.} --access to medical therapy means that
596 FDA is failing in its primary mission which is to protect
597 patients but also to allow clearance for devices to relieve
598 pain and suffering that many patients would otherwise have to
599 endure. Thank you.

600 [The prepared statement of Mr. Fischell follows:]

601 ***** INSERT 1 *****

602 | Mr. {Stearns.} Ms. Murphy, welcome.

|

603 ^TESTIMONY OF CAROL MURPHY

604 } Ms. {Murphy.} Thank you. Good morning. I am Carol
605 Murphy.

606 I have been a migraine sufferer for 40 years. I have
607 three to four aura migraines a week. I have been through
608 beta blockers, antidepressants, anti-seizures, abortive
609 medications. When you have done that, you go on to the next
610 step, so I have had occipital blocks, I had steroidal, I
611 cervical blocks, I have had Botox with minimum success.

612 At Michigan Head Pain and Neurological Clinic, once you
613 turn 60 years old, you don't fit any of the medical protocols
614 for migraine medicine and therefore they left me with the
615 narcotic oxycodone to take care of a migraine headache, and
616 that was it.

617 I finally got into the trial program at Ohio State with
618 the transcranial magnetic stimulator, TMS. I was told to put
619 the device on my head, activate it twice during an aura.
620 When I did that, the aura cycle kept going but at the end of
621 the aura when the pain should have started, it didn't. The
622 blood vessels did not fill up. There was no pain. There was
623 no headache. For 9 months, I lived like a normal person, and
624 then in June of 2006, Ohio State took it back because it was

625 going to go through the FDA process for approval. Give us 9
626 months, give us a year, Carol. Yeah. It is now June of
627 2011--July of 2011. Where is my machine? That is in
628 England. That is not here. I can't get it here.

629 A lot of people think that a migraine is a headache. It
630 isn't. When blood vessels swell in the brain, every part of
631 your body can be affected. For me, my feet and legs get so
632 cold that there is absolutely no way for me to sleep so going
633 to bed and sleeping it off doesn't work. And there is no way
634 of warming those legs until after the migraine stops. When I
635 take OxyContin, it dulls the pain but it doesn't break the
636 migraine cycle. With the TMS, no headache because the blood
637 vessels weren't dilated.

638 With migraines, I also experience urinary and bowel
639 problems. By the second day, I have abdominal pain. I also
640 have problems concentrating. The thoughts in my head are
641 clear but the words coming out of my mouth sometimes are not
642 right or they just don't come out at all. This doesn't
643 happen with the TMS because we don't have the dilation of the
644 blood vessels.

645 As I get older, falling becomes a major problem for me,
646 and my left leg drags during a migraine. So I need to be
647 more careful. I need to have the good balance. And with the
648 TMS, again, we don't have the lagging of the left foot.

649 Now I live my life between a rock and a hard place. I
650 can take the medication, I can deal with the fact that it is
651 addictive or I can crawl up in my little hole and stay there
652 until it is over. Either way, that is not quality of life.
653 I want my device back. I will go to England to get it. I
654 will rob Peter to pay Paul to get there because for me, it is
655 a quality-of-life factor.

656 I want to look forward to a life without any pain. I
657 want to know that I am not going to wait until 3 or 4 or 5
658 years for the FDA to turn around and approve this machine.

659 There are millions of migraine sufferers. Everyone has
660 their own story. I am one that medication just doesn't work
661 for. We as Americans should not have to go to England to get
662 a piece of machinery that I know that I used 5 years ago
663 safely. This is a product that was made in America, by
664 Americans, but obviously not for Americans. How long do we
665 have to wait? Five years is a long time. How many more
666 years? How many more migraines am I going to go through if I
667 am going to sit and wait for the FDA to approve this product?

668 Thank you for your consideration and time.

669 [The prepared statement of Ms. Murphy follows:]

670 ***** INSERT 2 *****

|

671 Mr. {Stearns.} Ms. Murphy, that is very compelling.

672 Thank you.

673 Ms. Conger, you are recognized for 5 minutes.

|
674 ^TESTIMONY OF MARTI CONGER

675 } Ms. {Conger.} And I timed the 5 minutes, practicing on
676 the airplane.

677 Hello, and I thank you very much for the invitation to
678 testify. I am a spine patient and a very angry one. I
679 became livid when I figured out that my government was the
680 main barrier between me and the best solution for my spine
681 problem.

682 I am here today as an advocate for the millions of U.S.
683 patients like me who are needlessly suffering, deteriorating
684 and sometimes dying while they wait for the FDA to approve
685 medical devices they desperately need, devices that are often
686 already in successful use in other countries.

687 Briefly, a little about me. My TOS specialist
688 identified my cervical spine issue in 2006 and quickly sent
689 me to University of California San Francisco Spine Clinic to
690 Dr. Dean Child, who had been involved in cervical spine
691 artificial disc trials, clinical trials.

692 Now, I have been dealing with multiple life-altering
693 health issues, and since I can't take narcotics or opiates, I
694 was already physically and mentally drained from chronic pain
695 and raging paresthesia. If you want to imagine that, just

696 walk around barefooted on a bristle brush, and that is
697 paresthesia in your feet.

698 My neurosurgeon's--my surgeon's diagnosis just had me
699 reeling. What else can go wrong? I already had this long
700 list of deals. But he immediately started educating me.
701 After he reviewed my films in detail, we discussed my
702 options, the benefits and consequences, and in my case, my
703 choices were, first, do nothing, wait for quadriplegia in the
704 next couple of years, or have fusions, which I later learned
705 meant I would likely have chronic pain in my neck and
706 possibly have cervical fusion in the future. The third
707 choice, wait a couple of months for an artificial cervical
708 disc in the FDA approval pipeline, one widely used and
709 successfully in Europe since 2003.

710 While I waited for device approval, my spine degenerated
711 to the point that my doctor and I feared I was in serious
712 danger. All my limbs were numb. My continence was an issue.
713 My balance and my grip were unreliable. I was a prisoner in
714 my own house for fear of going outside and having a
715 paralyzing accident, and I depended on everyone else to take
716 care of my needs. I knew I couldn't living this way safely
717 but I was not having fusions. Nor could I believe the newer
718 clinical cervical device technology which my doctor and I
719 felt was best for my problems were made 40 miles south of my

720 house and I could not get them installed in my Nation. Forty
721 miles from my house. By the way, those jobs have disappeared
722 to Europe because European countries will sometimes say, if
723 you don't have approval in the United States or your home
724 country, country of manufacture, you can't sell them here.
725 So they moved all those jobs, those \$160,000 to \$100,000 jobs
726 to Germany. Yet these devices were in successful use in
727 Europe and elsewhere.

728 My only option to get the best solution for me was for
729 me to go abroad. It took research and months of fundraising.
730 We drained our savings, what little we had. We accepted
731 \$5,000 in gifts from friends and family. I stripped my life
732 insurance policy of cash value. We incurred credit card
733 debt, and my 75-year-old husband had to return to full time,
734 and he has been working since.

735 Finally, I had my two-level ADR surgery in 2009 at the
736 Spine Clinic in England. My pain relief was immediate, and
737 my discs are functioning flawlessly. My U.S. neurosurgeon is
738 delighted. He does my follow-up.

739 And what about all the other--so I got the best solution
740 for me but it shouldn't have taken all my limited energy and
741 money to get them. What about all the other Marti Congers in
742 this country, people waiting for access to medical devices
743 that already have foreign approvals and years of track

744 record. I know, because I receive calls and emails every
745 week from spine patients from auto mechanics to engineers to
746 cardiac surgeons. They want to know how they might get the
747 treatment they need somewhere, somehow, because they are not
748 going to do the procedure here. And what about all the other
749 devices common in Europe and in Asia but bogged down in the
750 FDA process. Products often invented here aren't available
751 to U.S. patients for years after patients around the world
752 already have them. It simply shouldn't be this way. It
753 shouldn't.

754 I do appreciate, Mr. Stearns, that the agencies'
755 challenges that they face right now from all directions. I
756 appreciate their desire to protect people. However, our FDA
757 needs to restart, reset their priorities back to patients'
758 needs and away from political risk aversion. Patients are
759 looking for reasonable assurance and timely approval or
760 denial--not all devices make it--but absolute assurance, what
761 seems to be the goal here, is impossible, impossible, because
762 every human body is unique.

763 For products with strong track records, the FDA should
764 leverage regulatory findings from other trusted countries and
765 unions such as Japan, Australia, European Union and others,
766 and put them into the marketplace or at a minimum fast-track
767 them, then monitor--okay. Two sentences?

768 Mr. {Stearns.} Just if you could wrap up.

769 Ms. {Conger.} Yes. Monitor them in the marketplace.

770 Requiring known devices to restart the approval process from

771 the beginning when thousands of human already have them in

772 their body is ludicrous. The sooner we act on these changes,

773 the sooner U.S. patients will have access to the devices they

774 need at a reasonable price instead of waiting 2 to 10 years

775 to get the device here.

776 [The prepared statement of Ms. Conger follows:]

777 ***** INSERT 3 *****

|

778 Mr. {Stearns.} I thank the gentle lady.

779 Ms. Sagan, you are recognized for 5 minutes. I just

780 urge everybody if possible to keep it to 5 minutes.

|
781 ^TESTIMONY OF PAM SAGAN

782 } Ms. {Sagan.} Chairman Stearns, Ranking Member DeGette
783 and members of the committee, thank you for asking me to
784 testify before you today.

785 My husband and I have three children, the youngest of
786 whom, our daughter Piper, was diagnosed with type 1 diabetes
787 at the age of 2 in 1989. She has lived over 20 years with
788 this constant, frightening, deceptive and malicious disease.

789 I come before you today not only as a parent but as an
790 advocate for tools and technology for my daughter and others
791 with diabetes and with my enduring hope for a cure.

792 Piper has always been prone to hypoglycemic events--low
793 blood sugar. They seem to come on hard and fast. I remember
794 her almost drowning as a youngster after becoming unconscious
795 from low blood sugar while taking a bath. College also
796 brought one or two incidents a year where she slept into
797 hypoglycemia and didn't wake up the next morning, requiring
798 emergency medical care.

799 There is a chilling term that is the worry of every
800 parent of a child with diabetes called ``dead in bed.'' Kids
801 are found dead in the morning after a completely normal
802 evening the night before. Most of the time it is due to

803 severe hypoglycemia. I don't want this to happen to my
804 daughter or anyone else with diabetes, so you can understand
805 where my fire comes from.

806 Just this past winter, Piper, now a 24-year old, had
807 another severe hypoglycemic event. While working at a retail
808 store, the last thing she remembers is closing the front door
809 of the shop as she left to walk the 10 blocks to her
810 apartment. My cell phone rang at home, and she slurred to me
811 that she was locked out of her apartment. Upon further
812 conversation, I realized that she was low. She had wandered
813 her way home in a semiconscious state. She had crossed busy
814 San Francisco city intersections at rush hour, she had fallen
815 and scraped her hands as she walked, and she had lost bladder
816 control. She finally ended up at her apartment, the keys
817 were in her purse, but she didn't know what they were. She
818 pulled out her cell phone and pushed the number one, my cell
819 phone number. All this time, her continuous glucose monitor
820 was alarming, but her blood sugar was too low to take action,
821 and her insulin pump continued to pump insulin into her body,
822 lowering her blood sugar even more.

823 This is life with type 1 diabetes. Type 1 diabetes
824 occurs when the body's immune system attacks the cells in the
825 pancreas that produce insulin. Insulin regulates glucose in
826 one's body, and without it, a person with type 1 diabetes

827 cannot live. There is no cure for this disease and it
828 imposes an enormous physical, emotional and financial burden.
829 On average, a child with diabetes will have to take over
830 50,000 insulin shots or infusions in a lifetime. Every hour
831 of every day for the rest of her life, she will have to
832 balance insulin, food and activity to try to prevent low and
833 high blood sugars, and the devastating and costly
834 complications: seizures, comas, kidney failure, heart
835 disease, blindness and amputations. It astounds me that
836 diabetes costs our nation more than \$174 billion a year and
837 one in three Medicare dollars is spent to care for people
838 with diabetes.

839 Because of these burdens, people with diabetes and their
840 loved ones need timely access to innovative, life-saving
841 technologies to help better manage the disease. Some
842 breakthrough tools and technologies that protect against
843 dangerous diabetes episodes are already available all over
844 the world, but not available here in the United States.

845 I don't claim to be an expert on the regulatory process
846 at the U.S. Food and Drug Administration, but as a parent
847 with a daughter with diabetes, I am extremely frustrated that
848 better technologies to help people with diabetes are delayed
849 here in the United States. Low-glucose suspend systems have
850 been approved for nearly 3 years and used safely in over 40

851 countries worldwide, but they are not available here in
852 America. This technology is one critical example where our
853 Nation is lagging behind in the approval of devices that
854 would make living with this disease much safer. As
855 background, these pumps stop delivering insulin automatically
856 when a monitor indicates that the body's glucose levels are
857 low. With this kind of pump, my daughter wouldn't receive
858 more insulin when she is already low, causing her blood sugar
859 to drop further and potentially causing a seizure, coma and
860 even death. With the present FDA approval process, it will
861 require a clinical trial conducted in this country, and a
862 delay of years to conduct the study and compile the data
863 before a decision is made. Kids are dying from hypoglycemia
864 now. I want, and my daughter needs, this system available in
865 the United States today.

866 In 2006, I was thrilled that the FDA recognized the
867 importance of this technology and placed the artificial
868 pancreas on its Critical Path Initiative. That was 5 years
869 ago. With the funding from the Special Diabetes Program, for
870 which I am so grateful to all the members of this committee
871 for supporting, the artificial pancreas was tested favorably
872 in a hospital setting. Now it is time to move to outpatient
873 studies.

874 I implore Congress to continue to urge the FDA to move

875 forward on next steps relating to low-glucose suspend systems
876 and the artificial pancreas so that people with diabetes will
877 remain healthier and safer until a cure is found, and I would
878 lead the chorus of applause for the FDA when real progress
879 happens, but it has to happen very soon. My daughter's life
880 is depending on it.

881 [The prepared statement of Ms. Sagan follows:]

882 ***** INSERT 4 *****

|

883 Mr. {Stearns.} Thank you.

884 Mr. Mandel, you are recognized for 5 minutes.

|
885 ^TESTIMONY OF MICHAEL MANDEL

886 } Mr. {Mandel.} Members of the subcommittee, thank you
887 very much for the opportunity to testify on medical device
888 regulation and its impact on health and innovation.

889 This statement draws heavily on a recent policy brief
890 that I wrote for the Progressive Policy Institute where I am
891 chief economic strategist. I am going to talk about one
892 specific example where the FDA is apparently impeding
893 innovation. I will then briefly discuss what we can do to
894 boost innovation without hurting health and safety while
895 expanding high-quality health care to underserved
896 populations.

897 My major focus as an economist is the link between
898 innovation and jobs. U.S. job growth has been weak since
899 2000. Surprisingly, innovation has been weak as well once we
900 look beyond IT and communications. We got the iPhone but we
901 didn't get gene therapy. We got Angry Birds but we didn't
902 get enough health-improving, productivity-enhancing medical
903 technologies. The question is why. There are plenty of
904 culprits. Profit-seeking companies, inflexible doctors, out-
905 of-control lawyers, myopic academics, the list could go on
906 and on. But today I am going to focus on the FDA.

907 The FDA has a very tough and essential job: ensuring
908 the health and safety of the American public. But over the
909 years, people have regularly complained to me that the FDA
910 imposes excessive requirements on the approval of new drugs
911 and devices. No doubt the FDA has gotten stricter in recent
912 years about requiring evidence of safety and effectiveness.
913 However, by itself, that is not enough to show over-
914 regulation. Health and safety is paramount, and no one wants
915 dangerous drugs and devices put on the market. It could be
916 that we were under-regulating before. However, in May 2011,
917 I heard about one example that suggested over-regulation.
918 This was MelaFind, a name that I had never heard before, a
919 handheld computer vision device intended to help
920 dermatologists decide which suspicious moles and spots should
921 be biopsied for melanoma.

922 Not to go into detail here, but if MelaFind worked, it
923 was easy to see how it could improve health and cut costs.
924 Moreover, MelaFind could be used to augment care in low-
925 income and rural areas. Equally important, the device was
926 non-invasive. That meant it was as safe as possible, and it
927 was an IT-driven expert system, which meant that it would get
928 better over time as the computer power increased. Imagine my
929 surprise when I discovered that the FDA staff had deemed
930 MelaFind not approvable, and double my surprise when I read

931 the briefing document that the FDA staff prepared for a panel
932 of dermatologists, statisticians and other experts who were
933 voting on whether to recommend MelaFind for approval. The
934 FDA briefing document started with a very reasonable analysis
935 of the shortcomings of the MelaFind test results. I was
936 initially quite sympathetic to FDA's perspective but when the
937 FDA started listing its broader objection to MelaFind and
938 what it expected the device to do, it quickly became clear
939 that the agency was using a set of standards that no first-
940 generation device could ever reach.

941 Just a couple of striking ones. The FDA objected
942 because the study did not find ``a clinically significant
943 difference between MelaFind and the examining
944 dermatologist.'' The agency also objected because the device
945 was not demonstrated to make inexperienced doctors the equal
946 of experienced dermatologists. Let me repeat that. The FDA
947 apparently was saying that in order to be approved, that
948 MelaFind had to beat experienced dermatologists and had to
949 turn inexperienced doctors into the equivalent of board-
950 certified dermatologists. These are great goals. These are
951 fantastic goals. However, they are also goals that no first-
952 generation device can ever reach. Failing to approve
953 MelaFind is the equivalent of rejecting the first cell phone
954 on the grounds that callers might mishear important emergency

955 messages. Or think about a government body telling Steve
956 Jobs in 1977 that the first Apple computer was not approvable
957 because he had not submitted a study showing Apple users
958 could be trained to produce the same results as users of
959 mainframe computers.

960 Because MelaFind is non-invasive, it gives us a clear
961 window into the FDA's approach that we don't get from other
962 devices and drugs that may have negative side effects. As an
963 economist, it worries me that we are missing health-
964 improving, productivity-enhancing devices and drugs because
965 the FDA has too narrow a perspective. Thank you.

966 [The prepared statement of Mr. Mandel follows:]

967 ***** INSERT 5 *****

|

968 Mr. {Stearns.} Thank you.

969 Dr. Ianchulev, you are recognized for 5 minutes.

|
970 ^TESTIMONY OF SEAN IANCHULEV

971 } Dr. {Ianchulev.} Thank you. Mr. Chairman, Ranking
972 Member DeGette and members of the subcommittee, I am Dr.
973 Ianchulev, and I would like to thank you for the opportunity
974 to share my personal experience with the FDA and the
975 regulatory process and its impact on patient care, innovation
976 and development of new technologies in this country. These
977 are my own opinions, and I share them to you from the
978 perspective of a physician, innovator and developer of some
979 new therapeutics and devices.

980 In the way of background, I am a physician, eye surgeon
981 who uses medical devices and technology to treat and prevent
982 blindness. I am an associate clinical professor on the
983 faculty of UCSF School of Medicine, where I see firsthand the
984 translation of research into patient care, and as the
985 developer and inventor of new technologies in the field, I
986 have led innovative treatments through the regulatory process
987 with the FDA and I have direct experience with the drug and
988 device side of the FDA in addition to experience with the
989 European regulatory authorities.

990 Physicians such as myself feel privileged to be
991 educated, practice and advance medicine in the United States.

992 The United States has been a leader in cutting-edge
993 innovation traditionally, and my field, ophthalmology, is a
994 bright example to that effect. In fact, the most common
995 device implanted today is the intraocular lens implant for
996 cataracts, and this has been one of the most successful,
997 effective and safe treatments to date based on innovation of
998 the 1980s and 1990s and based on leadership of the FDA at
999 that time with a streamlined regulatory process.

1000 Today more than ever, we need best-in-class technology
1001 in service to our aging population and it is unfortunate that
1002 patients are starting to seek care from foreign doctors who
1003 are now trained and have hands-on experience with
1004 technologies we see much later in the United States, as we
1005 heard today. As a physician who not only delivers the
1006 standard of care but also innovates in my field, I have
1007 failed a number of times to treat patients with what I think
1008 is the best treatment for them. In fact, I see more and more
1009 patients seeking the often-challenging offshore route in
1010 search of interventions that are not available here with much
1011 added cost, frustration and pain. When recently asked by a
1012 patient suffering from a degenerative, blinding eye disease
1013 about a therapy not approved in the United States but
1014 available in other countries, I had to stay silent. The
1015 patient ended up traveling to Canada to receive treatment for

1016 which he paid out of pocket.

1017 But I would like to go beyond the anecdotal experience
1018 and ask the bigger question: what innovative first-class
1019 therapies are we delivering to patients today? Let us take
1020 the field of ophthalmology, which is a good example with its
1021 high degree of technical innovation and device utilization.
1022 To check the innovation pulse prior to this hearing on the
1023 way here, I reviewed all of the FDA-approved PMA devices in
1024 my field over the past 5 years. As you aware, the PMA class
1025 III devices is the lifeblood of innovation and some of the
1026 most advanced, complex devices for life-sustaining or, in my
1027 case, vision-sustaining, treatments are approved through this
1028 process. I reviewed the labels of all 12 such devices I
1029 could find on the FDA website. At the time of approval, all
1030 of them had been approved not only in the EU but in many as
1031 20 to 40 countries before they were approved in the United
1032 States. In addition, some of the devices already had vast
1033 clinical experience dwarfing the FDA clinical trial numbers
1034 and in some examples those were more than 100,000 patients
1035 treated worldwide before FDA approval. In one illustrative
1036 case with the cumulative world experience of more than 60,000
1037 patients, the FDA label spoke only of 300 patients in the
1038 registration trials, too few and too late.

1039 Avoiding a long discourse on the meaning of the

1040 symptomatic state, it is not hard to see that we have failed
1041 to deliver best-in-class innovation. More importantly, we
1042 now see that new technologies are not only perfected abroad
1043 but are developed and commercialized to their full extent and
1044 companies now execute not only on small feasibility studies
1045 but implement their main validation studies, their clinical
1046 research programs and even product launches abroad, as
1047 evidenced by a recent MDVC report. What follows with that is
1048 the departure of talent, expertise and patients.

1049 The FDA is the gateway for new therapies, and as a
1050 vigilant gatekeeper, the regulatory process has to ensure
1051 safety and efficacy, but it has to facilitate innovation, and
1052 examples of that are right in the halls of the FDA. As a
1053 drug developer who headed the clinical research and
1054 development programs at one of the most successful approved
1055 biologic therapies for eye disease, Lucentis for macular
1056 degeneration, I have added comparative experience from the
1057 CDER, whose input and oversight were critical in the
1058 execution of this highly complex, rigorous therapeutic
1059 program of biologics and resulted in the commercialization of
1060 a groundbreaking therapeutic which helps hundreds of
1061 thousands of patients today.

1062 So this program was not only successful but exemplary in
1063 many ways of how the regulatory process should work and was

1064 referenced by the FDA itself in a published guidance to
1065 industry for best-in-class drug development. The key
1066 learnings from this experience--explicit guidance to
1067 companies and investigators, consistency and transparency of
1068 feedback in the review process, and a high level of in-house
1069 expertise from the FDA reviewers.

1070 My experience with the development of new technologies
1071 is that the pathway to innovation is challenging and it is
1072 necessary to take calculated risks in a thoughtful and
1073 deliberate way and to protect patients. We need safe and
1074 effective treatment for all patients and it is critical that
1075 we have the best-in-class regulatory process to do justice to
1076 the high level of passion, hope, talent and resources this
1077 country invests in the innovation process in helping
1078 patients. Thank you.

1079 [The prepared statement of Dr. Ianchulev follows:]

1080 ***** INSERT 6 *****

|

1081 Mr. {Stearns.} Thank you.

1082 Dr. Curfman, you are recognized for 5 minutes.

|
1083 ^TESTIMONY OF GREGORY CURFMAN

1084 } Dr. {Curfman.} Thank you, Chairman Stearns, Ranking
1085 Member DeGette and other distinguished members of the
1086 subcommittee. My name is Gregory Curfman. I am a
1087 cardiologist and I am the Executive Editor of the New England
1088 Journal of Medicine.

1089 For nearly 200 years, the New England Journal of
1090 Medicine has been publishing research articles on new drugs
1091 and medical devices. We are strongly committed to
1092 innovation. Vigorous innovation in medical products is
1093 critical to the health of our Nation. But we have learned
1094 that innovation in medical treatments does not come easily.
1095 While some new drugs and devices succeed, others
1096 unfortunately fail, in many cases, owing to serious problems
1097 with safety. Innovation is essential to the future of our
1098 Nation but innovative medical products cannot succeed unless
1099 they are both effective and safe. Sensible quality assurance
1100 does not stifle innovation, it promotes it and avoids costly
1101 nightmare scenarios caused by flawed and potentially
1102 dangerous medical devices.

1103 Let me give two recent examples of innovative medical
1104 devices, one from the field of cardiology and the other from

1105 the field of orthopedic surgery, both of which were approved
1106 by the FDA by the 510(k) fast-track process, but which were
1107 later found to be seriously defective even while they were
1108 being implanted in many thousands of patients.

1109 The first example, from the field of cardiology, is the
1110 Sprint Fidelis implantable cardioverter-defibrillator lead,
1111 which was manufactured by Medtronic. This lead, which
1112 delivered an electric shock to the heart in order to halt
1113 potentially fatal heart rhythms, was approved by the FDA by
1114 the 510(k) process without clinical testing. The
1115 defibrillator lead received considerable hype as a major
1116 innovation in defibrillator technology. However, soon after
1117 fast-track approval of the Sprint Fidelis, it became clear
1118 that the lead was prone to fracture, which resulted in
1119 inappropriate shocks in many patients and caused at least 13
1120 deaths. The lead was eventually withdrawn, but only after it
1121 had been implanted in over a quarter of a million patients
1122 worldwide. Thus, inadequate premarket testing and a fast
1123 track to FDA approval, resulted in a devastating situation
1124 for patients.

1125 The second example, from the field of orthopedic
1126 surgery, and Congressman Waxman referred to this earlier, is
1127 a type of artificial hip implant known as the metal-on-metal
1128 design. Hip implants originally consisted of a metal ball

1129 inserted into a plastic cup. In newer models, which were
1130 widely hyped as a major technological innovation, the plastic
1131 was replaced with a metal alloy, the so-called metal-on-metal
1132 design. The new design was approved by the 510(k) fast-track
1133 process and did not undergo clinical testing, only bench
1134 testing. Not long after FDA approval, reports of shedding of
1135 metallic debris and failure of the metal-on-metal implants
1136 began to surface, and upwards of tens of thousands of
1137 patients have thus far been adversely affected.

1138 Unfortunately, bench testing of the device did not
1139 faithfully reproduce the wear and tear of real life. Thus, an
1140 apparently minor alteration in design--replacement of plastic
1141 with a metal alloy--resulted in nothing short of a public
1142 health nightmare.

1143 These are sophisticated engineering devices that we are
1144 talking about. These two examples vividly demonstrate that
1145 the glamour of innovation does not always work out well for
1146 patients. Innovation in medical devices must go hand in hand
1147 with a careful assessment their efficacy and safety. Such
1148 quality control measures do not imperil innovation; they
1149 advance it, they secure it.

1150 As for the European Union, the timelines to device
1151 approval there are only modestly shorter than in the United
1152 States, and it is of concern that in Europe, in contrast to

1153 the United States, the highest risk-devices, so-called class
1154 III devices, do not have to be shown to improve clinical
1155 outcomes prior to their approval. That is something to think
1156 about.

1157 Mr. Chairman, innovation in medical devices is a high
1158 priority for our Nation, but to be truly innovative and to
1159 avoid costly mistakes, there must be solid evidence that new
1160 medical devices are both effective and safe. Thank you, Mr.
1161 Chairman.

1162 [The prepared statement of Dr. Curfman follows:]

1163 ***** INSERT 7 *****

|
1164 Mr. {Stearns.} I thank you, and I thank all our
1165 witnesses.

1166 Dr. Ianchulev, you mentioned a capital report in your
1167 testimony. Do you mind submitting it for the record?

1168 Dr. {Ianchulev.} I have it here.

1169 Mr. {Stearns.} Okay. That would be fine.

1170 Let me start by asking my questions. Dr. Fischell, I
1171 will start with you. Your résumé obviously is very
1172 impressive. You are a physicist, an inventor. It says you
1173 have over 200 U.S. and foreign medical patents. At one time
1174 you were honored as inventor of the year in the United
1175 States, so you do have a high degree of credibility. So my
1176 question to you is, you state in your testimony that the
1177 environment that exists today at the FDA device center over
1178 the past few years, you specifically pointed out, is the
1179 worst that you have experienced in 42 years. Now, that is a
1180 pretty strong, dramatic statement. Can you give us specifics
1181 why you think that is true?

1182 Mr. {Fischell.} There is a new attitude of the
1183 reviewers at the FDA. They are very proud to be
1184 conservative. Conservative says oh, I am going to throw it
1185 back, I won't approve it, therefore, I am protecting the
1186 American people from potential harm, and in some cases, they

1187 should have. One of the problems is that the reviewers are
1188 not expert in the field. For example, with our migraine
1189 device, we proved in clinical trial it cured migraine, it
1190 cured sensitivity to light and sound, but we didn't reach the
1191 95 percent certainty for nausea, only 88 percent certainty.
1192 They said it is therefore not approvable for pain, for
1193 migraine, which it cured in an excellent way. So I think it
1194 is this conservativeness that the people have that is
1195 encouraged and say oh, you are really a good guy, and to me,
1196 that is the main problem. I think we need more expertise at
1197 the reviewer level. We have a medical advisory board of
1198 eight leading migraine doctors in the world who go to the FDA
1199 and say what should be approved. The person there is a
1200 couple months out of college with no training in migraine and
1201 they stop it.

1202 Mr. {Stearns.} Dr. Shuren is here in the audience, and
1203 I want to compliment him for staying and listening here.
1204 Normally sometimes the Administration speaks first. He was
1205 very confident and conscientious enough to say he would
1206 listen to you, so I think that is a credit to him, and I want
1207 to compliment him for staying and listening. Oftentimes the
1208 Administration comes over and speaks and they are out the
1209 door. So it is a compliment to him for staying here.

1210 But let us I put you in charge of FDA tomorrow, okay?

1211 What would you do different or what would you tell Dr. Shuren
1212 that you would suddenly create this new environment that
1213 would give the United States the answer to some of these
1214 problems that our witnesses have said?

1215 Mr. {Fischell.} I would--I have carefully thought about
1216 this and the problems that Congressman Waxman has raised, and
1217 what I think should be done is, when a 510(k), for example,
1218 goes to the FDA, the reviewer then should seek like three
1219 experts in that field to review the clinical trials
1220 suggested, and when that clinical trial is done, to review
1221 the results so that it is reviewed by people expert in the
1222 field, not just a reviewer with no experience in that field.
1223 I think that would change safety and efficacy.

1224 Mr. {Stearns.} So the bottom line is that people that
1225 are making these decisions don't have the confidence, in your
1226 opinion?

1227 Mr. {Fischell.} I was with Commissioner Hamburg just a
1228 couple of weeks ago, who said they have a lot of trouble with
1229 retaining people and what have you, and I think that the FDA
1230 could easily call upon within a week of submission experts in
1231 the field like three experts in leads for defibrillators, and
1232 say please review this because you have spent 10 years of
1233 your life on it, I have never heard of it before. Does it
1234 not seem obvious that those who are expert in the field

1235 should be reviewers, not a person who happens to be there?

1236 Mr. {Stearns.} But it is interesting, you are saying
1237 that in your 42 years of experience, you have never seen it
1238 as recent in the last couple years like it is today, so your
1239 complaint is very serious on criticism of the present FDA
1240 right now.

1241 Mr. {Fischell.} I think there is a different attitude
1242 there than we have seen before.

1243 Mr. {Stearns.} Thank you for saying that.

1244 Dr. Ianchulev, Dr. Shuren, who is behind you, mentions
1245 in his testimony that poor submission quality is a big reason
1246 behind the sharp increase in review times we have seen in the
1247 past 7 years. That is going to be his case. Now, you have a
1248 lot of experience in submitting device applications to the
1249 center. Do you agree with his assessment?

1250 Dr. {Ianchulev.} Yes. I can make a comment on that.
1251 It is always hard to be self-critical. I am sure my
1252 submissions can probably be better, but a couple of
1253 observations that I have realized working on that front in
1254 the trenches. Very often, as we know, companies that operate
1255 in the device space especially and it is slightly different
1256 in the drug space with the big pharmaceuticals are smaller
1257 companies, companies that have fewer than 50 employees, so
1258 one can imagine that they don't have always in-house

1259 expertise and specialization. But at the same time, a lot of
1260 them outsource all of their regulatory processes, especially
1261 today when they are so challenged and so complex, they
1262 outsource it to regulatory experts, and in my experience,
1263 that has been usually the way of submissions to the FDA to go
1264 through an outside consultant or expert with usually 20-plus
1265 years of regulatory experience. So I really can't comment to
1266 every submission. I am sure that they have better visibility
1267 to that but I can imagine that that expertise on the
1268 consulting firm has not changed.

1269 And then also, I think that is a good point because it
1270 would be really nice to see best-in-class examples of
1271 submissions where the agency proactively can give that
1272 guidance if they are concerned about the status and quality
1273 of those submissions, that people that work with them can see
1274 what the expectations are up front, see good examples of good
1275 submissions and really adjust their practices.

1276 Mr. {Stearns.} I thank the gentleman. My time is
1277 expired.

1278 The gentlelady from Colorado, Ms. DeGette, the ranking
1279 member, is recognized for 5 minutes.

1280 Ms. {DeGette.} Thank you very much, Mr. Chairman. I
1281 want to thank all the witnesses for coming today and
1282 particularly the three patient advocates who have come their

1283 stories.

1284 I just want to clarify with all three of you. Your
1285 stories are all compelling and they touch all of us because
1286 we all have relatives or friends in the same situation. By
1287 talking about how these devices could be brought to market
1288 and help you or your families, none of you are saying that
1289 you would sacrifice safety or thoroughness of review,
1290 correct? Ms. Murphy, you're not saying you would sacrifice
1291 safety or thoroughness of review?

1292 Ms. {Murphy.} No, I am not.

1293 Ms. {DeGette.} And Ms. Conger?

1294 Ms. {Conger.} Safety and what?

1295 Ms. {DeGette.} And thoroughness of review to make sure
1296 that it is safe.

1297 Ms. {Conger.} Within reasonable.

1298 Ms. {DeGette.} Right. Ms. Sagan?

1299 Ms. {Sagan.} Absolutely.

1300 Ms. {DeGette.} You would not sacrifice--

1301 Ms. {Sagan.} I would not sacrifice safety.

1302 Ms. {DeGette.} And Dr. Fischell, you are not saying
1303 that either. You think that these devices should be safe,
1304 correct?

1305 Mr. {Fischell.} Absolutely, but it should be done in a
1306 timely manner.

1307 Ms. {DeGette.} In a timely and efficient manner.

1308 Now, Dr. Fischell, I don't know if you were aware, you
1309 are an inventor and you submit these devices to the FDA.
1310 Now, the budget that was passed by the Republican majority in
1311 the House two times this spring cut the FDA's funding by
1312 about \$241 million. So if we are going to hope to be able to
1313 hire experts to review these applications quickly and to have
1314 the expertise, do you think that a substantial cut in the FDA
1315 budget would assist us in being able to expedite these
1316 reviews?

1317 Mr. {Fischell.} I am sure that every company involved
1318 including about six companies I am involved with would be
1319 happy to pay for the fees paid to such experts to do the job
1320 in a prompt way.

1321 Ms. {DeGette.} Right, but certainly budget cuts is not
1322 going to help us, is it?

1323 Mr. {Fischell.} No, but the budget--this would not
1324 increase the budget.

1325 Ms. {DeGette.} Right.

1326 Mr. {Fischell.} It would be paid for by the--

1327 Ms. {DeGette.} Okay. I actually kind of agree with
1328 that.

1329 Let me ask you, Ms. Sagan, because you mentioned the
1330 Special Diabetes Program, which makes funds available for

1331 type 1 diabetics and also American Indian populations, and
1332 last year we reauthorized that. As you said, a lot of those
1333 funds are going toward clinical trials for the artificial
1334 pancreas. Now, just so you know, we sent that letter that I
1335 mentioned that almost all the members of this subcommittee
1336 including the chairman signed asking about quick approval of
1337 the artificial pancreas, and also I spoke with Commissioner
1338 Hamburg about this issue of the low blood glucose, and I am
1339 pleased to tell you that we got a quick response to that
1340 letter in June and the FDA issued a guidance on that low
1341 blood glucose monitor stopping, so we can move forward on
1342 these things and we do have hope that we will move quickly.

1343 But from your perspective and from your daughter's
1344 perspective, I know you probably agree, we don't want to
1345 approve an artificial pancreas if it is going to be defective
1346 because it could kill the patients, right?

1347 Ms. {Sagan.} Yes.

1348 Ms. {DeGette.} So we want to make sure it is going to
1349 work.

1350 Ms. {Sagan.} Yes, we do.

1351 Ms. {DeGette.} Yes. And that is kind of the same way I
1352 feel too. So I guess I wanted to ask you, what is your
1353 perspective as an advocate of how the FDA should balance the
1354 safety with the speed in approval that we need for these

1355 medical devices?

1356 Ms. {Sagan.} Well, in terms of the low-glucose suspend,
1357 I don't think there is an issue with safety.

1358 Ms. {DeGette.} I agree with you on that, but in
1359 general--

1360 Ms. {Sagan.} In general, if--I mean, I believe that
1361 there should be clear guidance documents and a decision made
1362 in a timely manner. If it is a 90-day period, it should be
1363 90 days, and it shouldn't be further delayed after that. We
1364 have to have safety and we are so ready to go to outpatient
1365 clinical trials with artificial pancreas. We have done all
1366 the inpatient clinical trials.

1367 Ms. {DeGette.} Now, Dr. Curfman, I just want to finish
1368 with you because you heard all of these stories, and in your
1369 job you do all the time. What can be done to make sure that
1370 we expedite safe and efficacious devices but at the same do
1371 the thorough reviews that we need? Is there something that
1372 can be improved at the FDA right now to do that?

1373 Dr. {Curfman.} We are looking for a balance. It has to
1374 be a balanced approach. On the one hand, we want to speed
1375 innovation to patients, absolutely. On the other hand, we
1376 want to be sure that the devices work, that they actually
1377 improve human health and that they are safe.

1378 Ms. {DeGette.} Do you think there is any problem at the

1379 FDA right now?

1380 Dr. {Curfman.} I think that there are two things that I
1381 would look at at the FDA. Number one, I do think that the
1382 510(k) process needs to be looked at. I think there are
1383 issues there. Some devices are being looked at under the
1384 510(k) that probably shouldn't be. On the other hand, there
1385 are also inefficiencies in the process that are slowing down
1386 approval in some cases. My sense is that it has gotten
1387 better but I think that more work can be done to make it a
1388 more efficient process.

1389 Ms. {DeGette.} Thank you very much.

1390 Dr. {Burgess.} [Presiding] I thank the gentlelady for
1391 yielding.

1392 Dr. Fischell and Dr. Curfman, let me just be sure I have
1393 some of my facts straight. Dr. Fischell, do I understand
1394 that you are affiliated with Johns Hopkins University?

1395 Mr. {Fischell.} I worked at the Johns Hopkins
1396 University for 30 years and was on the medical faculty as
1397 well as working as a physicist at the Applied Physics Lab.

1398 Dr. {Burgess.} So an academic at Johns Hopkins?

1399 Mr. {Fischell.} Yes.

1400 Dr. {Burgess.} And Dr. Curfman, are you at Mass
1401 General? Where is your hospital affiliation?

1402 Dr. {Curfman.} Yes, at Mass General Hospital and

1403 Harvard Medical School.

1404 Dr. {Burgess.} So just on the face of it, it seems like
1405 the two of you are terribly similar. It appears as if your
1406 politics are similar, you are both academics at big Eastern
1407 facilities, and yet your conclusions are significantly
1408 different, at least as I perceive on the panel today. You
1409 are shaking your head no, you feel exactly as Dr. Fischell
1410 does. Is the difference because he is an innovator and you
1411 are a reviewer? I know in my days in medicine, we used to
1412 regard that there were two types of doctors. There are
1413 thinking doctors and there are doing doctors. As an OB/GYN,
1414 I was a doing doctor, all kinds of things we did in our
1415 practice, but I didn't think very much. So you are the
1416 thinking doctor here, and Dr. Fischell is the doing doctor.
1417 Is that the difference here?

1418 Dr. {Curfman.} No, I think we are really on the same
1419 page but innovation requires two things. It requires fresh
1420 ideas, new ideas, interesting new approaches, but it also
1421 requires careful testing to be sure that the device works.

1422 Dr. {Burgess.} And I don't disagree with that. I want
1423 to get back to the 510(k) process in a minute, but Dr.
1424 Fischell, you said something that I just thought was so
1425 important. I mean, in this committee in 2007, we
1426 reauthorized the user fees for both the prescription drugs

1427 and medical devices here in this committee, and one of the
1428 big fights that we had that I lost was over the people that
1429 make up these advisory panels to the FDA, and at that time,
1430 of course, Republicans were not in charge and that is why I
1431 lost, but the pendulum swung so far that we cannot have
1432 anyone on a review panel that might have any appearance of a
1433 conflict of interest, and as a consequence, we excluded the
1434 universe of people who actually had some idea about what
1435 these products did. So in retrospect, I guess what I am
1436 trying to get you to say that I was right with those
1437 amendments that were defeated, but can you speak to that for
1438 just a moment? Because you were on that path a moment ago.

1439 Mr. {Fischell.} Yes.

1440 Dr. {Burgess.} And I want former Chairman Waxman,
1441 Ranking Member Waxman to hear this.

1442 Mr. {Fischell.} Well, there is always--

1443 Dr. {Burgess.} So start out with ``Dr. Burgess, you
1444 were correct.''

1445 Mr. {Fischell.} Yes, I do believe you are correct, and
1446 even though I am a very good friend of Congressman Waxman,
1447 and it is a matter of, there is an old saying, you can either
1448 have somebody who is expert in it and they--or someone who
1449 has never worked in the field, and if you have someone who
1450 has no knowledge of the field, that doesn't work very well.

1451 And so you need people who really have knowledge in that
1452 field, and also the FDA seems to be exceedingly slow. They
1453 don't even follow their own guidelines. For example also, in
1454 this device for migraine, there is no predicate device. We
1455 invented something new. And so we had to go to a 510 de novo
1456 510(k). To get a de novo 510(k), you must first say to the
1457 FDA that we cannot find--no, we first suggest devices that
1458 could be predicate devices. We knew there were none. And
1459 they said you are wrong, there are none. We say it is de
1460 novo. They said oh, okay, then it can be de novo. You
1461 cannot go to the FDA and say it is a de novo device.

1462 Dr. {Burgess.} Do you think--

1463 Mr. {Fischell.} That cost us several months at the
1464 beginning.

1465 Dr. {Burgess.} Do you think you got good advice from
1466 the FDA about what they would need to see from you to get
1467 this device approved in a reasonable period of time?

1468 Mr. {Fischell.} No. We wanted to cure migraine
1469 headache. They needed us to cure photophobia, phonophobia
1470 and nausea with a 95 percent certainty.

1471 Dr. {Burgess.} Let me ask you a question on the nausea.

1472 Mr. {Fischell.} We got 95 percent on two of them but
1473 only 88 percent in nausea and they therefore said, I will
1474 never forget the words, it is not approvable.

1475 Dr. {Burgess.} On the nausea question, does a placebo
1476 score an 88 percent if you--

1477 Mr. {Fischell.} No, no, no. We were much better than
1478 the placebo but so few patients had nausea that we didn't get
1479 the statistic.

1480 Dr. {Burgess.} And this is a noninvasive device?

1481 Mr. {Fischell.} Correct, and not only that--

1482 Dr. {Burgess.} You don't have to open anyone's head and
1483 put anything inside?

1484 Mr. {Fischell.} A prior device made by Neuronetics for
1485 depression has 20 percent stronger magnetic pulse and 30,000
1486 times more pulses. It is approved and working by the prior
1487 FDA. Even though we were a tiny fraction of that, we could
1488 not gain approval.

1489 Dr. {Burgess.} Let me just, Mr. Mandel, if I could,
1490 just ask you briefly on the MelaFind. In the continuum of
1491 things that are approved, where does MelaFind fall? Is it a
1492 reasonable device for a practicing physician to have in their
1493 hands?

1494 Mr. {Mandel.} I think the company is intending it to be
1495 an adjunct for dermatologists, so I think you have to
1496 distinguish between the first-generation device, which would
1497 be restricted, I think, to experts with a lot of savvy, and
1498 then the company wouldn't say this but I would, if you kind

1499 of look down the path future in the future, you could see how
1500 the improvements would enable that it could be more used more
1501 broadly than that, and when I think about what is being lost
1502 right now, it is not only the device as it exists but it is
1503 the future as well.

1504 Dr. {Burgess.} Well, I would just say from the
1505 perspective of somebody who used to practice general OB/GYN,
1506 to have a device, we are told we must do skin screenings
1507 every year when a patient comes in for a visit to have
1508 something that could help us determine, rather than just
1509 sending everything back to the dermatologist or off to the
1510 dermatologist to be biopsied at great cost, something to help
1511 us discriminate a little bit finer because not all of us
1512 remember what we learned in medical school about the
1513 irregular borders, the degree of coloration.

1514 Mr. {Mandel.} The FDA says it wants to have a device.
1515 The FDA says that it wants the device to be able to do that,
1516 to be able to help an inexperienced doctor, but there is no
1517 way to get from here to there without the steps in between.
1518 It is like asking--it is like refusing to approval the
1519 initial cell phone until you can have an iPhone first.

1520 Dr. {Burgess.} I understand. Well, I thank you, and I
1521 will yield back my time and yield to Mr. Waxman for
1522 questions.

1523 Mr. {Waxman.} Thank you very much. Thank you all. As
1524 witnesses, you have been very compelling in your stories and
1525 your experiences, and all of us want to see these things move
1526 faster. We want to get those therapies to those who need it.
1527 The question that comes to my mind, the proposals that would
1528 weaken the standards for the Food and Drug Administration, I
1529 think a lot of the problem, and I look forward to hearing
1530 from Dr. Shuren after this panel, but I think a lot of the
1531 problem is that either the FDA does not have the resources or
1532 there are problems at FDA in processing what is going on or
1533 there are problems with the developers, the manufacturers who
1534 aren't getting their studies done adequately. And I must
1535 say, when I hear about weakening the standards, it bothers me
1536 because we hear all the time reports about horrific patient
1537 suffering from dangerous medical devices. In the last year,
1538 the New York Times reported on radiation machines that have
1539 killed and disfigured patients, malfunctioning linear
1540 accelerators that left a woman nearly comatose. We have
1541 heard from the father of a patient who died due to an
1542 overdose of radiation therapy, and we have also heard about
1543 problems with the Sprint Fidelis implantable heart devices
1544 that caused at least 12 deaths. I don't think devices are
1545 something that we shouldn't take seriously as we do drugs.
1546 They both must meet a safety and efficacy standard. In the

1547 face of these reports of problems, it is hard to agree with
1548 the sentiment that we need to reduce FDA's authority to make
1549 sure medical devices are safe and effective.

1550 Dr. Curfman, you testified on this subject. Should we
1551 be looking at strengthening or weakening FDA's standards and
1552 FDA authority for medical device approval?

1553 Dr. {Curfman.} Thank you. It is a balance. We all
1554 want devices to move quickly to patients so that our patients
1555 are helped by them but at the same time they need to be
1556 evaluated, and the clinical trial, the randomized clinical
1557 trial is now the gold standard for evaluating drugs and
1558 devices, and we are very fortunate in our country to have
1559 some of the leading clinical trial centers in the world in
1560 the United States. This has become a very expert scientific
1561 discipline to run a good clinical trial, to do it right, to
1562 do it rigorously, to get the right answers. And we are very
1563 fortunate now that this science of doing clinical trials has
1564 become very, very sophisticated. We have in the United
1565 States among the very best clinical trialists in the world
1566 and they understand the importance of doing these trials
1567 efficiently and quickly, and we at the New England Journal
1568 understand the importance of publishing the results of these
1569 trials quickly and efficiently.

1570 Mr. {Waxman.} We had problems with drugs, and the

1571 concern about the delay of approval of drugs, so a number of
1572 years ago when I was chairman of this subcommittee, we put
1573 into law that there would be a user fee that the
1574 manufacturers of the pharmaceuticals would pay so that FDA
1575 could hire the personnel. I don't like that idea. I think
1576 this is a government function and we ought to be willing to
1577 pay for essential government functions, and the FDA is one of
1578 those essential government functions. But there was no way
1579 we were going to get more appropriations.

1580 Now, in the medical device area, we do not have a user
1581 fee. We are relying on the money that the government
1582 appropriates for FDA. I would be interested if anybody on
1583 this panel thinks it is appropriate, given your concerns,
1584 that we reduce FDA's money. I think the Republicans are
1585 proposing to reduce FDA by \$250 million, which would make
1586 them less able to approve drugs and devices and to do the
1587 other things that they need to do like food safety. Does
1588 anybody think it is a good idea to reduce the funding for
1589 FDA?

1590 Ms. {Conger.} Yes, I do, because I don't think that the
1591 FDA, the organization as itself is functioning as efficiently
1592 as it could be because--

1593 Dr. {Burgess.} Well, you think they should be--

1594 Ms. {Conger.} --they drag--

1595 Dr. {Burgess.} I only have a limited time. So you
1596 think they should be because FDA is not doing a good job. I
1597 want FDA to do a good job, but FDA has to have the resources.
1598 There is a user fee and there is a fight--

1599 Ms. {Conger.} And the right people.

1600 Dr. {Burgess.} They need the right people. They need
1601 to pay the right people. You are not going to get good,
1602 competent people to work for the government if you underpay
1603 them.

1604 Ms. {Conger.} And don't--

1605 Dr. {Burgess.} Excuse me. I am not in a conversation.

1606 Ms. {Conger.} I am sorry.

1607 Dr. {Burgess.} Perhaps another time. But the fact of
1608 the matter is, proposals are to weaken the standards, spend
1609 less money on the FDA, and all this has to be put in the
1610 perspective of the Supreme Court decision that I think was
1611 misguided when they said some medical devices are immune from
1612 lawsuits at the State level.

1613 Dr. Curfman, do you have any view on the Supreme Court
1614 decision preempting lawsuits at the State level?

1615 Dr. {Curfman.} Well, it is pretty irrational because
1616 there is a different standard for drugs and devices. There
1617 is preemption of State-level legal action for devices. There
1618 is no preemption of State legal action for drugs. So it just

1619 doesn't make any sense. There may be technical legal reasons
1620 why it came out that way but we need to do something about
1621 that to make this a more rational and logical system.

1622 Mr. {Waxman.} Well, I just want to say in closing, I
1623 don't think we are going to be moving in the right direction
1624 if we reduce the money that goes to FDA, we don't get a user
1625 fee to help them pay for the people reviewing the medical
1626 devices, and then the answer isn't to say oh, just put them
1627 on the market and we will see what happens. If people get
1628 hurt, they won't use them anymore. If they are hurt because
1629 of negligence, they can't sue. And then the FDA can't even
1630 conduct the oversight on the safety and the efficacy of these
1631 products.

1632 I know my time is expired. The chairman has been as
1633 generous to me as he was to himself, and I thank him for it.

1634 Dr. {Burgess.} And I thank the gentleman for
1635 recognizing that. I will also point out that Dr. Sharfstein
1636 was here before our committee last year and testified that
1637 they didn't need any more money, they had plenty.

1638 Let me yield to Mr. Terry from Nebraska for questions.

1639 Mr. {Terry.} Thank you.

1640 First, I mean, we on our side have been in discussions
1641 about FDA and these delays. I haven't heard any of us talk
1642 about weakening the standards, so I am sorry, I don't know

1643 where that is coming from. We are frustrated that FDA has
1644 become--the delays have become so difficult for the inventors
1645 and manufacturers that they feel that they have to set up
1646 shop in Europe in order to proceed. So we are trying to work
1647 through that, Dr. Curfman. I don't know where you came up
1648 with the idea or you and Henry Waxman that we are weakening.

1649 But Ms. Conger, I felt badly the way that you were
1650 treated. A question was thrown out that you weren't allowed
1651 to answer. If you would like to use a little bit of my time
1652 to answer the question?

1653 Ms. {Conger.} The question about?

1654 Mr. {Terry.} Mr. Waxman's about funding.

1655 Ms. {Conger.} The funding, yes. I have been in
1656 business, and I have seen organizations that stagnate and
1657 stagnate, and the big kahunas on the top can't understand why
1658 their brilliant ideas aren't filtering down into the little
1659 plants and the roots and why aren't they going, and it is
1660 very simple. It is that you do what you get rewarded for.
1661 You do the things you don't get in trouble for. And while we
1662 may have some very, very fresh ideas and even some of the
1663 things that I brought up, we still have an old, ingrained
1664 guard that has been taught to keep your head low and just
1665 keep doing it the old way, and the FDA CDRH can no longer
1666 afford to do it the old way. They have their competitors in

1667 other nations who are already bringing them tons of data
1668 about products that are successful in millions of patients--

1669 Mr. {Terry.} Ms. Conger, that is a really good point
1670 there.

1671 Ms. {Conger.} Yeah.

1672 Mr. {Terry.} And one that--

1673 Ms. {Conger.} And then start them all over again.

1674 Excuse me.

1675 Mr. {Terry.} Dr. Curfman, you are the defender here of
1676 the status quo of the FDA.

1677 Dr. {Curfman.} No, no.

1678 Mr. {Terry.} So let me ask you this. Well, hold on.
1679 Her point is one that is going through my mind, and let us
1680 use the low-glucose suspend system where the conclusion of
1681 this mother, Ms. Sagan, is that low-glucose suspend systems
1682 have been approved for nearly 3 years and used safely all
1683 over, 40 countries worldwide, but they are not available
1684 here. It seems to me that our FDA refuses to acknowledge
1685 results and data from other countries on the same device. Is
1686 that an appropriate standard? Is that appropriate?

1687 Dr. {Curfman.} Well, Mr. Terry, let me just comment
1688 about my own interaction and experience with the FDA. I know
1689 many people--

1690 Mr. {Terry.} Would you answer my question?

1691 Dr. {Curfman.} Yes, I am answering it. I know many
1692 people who have served on advisory committees to the FDA and
1693 they are highly expert. They are the best experts in the
1694 world. They are providing the very best advice that the FDA
1695 can get, the best advice anywhere in the world, and in the
1696 end, decisions about what devices are going to put in the
1697 market have to be based on evidence, not on feelings, not on
1698 impressions.

1699 Mr. {Terry.} So are you saying that the--feelings and
1700 not real data?

1701 Dr. {Curfman.} Data from anywhere needs to be judged on
1702 its merits, and that is what advisory committees do, and that
1703 is why the FDA brings in the very best people from the
1704 medical community, the scientific community--

1705 Mr. {Terry.} And start all over.

1706 Dr. {Curfman.} --and make these judgments, and to
1707 evaluate the clinical trial data--

1708 Mr. {Terry.} With my 48 seconds, let me ask you--

1709 Dr. {Curfman.} --and to see if it really supports--

1710 Mr. {Terry.} Well, I appreciate you trying to run out
1711 the clock here, but you were very critical of the European
1712 system of approval. Can you detail their inadequacies?

1713 Dr. {Curfman.} Sure. I have several concerns about it.
1714 First of all, as you know, Mr. Terry, the European system is

1715 based on 76 private bodies, 76 in Europe, six in the UK, that
1716 make the decisions about which products go on the market. So
1717 it is very diverse. It is very spread. It is not a unified
1718 process. And there is a lot of inconsistency among these 82
1719 private bodies that make these decisions. So that is one
1720 concern that I have: inconsistency of standards across all
1721 of these regulatory bodies.

1722 Secondly, there is very little or almost no transparency
1723 to the approval process in Europe. The FDA has a beautiful
1724 website. All of the information about new devices and drugs
1725 is available there. Anybody can find it. It is available to
1726 the public. This is not true in Europe, and if you try to
1727 get information in Europe, they tell you that is proprietary
1728 and you can't get it.

1729 Third, and I think of most concern, in Europe, for class
1730 III devices, these are the most complex medical devices, it
1731 is not necessary to show that that device is going to improve
1732 a person's health before it goes on the market. That is of
1733 great concern to me. We are living in an era now where
1734 outcome-based medicine is what it is all about. This is core
1735 to medicine and health today, to show that something improves
1736 a person's health, and that isn't a requirement for putting a
1737 device on the market in Europe. I think that is of great
1738 concern.

1739 Dr. {Burgess.} The gentleman's time is expired, and I
1740 see several people have their hands up, but we do need to go
1741 to the chairman emeritus of the full committee, Mr. Dingell,
1742 for questions.

1743 Mr. {Dingell.} Thank you very much, Mr. Chairman. My
1744 questions are going to require yes or no answers, and I am
1745 sorry about that but there is a very limited amount of time
1746 and a lot of questions to be asked.

1747 These questions will go to Dr. Curfman. Your testimony
1748 references two examples of innovative devices that were
1749 approved without a clinical trial. As you know, new drug
1750 applications require clinical trials for approval. Do you
1751 believe that the two examples referenced in your testimony
1752 were inappropriate for the 510(k) process? Yes or no.

1753 Dr. {Curfman.} Yes.

1754 Mr. {Dingell.} Now, Doctor, there have been reports of
1755 some class III devices being reclassified as class II
1756 devices, allowing them to gain approval through the 510(k)
1757 process without need for clinical trials. In your work at
1758 New England Journal of Medicine, have you found this to be a
1759 common industry practice? Yes or no.

1760 Dr. {Curfman.} Yes.

1761 Mr. {Dingell.} Doctor, as you know, class III devices
1762 are devices by their nature should require a stricter review

1763 by FDA. These devices are often necessary to sustain the
1764 life of a patient and are in some instances implanted into
1765 the patient's body. Is it true that a device that goes
1766 through premarket approval process can be approved based on a
1767 single clinical study? Yes or no.

1768 Dr. {Curfman.} Generally, no.

1769 Mr. {Dingell.} Should they be approved on the basis of
1770 a single clinical trial?

1771 Dr. {Curfman.} No.

1772 Mr. {Dingell.} Do you believe that the clinical trial
1773 standards laid out by FDA in the premarket approval process
1774 are rigorous enough to prove safety and effectiveness of
1775 class III devices? Yes or no.

1776 Dr. {Curfman.} Most often, yes.

1777 Mr. {Dingell.} Do you believe that a single study is
1778 sufficient to approve a class III device? Yes or no.

1779 Dr. {Curfman.} No.

1780 Mr. {Dingell.} As you know, device manufacturers are
1781 required to conduct postmarket surveillance. Do you believe
1782 that the current postmarket surveillance requirements are
1783 adequate? Yes or no.

1784 Dr. {Curfman.} No, but they are getting better.

1785 Mr. {Dingell.} So you think that is something we ought
1786 to have a look at?

1787 Dr. {Curfman.} Indeed.

1788 Mr. {Dingell.} Now, Doctor, do you believe that the
1789 device manufacturers have met their responsibility to conduct
1790 rigorous postmarket surveillance to ensure the safety of
1791 their devices? Yes or no.

1792 Dr. {Curfman.} No, that is a big problem.

1793 Mr. {Dingell.} Your testimony references the EU medical
1794 device approval process and the timelines to approval are
1795 only modestly shorter in the EU. How much shorter is the
1796 timelines for approval? Can you give us some kind of a
1797 horseback guess on that?

1798 Dr. {Curfman.} Depending on what you are measuring, it
1799 can be a few months to a year. In the lifespan of a drug or
1800 a device, that is a small fraction of the total.

1801 Mr. {Dingell.} Now, as you know, the standards for
1802 approval in the United States and EU are different. Do you
1803 believe that the EU approval process adequately takes into
1804 consideration the success of a device in treating a patient?
1805 Yes or no.

1806 Dr. {Curfman.} No.

1807 Mr. {Dingell.} Do you believe that the approval process
1808 in the EU is transparent to the public when approving devices
1809 for use? Yes or no.

1810 Dr. {Curfman.} No.

1811 Mr. {Dingell.} Should be more transparent, should it
1812 not?

1813 Dr. {Curfman.} Much more transparent, yes.

1814 Mr. {Dingell.} Thank you very much for this. This goes
1815 to Dr. Fischell and Dr. Ianchulev. I would like to end my
1816 questions with you regarding your experience with FDA
1817 regarding the medical device approval process. Please again
1818 answer yes or no. Are you working with the FDA review staff
1819 and the approvals of your device? Did you find that the FDA
1820 review staff was responsive to questions or concerns? Yes or
1821 no.

1822 Mr. {Fischell.} No.

1823 Mr. {Dingell.} Now, were the requirements for the
1824 approval of your device made clear to you by the FDA review
1825 staff in the beginning? Yes or no.

1826 Dr. {Ianchulev.} No.

1827 Mr. {Fischell.} No.

1828 Mr. {Dingell.} Have you found the review process to be
1829 consistent? Yes or no.

1830 Dr. {Ianchulev.} No.

1831 Mr. {Fischell.} No.

1832 Mr. {Dingell.} Do you believe that the review staff at
1833 the FDA are adequately trained to review the devices based on
1834 the most up-to-date science? Yes or no.

1835 Dr. {Ianchulev.} No.

1836 Mr. {Fischell.} No.

1837 Mr. {Dingell.} Now, I would just like to comment in the
1838 26 seconds left to me, Mr. Chairman.

1839 Mr. {Stearns.} Will the gentleman yield just for
1840 question? You might want to give them a chance to--it looked
1841 like some of them didn't have a chance to answer.

1842 Mr. {Dingell.} My time is running.

1843 Mr. {Stearns.} Okay. No problem.

1844 Mr. {Dingell.} My time is running, Mr. Chairman.

1845 Way back, we had a nasty experience in this country. It
1846 related to a substance which caused problems with regard to
1847 babies given to mothers for morning sickness. It was
1848 approved in Europe but it was not approved over here. It
1849 resulted in a whole big change in our food and drug laws, and
1850 it was a matter of very special concern. The precise name of
1851 the pharmaceutical, I don't remember.

1852 Mr. {Fischell.} Thalidomide.

1853 Mr. {Dingell.} Thalidomide. Thank you very much. It
1854 caused a huge stir and a tremendous amount of difficulty
1855 because of the way the Europeans went into these matters as
1856 opposed to the way that we went into them, and I am very
1857 loathe to see us weakening our laws to simply carry forward
1858 the goals of the Europeans, who occasionally make mistakes

1859 too.

1860 Mr. Chairman, your are most gracious. Thank you.

1861 Mr. {Stearns.} The gentleman yields back.

1862 I would like to put into the record, the gentlelady, the

1863 ranking member has asked the supplemental memorandum July

1864 20th be put into the record. By unanimous consent, so

1865 ordered.

1866 [The information follows:]

1867 ***** COMMITTEE INSERT *****

|
1868 Mr. {Stearns.} Mr. Terry wanted to put this New York
1869 Times article in, the medical treatment out of reach. So
1870 ordered.

1871 [The information follows:]

1872 ***** COMMITTEE INSERT *****

|

1873 Mr. {Stearns.} Then I have a 510(k) survey results
1874 researchers from Northwestern University into the record.
1875 The Northwestern researchers surveyed more than 350 medical
1876 device development specialists on their experience with FDA
1877 and medical device review process compared with that of the
1878 European Union, and they show that two-thirds of the small
1879 medical device and diagnostic companies are obtaining for new
1880 products in Europe first and the survey shows that 76 percent
1881 of the respondents said preparation requirements for 510(k)
1882 submission were uncertain or unclear, and I think this is a
1883 good study to be part of the record, and FDA needs to provide
1884 predictability and certainty for companies or they will
1885 continue to go to Europe. With that unanimous consent, so
1886 ordered.

1887 [The information follows:]

1888 ***** COMMITTEE INSERT *****

|
1889 Ms. {DeGette.} Mr. Chairman.

1890 Mr. {Stearns.} Yes?

1891 Ms. {DeGette.} Also, just to clarify, attached to our
1892 memo are two letters, one from the--five, sorry--four--some
1893 number--five letters supplementing that.

1894 Mr. {Stearns.} All right. By unanimous consent, that
1895 is so ordered.

1896 And now we will go to the gentlelady, Sue Myrick is
1897 recognized for 5 minutes.

1898 Mrs. {Myrick.} Thank you, Mr. Chairman.

1899 Dr. Fischell, I would like to just cover a couple things
1900 with you. Thank you, all of you for being here today and
1901 your testimony, by the way. You have been doing this for a
1902 long time, not just innovating but helping patients, et
1903 cetera, and a comment was made a little while ago about
1904 European inconsistencies and standards, I believe by Dr.
1905 Curfman. You have been talking, all of you, kind of about
1906 the fact that, you know, the Europeans are doing things
1907 quicker and we are taking a lot longer. Do you feel from
1908 what you have had experience with over the years and looking
1909 at the European standards that there is a lot of
1910 inconsistencies and that they are not doing a good job?

1911 Mr. {Fischell.} No, I don't think that is the case, and

1912 I would like to once give the example of the migraine device.
1913 When we showed to the European notified body that we had done
1914 a clinical trial that proved it was safe and effective in the
1915 treatment of migraine, when we showed that there was already
1916 an FDA-approved device used for many years that had 20 percent
1917 stronger pulses and 30,000 times more and that was approved,
1918 it seems to me that the Europeans were logical in saying it
1919 is now approved for use in Europe. That seems logical to me.

1920 Mrs. {Myrick.} Well, and the other thing was, and Dr.
1921 Curfman, you said sometimes they are just a few months to a
1922 year behind. They have been waiting since 2006 for approval
1923 of that particular machine, which is a little longer than a
1924 few months to a year. But anyway, I wanted to ask you
1925 another question because you mentioned when you talked about
1926 the innovation and people going overseas and whatnot, if you
1927 were starting out today, would you still be able to find the
1928 same availability of funding for what you are doing? Because
1929 you mentioned something about funding in your remarks.

1930 Mr. {Fischell.} We have--a month ago a venture
1931 capitalist said they would not give us the last money we need
1932 to get this product approved, the migraine product in the
1933 United States, because the FDA approval process is so risky
1934 that they would not risk the capital. We have worked with
1935 VCs over many years and we were well funded to do our stents,

1936 to do our defibrillator and pacer. They are no longer
1937 funding us. It is a real struggle now to get the funds to do
1938 the innovation, to make the jobs in America because the FDA
1939 has scared the venture capitalists.

1940 Mrs. {Myrick.} Well, and that brings me to another
1941 point. We have got over 40 device manufacturers in Charlotte
1942 alone, where I am from. North Carolina has a tremendous
1943 number because of all the medical there, you know, device
1944 manufacturers which is creating jobs. They pay well and, you
1945 know, the delays in approval are keeping these jobs from
1946 being created here in America and so, you know, to me, this
1947 has a tremendous impact on what is happening here, what the
1948 FDA does relative to us being able to create those jobs that
1949 are obviously being created in other countries instead of
1950 here.

1951 Mr. {Fischell.} You know, a migraine company only has
1952 12 people employed and yet we are now hiring people in Europe
1953 to get it out into the population there. That doesn't make
1954 an American happy.

1955 Mrs. {Myrick.} No, it doesn't make any of us, very
1956 frankly.

1957 Ms. Conger, I would like to ask you because of, you
1958 know, we know that the job of FDA is to make things safe.
1959 None of us are trying to say you shouldn't have safe devices

1960 and they should be effective, but they are supposed to also
1961 foster innovation, and just from our perspective, what do you
1962 think the balance should be between those two in how the FDA
1963 is running.

1964 Ms. {Conger.} Based on my research about other approval
1965 methods and their successes and failures, and I compare it to
1966 our current overly bureaucratic, overly politically worried
1967 system. We can have all three. We can have safety,
1968 reasonable safety, efficacy and innovation if we were using
1969 parts of models of other countries that are doing it so well.
1970 We have the opportunity to take the learnings of others, add
1971 it to the gems we know we do well, and come out with a better
1972 system. As it is set up now, it is not going to work.

1973 Mrs. {Myrick.} Can I quickly ask, Dr. Ianchulev, you
1974 worked in both systems relative to the European standards. I
1975 would just like your comment.

1976 Dr. {Ianchulev.} Yes. Actually, I am licensed in
1977 Europe as well as a physician and to me that has been--when I
1978 came to this country almost 20 years ago, I came here to
1979 innovate and practice cutting-edge medicine, and I have seen
1980 to my surprise that a lot of my European colleagues now have
1981 more advanced experience than what I can get here and deliver
1982 to my patients. And I have experienced the review process on
1983 the regulatory side in Europe and I would say that I haven't

1984 noticed it to be irrational nor have I heard from my
1985 colleagues or patients in Europe to feel that the environment
1986 is unsafe. At the same time, I should say that we don't have
1987 to rubber stamp something. It is a matter of looking at this
1988 is not a bearing point and another way to benchmark ourselves
1989 to find something that works for us and for our patients.

1990 Mrs. {Myrick.} I appreciate it. Thank you, Mr.
1991 Chairman.

1992 Mr. {Stearns.} I think just to confirm what you
1993 indicated to the gentlelady, over in Europe they have more
1994 advanced experience, you said?

1995 Dr. {Ianchulev.} In my field, for example, we have a
1996 lot of medical devices that we use, mainly new types of
1997 intraocular lenses, and to be more specific, there are other
1998 ones right now, new minimally invasive treatments for eye
1999 diseases such as glaucoma, and it is interesting that on the
2000 device side on the European side, you can see access to those
2001 technologies and experience in the hands of physicians, which
2002 is probably the only true way to appreciate not just read an
2003 article in a journal but really to have experience with the
2004 device. That is what physicians need to understand it.

2005 I think on the drug side, it is opposite. I have
2006 noticed a lot more experience happens first here and then
2007 travels to Europe, and that was my experience with Lucentis

2008 why we got it approved here and followed one year later
2009 there. It is just my personal experience is--

2010 Mr. {Stearns.} Okay. Thank you.

2011 The gentleman from Texas is recognized for 5 minutes,
2012 Mr. Green.

2013 Mr. {Green.} Thank you, Mr. Chairman, and I would like
2014 unanimous consent to have a statement placed into the record,
2015 and I do have concerns because I know medical device
2016 companies who produce in our countries but there are rules
2017 particularly in Europe that they can't market a device there
2018 that is not admitted into the home country so they end up
2019 having to move their production facilities to another
2020 country. We may not want to lower our standards to the
2021 European standards, because I am going to ask Dr. Curfman
2022 some questions about that, but Dr. Curfman, I understand
2023 actually in some cases FDA is much quicker than in Europe on
2024 the reviews. Can you outline some of the concerns with the
2025 medical device approval system in the European Union?

2026 Dr. {Curfman.} Well, I think again the most important
2027 thing in a review process is to ensure that a new device or a
2028 new drug is actually going to result in a better health
2029 outcome for the patient.

2030 Mr. {Green.} And Europe doesn't require that?

2031 Dr. {Curfman.} Europe doesn't require that. We do.

2032 And I think that that is really a fundamental difference in
2033 the two processes.

2034 Mr. {Green.} And the structural way that the FDA does
2035 our approval but in Europe from what I understand, there are
2036 74 for-profit entities that actually can be--you can almost
2037 cherry pick who you want to take your device to. Is that
2038 correct?

2039 Dr. {Curfman.} That is correct.

2040 Mr. {Green.} And the European Union allows any of those
2041 74 to make that determination that the FDA does in our
2042 country?

2043 Dr. {Curfman.} That is correct.

2044 Mr. {Dingell.} If the gentleman would yield, those
2045 things are called forum shopping over here.

2046 Mr. {Green.} Oh, I understand. But that gives the
2047 companies--and I am amazed that Europe doesn't have some more
2048 quality control on what they do, but that is beside the
2049 point. Can you continue about the difference between us, the
2050 United States requirements under FDA and in Europe?

2051 Dr. {Curfman.} Well, I think another point that we
2052 touched upon briefly is the issue of transparency, and that
2053 is putting information out to the public, getting it up on a
2054 website. The FDA does a beautiful job of that. The FDA's
2055 website is highly sophisticated, very deep in information.

2056 That doesn't exist in Europe.

2057 Mr. {Green.} In our country, if someone is wanting to
2058 use a device, it is available, the information from the FDA
2059 because it is public record.

2060 Dr. {Curfman.} That is correct.

2061 Mr. {Green.} But those 74 entities, I understood from
2062 earlier testimony that that is proprietary information.

2063 Dr. {Curfman.} That is proprietary information, and
2064 there is no information about who the decisions are being
2065 made, what the process was, who the people were who were
2066 involved in making those regulatory decisions. In the FDA,
2067 that is all very transparent. You know exactly who did what.

2068 Mr. {Green.} Well, I understood a statement earlier,
2069 and you wouldn't believe it from our panel today that the FDA
2070 is actually faster than the European Union on devices. Do we
2071 have a percentage or has anyone looked at that? And if
2072 somebody has some other--I want to hear Dr. Curfman first
2073 because he is in the business right now. Is that information
2074 that is readily available?

2075 Dr. {Curfman.} I would imagine that Dr. Shuren would
2076 have that information probably more than I would.

2077 Mr. {Green.} Well, Mr. Chairman, hopefully we can get
2078 that. Again, it sounds like we are comparing apples and
2079 oranges with results.

2080 What are the problems with abandoning the effectiveness
2081 criteria for medical device approval in moving to the
2082 European standard?

2083 Dr. {Curfman.} Well, you know, in medicine and health
2084 care today in the United States, we talk about evidence-based
2085 medicine. This is the core of our process in finding new
2086 therapies. New therapies need to be supported by real
2087 evidence, by clinical trials, by scientific data, not just
2088 casual impressions that they work in that patient so they
2089 will work in every patient but real solid clinical trials,
2090 and doing clinical trial is very difficult but we have gotten
2091 in the United States very good at it. It has become a very
2092 refined science so that we can get very good and precise
2093 answers to these questions about whether new drugs and
2094 devices really work by helping people's health. We can do
2095 that today.

2096 Mr. {Green.} I only have about 26 seconds. In Europe,
2097 if I was a medical device company and hired one of those
2098 entities, those for-profit entities to do it, that patient
2099 wouldn't be able to know anything about how the clinical
2100 went. Is that proprietary information in Europe?

2101 Dr. {Curfman.} Yes, not only the patient but
2102 physicians. Nobody would really know that. There is no way
2103 to get it. And if you try to get it, they simply say it is

2104 proprietary information, we won't release it. It is
2105 astonishing that that would be allowed to happen because it
2106 is so strikingly different here.

2107 Mr. {Green.} Thank you, Mr. Chairman.

2108 Ms. {Sagan.} Mr. Chairman, I feel compelled to ask to
2109 be able to make a statement. I am sorry. In terms of the
2110 low-glucose suspend insulin pump, there is no safety issue.
2111 It is not safe to not allow the low-glucose suspend system to
2112 come into being, into practice in the United States. If you
2113 understand type 1 diabetes, it is too dangerous to allow
2114 insulin to be pumped into a body that is experiencing low
2115 blood glucose, more dangerous than running a 90-minute period
2116 of running high glucoses. My daughter's glucose level has
2117 been at 500 many, many, many times, and the long-term
2118 complications of high sugars are far diminished by the short-
2119 term complications.

2120 Mr. {Green.} I thank the gentlelady.

2121 We have a request that we recess our committee. We are
2122 doing some votes in another subcommittee, and the chairman
2123 has asked that I recess the committee temporarily so that all
2124 members could go to this other committee, so with your
2125 indulgence and forbearance, I would appreciate your waiting,
2126 and I tell all members that we are going to recess the
2127 committee and we will try to get back shortly.

2128 [Recess.]

2129 Mr. {Stearns.} The subcommittee will reconvene, and I
2130 thank all of you. If the witnesses would please come to the
2131 table again, we will start the questions here, and we were
2132 able to receive a unanimous consent agreement that the votes
2133 at this other committee will be rolled until after our votes
2134 in the House, which will probably occur between 1:15 and
2135 1:30. So I don't want to hold up the witnesses here anymore.

2136 Are Mr. Mandel and Dr. Ianchulev close by? I just want
2137 to make sure--they can't be far. I think under the time
2138 constraints we have, I think we will start with the gentleman
2139 from Georgia, Mr. Gingrey, for questions and we will just
2140 keep moving forward here. So the gentleman is recognized for
2141 5 minutes.

2142 Dr. {Gingrey.} Mr. Chairman, thank you. Thank you very
2143 much. I am going to confine my questions and remarks to Dr.
2144 Curfman. Dr. Curfman, of course, as executive director of
2145 the New England Journal of Medicine and a cardiologist, I too
2146 am an M.D., as you know, and certainly it is an honor have
2147 you come before the committee to testify, and we thank you
2148 for being here today, as we do the other witnesses. I think
2149 you have been very patient and you have been very good with
2150 us.

2151 Dr. Curfman, in your testimony, you state your support

2152 for, and I quote ``high-priority innovation in medical
2153 devices'' but conclude that the glamour of innovation does
2154 not always work for patients if we cut corners in quality
2155 control. Is that a fair assessment?

2156 Dr. {Curfman.} Yes, that is exactly right.

2157 Dr. {Gingrey.} As examples of cutting corners in
2158 quality control, your testimony focuses on two products that
2159 you say ran through the 510(k) fast-track process versus the
2160 more rigorous premarket approval process. Had the Sprint
2161 Fidelis defibrillator gone through the more rigorous PMA,
2162 that premarket approval, versus the 510(k), do you believe
2163 that some patient injuries might have been avoided?

2164 Dr. {Curfman.} I think that probably the way to have
2165 done that would be to phase it in rather than doing a
2166 clinical trial, that instead of launching this into many
2167 thousands of patients in a short period of time, to set some
2168 benchmarks for the lead in a limited number of patients and
2169 try to see if any problems were emerging there. The problem
2170 with this lead was that it was made quite a bit thinner than
2171 previous leads, and it was--

2172 Dr. {Gingrey.} And in your testimony, you said that
2173 that approval process of Medtronic's Sprint Fidelis lead was
2174 fast-tracked, it was through that 510(k) process.

2175 Dr. {Curfman.} Yes. There was no clinical testing. So

2176 what I would propose is that there be some clinical testing--

2177 Dr. {Gingrey.} Right. Well, I understand that.

2178 Dr. {Curfman.} --in a limited number of patients.

2179 Dr. {Gingrey.} I want to ask you this, because I am
2180 holding in my hand a PMA record, premarket approval record,
2181 number P920015 for the Medtronic's Sprint Fidelis lead dated
2182 2007, which in fact means that the Sprint Fidelis product did
2183 go through the more rigorous PMA supplement process and not
2184 the 510(k) as your testimony suggests. Are you aware that
2185 your testimony on this is factually wrong?

2186 Dr. {Curfman.} I don't think it is wrong.

2187 Dr. {Gingrey.} Well, here it is.

2188 Dr. {Curfman.} Well, I would have to--

2189 Dr. {Gingrey.} Let me just follow up on that, and maybe
2190 you can check your notes or maybe talk with your secretary or
2191 whomever gave you this information. Your testimony also
2192 cites the federal preemption for medical devices that
2193 prevented U.S. patients from suing Medtronic. Doctor, the
2194 federal preemption for medical devices only applies to class
2195 III products that go through the PMA process, not those that
2196 go through 510(k). The fact that this reality did not raise
2197 a red flag for you when drafting and reviewing your testimony
2198 here today is troubling, to say the least.

2199 The second example you cite in your testimony as proof

2200 of 510(k) failure is this metal-on-metal hip. Dr. Curfman,
2201 the Safe Medical Devices Act of 1990 directed the FDA, and I
2202 will say that again, this act directed the FDA to review
2203 certain class III devices and to ascertain whether they
2204 should be reclassified and go through this premarket approval
2205 process, so-called PMA, as I held up on the other one with
2206 Medtronic. One of these devices is the metal-on-metal hip
2207 yet 20 years later the FDA has yet to conduct a review. So
2208 it appears that the failure of this product is not due to
2209 510(k) process but to regulatory inaction by our own FDA. So
2210 Dr. Curfman, do you believe that the FDA should follow the
2211 direction of Congress and implement the Safe Medical Devices
2212 Act of 1990 in order to better protect patient safety?

2213 Dr. {Curfman.} Well, I think that it is important for
2214 some of these previously approved devices to be looked at
2215 again, and--

2216 Dr. {Gingrey.} Indeed, that is what the 1990--

2217 Dr. {Curfman.} --I would support that.

2218 Dr. {Gingrey.} --act called for.

2219 Dr. {Curfman.} That is correct. Yes, exactly. So I
2220 think that it should be done selectively but I think that
2221 some of these previously approved devices do need to have
2222 another look.

2223 Dr. {Gingrey.} Well, absolutely, and I agree with you

2224 completely, Dr. Curfman, and I think we could have avoided
2225 some huge problems if that had been done. Both instances you
2226 cite to support the failure of this 510(k), the fast-track
2227 process, appear to be either inaccurate or factually
2228 incorrect, and with all due respect, these inaccuracies call
2229 into question, I hate to say it, but, you know, as a
2230 distinguished doctor and executive editor of one of our most
2231 distinguished medical journals, the New England Journal of
2232 Medicine, these little simple inaccuracies call into question
2233 what you describe as your careful analysis of these two
2234 studies you reference in your testimony.

2235 Dr. {Curfman.} No, I disagree, Dr. Gingrey. I think
2236 that everything that I have said is accurate. I point out to
2237 you that the Sprint Fidelis lead was removed from the market
2238 in 2007. This document that you have given me is dated 2007.
2239 So something doesn't quite add up here. It was pulled from
2240 the market in 2007 by Medtronic. So I am not sure what this
2241 document--

2242 Dr. {Gingrey.} Well, I would be happy--I think my time
2243 is expired.

2244 Mr. {Stearns.} The time has expired.

2245 Dr. {Gingrey.} Doctor, I would be happy to have you
2246 follow up with written testimony to the committee.

2247 Dr. {Curfman.} I would be happy to do that.

2248 Mr. {Stearns.} I think the gentleman from Georgia--

2249 Dr. {Gingrey.} If there are some corrections that you
2250 would like to put into the record, we would be glad to put
2251 that into the record.

2252 Dr. {Curfman.} I would be happy to do that.

2253 Mr. {Stearns.} Dr. Gingrey, if you feel comfortable,
2254 you could also ask him questions and we can ask him to reply
2255 for our record too.

2256 With that, I recognize Ms. Christensen--

2257 Dr. {Gingrey.} Thank you, Mr. Chairman. I yield back.

2258 Mr. {Stearns.} --for 5 minutes.

2259 Dr. {Christensen.} Thank you, Mr. Chairman, and I want
2260 to thank the panelists, especially those who are patients or
2261 representing patients. I think everyone up here felt your
2262 pain. And just before I ask my question, I just wanted to
2263 say that I understand that despite all of the comparisons
2264 between Europe and the United States, I still understand that
2265 the U.S.-based companies dominate the industry globally,
2266 medical device industry, and it is also interesting to note
2267 that the medical device industry is one of the few sectors
2268 with a positive trade balance today in our struggling
2269 economy.

2270 Dr. Curfman, it seems like you are getting all of the
2271 questions today. I would like to ask you about the effect of

2272 regulation on innovation within the medical device technology
2273 field. In your written testimony, you stated that innovation
2274 is essential--I am quoting you here--`innovation is
2275 essential to the future of our Nation's health but innovative
2276 medical products cannot succeed unless they are both
2277 effective and safe.'" Can you explain how innovation in the
2278 medical field is fostered by sensible quality safeguards?

2279 Dr. {Curfman.} Yes. Thank you, Dr. Christensen. I
2280 think that real innovation, real innovation needs to involve
2281 products in which the efficacy has been clearly demonstrated
2282 and the safety has been clearly demonstrated. Otherwise it
2283 is not real innovation. We have talked about creating jobs
2284 in the medical device industry, and I think we all feel that
2285 that is a very important goal, but we don't want jobs to be
2286 created to create defective medical devices that don't work,
2287 that cost a lot of money, that pull money out of our health
2288 care system that could be better used in other ways on things
2289 that do work or on devices that are not safe. So this is why
2290 I have tried to make a case that an important part of
2291 innovation is to really establish that the product works and
2292 that it is safe and that if you don't do that, it is not real
2293 innovation.

2294 Dr. {Christensen.} FDA must--and we have to support
2295 them in protecting the health and safety of millions of

2296 patients in our country, and the agency can only accomplish
2297 this when novel drugs and new devices are rigorously
2298 evaluated for safety and efficacy. In your opinion, do
2299 manufacturers always take appropriate premarket steps
2300 necessary to protect patient safety?

2301 Dr. {Curfman.} In my experience, they do not always do
2302 that, and that is why oversight is necessary. That is why
2303 regulation is necessary. That is why it is important for
2304 third parties to be taking a look at these products and doing
2305 some oversight and ensuring that efficacy and safety are
2306 really established.

2307 Dr. {Christensen.} So that must contribute to some of
2308 the delays as well?

2309 Dr. {Curfman.} It does. There is a process involved.
2310 It does take time. I am sure that these delays can be
2311 reduced. I think that that should be a goal of the FDA. But
2312 that doesn't mean that the process should be eliminated.

2313 Dr. {Christensen.} Well, many have criticized, and we
2314 have heard it today, FDA for stifling innovation with their
2315 rules and regulations concerning medical devices. In your
2316 opinion, has FDA made the approval process for medical
2317 devices too onerous for medical device manufacturers?

2318 Dr. {Curfman.} My experience with the FDA is that they
2319 are keenly interested in innovation. They are keenly

2320 interested in improving the lives of patients. They want to
2321 get products to market. That is my sense. At the same time,
2322 they know that a process establishing efficacy and safety is
2323 a critical part of that process.

2324 Dr. {Christensen.} Well, are there ways that the FDA
2325 could strengthen some of the aspects of their approval
2326 process?

2327 Dr. {Curfman.} Well, as Congressman Waxman said, in
2328 order to do that, they need resources. So I think that the
2329 first thing is that we can't cut their budget and expect them
2330 to improve their processes. There is just a disconnect
2331 there. So I think we need to look at the budgeting process
2332 and be sure that they have the resources that they need to do
2333 the job.

2334 Dr. {Christensen.} Thank you. And I think more than
2335 ever now, we need to make sure we are making smart choices on
2336 the budget and cuts to FDA as we have done already make no
2337 sense. They really hurt patients. They hurt companies that
2338 want to bring innovative drugs and medical devices to the
2339 market. Thank you. I am out of time.

2340 Mr. {Stearns.} I thank the gentlelady.

2341 I think by mutual agreement, we are going to the
2342 gentleman from California, Mr. Bilbray. You are recognized
2343 for 5 minutes.

2344 Mr. {Bilbray.} Thank you, and I appreciate the doctor's
2345 questions. I think the delegate from the Virgin Islands has
2346 a background here. You know, we have got some indicator
2347 species here as we say in the environmental community that
2348 are not being observed, and that is, the venture capital that
2349 goes into this innovative technology. It is not--you know,
2350 by the time it gets to the FDA, it is at the end of the line,
2351 and I just want to say right now, July 11, everybody is put
2352 on notice, 50 percent of the venture capital investment in
2353 medical devices and research has dropped off in my region.
2354 Now, that is the krill of medical breakthroughs, and, you
2355 know, when the krill dies, in a few years you are going to
2356 say well, what happened, why isn't there any new information.
2357 Because the big guys use that krill to feed on. So there is
2358 a concern here that we may be contributing to the extinction
2359 of a species that we take for granted but it essential in the
2360 food chain of medical breakthroughs.

2361 Dr. Curfman, I have got a question for you. Do you
2362 believe the defibrillators that we have got out in the public
2363 are as effective in the hands of a layman as they would be in
2364 a trained physician?

2365 Dr. {Curfman.} You are talking now about
2366 defibrillators--

2367 Mr. {Bilbray.} The defibrillators--

2368 Dr. {Curfman.} The manual defibrillators?

2369 Mr. {Bilbray.} The manual defibrillators.

2370 Dr. {Curfman.} Well, the automatic external
2371 defibrillators can be operated by a layperson with only a
2372 small amount of training, and they are designed to do that
2373 and they can certainly be lifesaving.

2374 Mr. {Bilbray.} But they can be lifesaving. We agree
2375 with that.

2376 Dr. {Curfman.} Yes.

2377 Mr. {Bilbray.} But do you think that they are just as
2378 effective in a layman's hands as it would be in a trained
2379 cardiologist's hands?

2380 Dr. {Curfman.} Well, you need some training to use
2381 these. They are not totally intuitive. If you have never,
2382 never used one, you are going to have to figure it out. They
2383 are certainly a lot easier than older ones.

2384 Mr. {Bilbray.} Do you have any idea how long it took us
2385 to finally approve this and get it out in the field?

2386 Dr. {Curfman.} Well, it took some years, yes.

2387 Mr. {Bilbray.} Okay. Do we have any idea of how many
2388 people died of cardiac arrest in public during that period?
2389 We don't have any idea at all. But we can only imagine.

2390 You know, I have just got to say, we talk about the
2391 morning sickness medicine of the 1950s that caused birth

2392 defects, and that is what you remember as the chairman
2393 emeritus said. They don't think about Benedictine in the
2394 1980s that was perfectly safe but driven off the market, and
2395 a lot of it was because you remember the stuff when it goes
2396 bad but you don't think about all the savings, and I think we
2397 all agree. Aspirin, classic example, hundreds of people die
2398 every year, and it has probably done more to help with health
2399 of probably any device

2400 My question is this. When we talk about the device that
2401 Mr. Mandel talked about and with 3 percent increase annually
2402 in child melanoma annually since the 1970s, we have got a
2403 device that physicians could use that may help in that
2404 application but because it cannot be proven to as effective
2405 as a dermatologist, don't you think we have got to start
2406 talking about reality, that early detection is the most
2407 essential part of surviving melanoma. Wouldn't you agree?

2408 Dr. {Curfman.} Absolutely.

2409 Mr. {Bilbray.} And why would we say that we do not want
2410 to give a device to general practitioners that see the
2411 overwhelming majority of children--why would we as an agency
2412 say this should only be used at the back end of the process,
2413 dermatologist, after the general practitioner has sent them
2414 over?

2415 Dr. {Curfman.} Like any device, the efficacy needs to

2416 be established. This is a device where there are probably
2417 not going to be any safety issues but there are efficacy
2418 issues. It is a device that costs money. It has to be shown
2419 to be accurate.

2420 Mr. {Bilbray.} Costs money.

2421 Dr. {Curfman.} It has to be accurate. It has to work
2422 and it has to be shown to work.

2423 Mr. {Bilbray.} But--

2424 Dr. {Curfman.} And the evidence has to be there, and if
2425 you don't have the evidence, you can't just approve the
2426 device.

2427 Mr. {Bilbray.} But if you have the evidence to apply--

2428 Dr. {Curfman.} You need the evidence. You need the
2429 evidence in a real clinical study.

2430 Mr. {Bilbray.} Excuse me. But if the technology works
2431 for a dermatologist, okay--

2432 Dr. {Curfman.} Who says? That is the point of doing
2433 clinical studies, to get the evidence.

2434 Mr. {Bilbray.} Okay. Let us back up then. The same
2435 clinical trials that say you apply, why would you shift it?
2436 If it works good for a dermatologist and it works, why would
2437 a bureaucracy, why would a government agency say we don't
2438 want this to be applied at the general practitioners, we are
2439 going to make a judgment call that we want it to be applied

2440 for dermatologists. Now, don't you agree as the manual
2441 defibrillators but especially with melanoma, that early
2442 detection, if there is an opportunity, early detection with
2443 general practitioners, that is an essential part of treating
2444 that disease and addressing that disease and that is
2445 prevention. The earlier the better, right?

2446 Dr. {Curfman.} Absolutely.

2447 Mr. {Bilbray.} Okay.

2448 Dr. {Curfman.} So what you need to do is show that the
2449 device detects it earlier and improves patient outcomes.

2450 Mr. {Bilbray.} Okay. If you wanted to prove that, then
2451 why would you not allow a review board to look at this and
2452 review it? Why would you say we are not going to allow a
2453 review board to take a look at this and review it?

2454 Dr. {Curfman.} I think that you have to have the proper
2455 data in hand for the review board to look at, and I am not
2456 completely familiar with this device so I can't really say
2457 how much data they had, but I am assuming that they don't
2458 have enough data for the review board to review it.

2459 Mr. {Bilbray.} And let me just mention, Mr. Chairman, I
2460 think the one we asked about that has been brought up here,
2461 do you agree that we had a great success in the 1990s with
2462 AIDS by allowing patients to sit on the review boards? Do
2463 you think that diabetics and cancer patients should have the

2464 same opportunity in this century as we gave in the last
2465 century to AIDS patients?

2466 Dr. {Curfman.} Yes.

2467 Mr. {Bilbray.} Thank you, Mr. Chairman.

2468 Mr. {Stearns.} I thank the gentleman. His time is
2469 expired.

2470 Panel, we are going to ask one more 5 minutes and then
2471 you will be excused, so we will finish.

2472 Mr. Griffith is recognized for 5 minutes.

2473 Mr. {Griffith.} Thank you, Mr. Chairman. I would like
2474 to yield 3 minutes of my 5 minutes to Mr. Gingrey and then 2
2475 minutes to Mr. Lance.

2476 Mr. {Stearns.} So ordered.

2477 Dr. {Gingrey.} Well, I thank the gentleman for yielding
2478 time to me. I wanted to, during the last discussion when my
2479 5 minutes expired and I was talking with Dr. Curfman, I had a
2480 question for Mr. Fischell. On that note, I want to return to
2481 you fairly quickly. Given my concerns, Mr. Fischell, with
2482 the testimony of Dr. Curfman, I was wondering if you could
2483 share your thoughts on the veracity of those two studies that
2484 were outlined in Dr. Curfman's testimony. He didn't think
2485 too highly of them. Could you give us your opinion on those
2486 studies?

2487 Mr. {Fischell.} I am not an expert on that, and I think

2488 that they were PMA supplements, which are treated differently
2489 from PMAs, and I think that may account for some of the
2490 difference here. But I am by no means an expert on that
2491 subject.

2492 Dr. {Gingrey.} Well, I appreciate your honesty on that.
2493 The PMA supplement is reviewed in those articles using the
2494 same standard as the original postmarket analysis, PMA. So I
2495 want that to be in the record and I want that statement to be
2496 in the record.

2497 In the last minute or so that I have before I think my
2498 friend wants to yield to another colleague on this side of
2499 the aisle, look, I think we are all here for the right
2500 reasons. There is certainly a difference of opinion on one
2501 end of the table from most of the other witnesses in regard
2502 to the FDA and are they doing their job in a most efficient,
2503 timely manner that is safe for patients. Obviously, as Dr.
2504 Curfman pointed out, safety is hugely important, but to make
2505 it so difficult losing venture capitalists, we are losing
2506 research and development, we are losing new products to the
2507 European Union, and then they come back over here and finally
2508 get to our market but all the jobs--

2509 Mr. {Stearns.} The gentleman's time has expired.

2510 Dr. {Gingrey.} --are gone. That is what this is all
2511 about, and I thank the gentleman for yielding to me and I

2512 yield back.

2513 Mr. {Stearns.} The gentleman, Mr. Lance, is recognized
2514 for 2 minutes.

2515 Mr. {Lance.} Thank you very much. I will take 1
2516 minute, and I appreciate the courtesies of my colleague, Mr.
2517 Griffith.

2518 Dr. Fischell, I represent a district that is really the
2519 medicine chest of the country in north central New Jersey,
2520 more pharmaceutical and medical device employees than any
2521 other district in the United States. In your testimony, you
2522 state that beyond the adverse impact FDA is having on patient
2523 care, it is weakening the U.S. leadership position in medical
2524 technology innovation and as a result our economy. Would you
2525 comment briefly on that statement with which I agree and is
2526 so terribly important to the district I serve?

2527 Mr. {Fischell.} Well, it has been very clear to me
2528 personally by the fact that from 20 to about 5 years ago,
2529 venture capitalists would come to me and say Dr. Fischell, I
2530 would like to support your latest innovation, tell me what it
2531 is. Now I have recently gone to venture capitalists and said
2532 we have this great new cure for migraine and I need another
2533 \$2 million to finish it. They said because of the FDA, we
2534 can't give it to you, it is too risky. That is the
2535 difference.

2536 Mr. {Lance.} Well, thank you very much, and I
2537 appreciate having the opportunity to speak with you on that,
2538 and I yield back the balance of my time.

2539 Ms. {DeGette.} I am wondering if Mr. Griffith would
2540 just yield to me for one brief moment?

2541 Mr. {Griffith.} One brief moment, I yield to the
2542 gentlelady.

2543 Ms. {DeGette.} Thank you very much.

2544 I just want to point out, there was a Bloomberg News
2545 article today that said venture capital funding for medical
2546 device and equipment makers gained 20 percent to \$840 million
2547 in 90 deals over the last 3 months, so I think the record
2548 needs to reflect that there is still ample venture capital
2549 for medical devices as well as for all of biotechnology, and
2550 anything this committee can do to encourage that--

2551 Dr. {Gingrey.} Mr. Griffith, would you yield to me for
2552 unanimous consent?

2553 Mr. {Stearns.} No, I think we are just going to wrap up
2554 here.

2555 Dr. {Gingrey.} Mr. Chairman, I do have a UC request.

2556 Mr. {Stearns.} Okay. Go ahead.

2557 Dr. {Gingrey.} I would like to for unanimous consent
2558 request to submit for the record these materials that I am
2559 holding be inserted into the record, and it is important

2560 because these materials show that the Medtronic device that
2561 Dr. Curfman was talking about--

2562 Mr. {Stearns.} Okay. I think what we will do is--

2563 Dr. {Gingrey.} --was approved through PMA and not the
2564 510(k) process. That is all this does.

2565 Mr. {Stearns.} The minority needs to see it, and we
2566 also have here a quote from the New York Times--

2567 Ms. {DeGette.} Reserve the right to object.

2568 Mr. {Stearns.} --and the LexisNexis also, so we have
2569 three items.

2570 Let me close, and we are going to recess the committee
2571 and thank the panel for their very compelling testimony and
2572 we appreciate your forbearance, and so we will take up the
2573 second panel after the set of votes, and so the subcommittee
2574 is temporarily in recess.

2575 [Recess.]

2576 Mr. {Stearns.} The subcommittee will come to order, and
2577 now we will proceed to our second panel, and Dr. Shuren, you
2578 have been very patient with us and we appreciate that, and we
2579 are glad to have Mr. Waxman with us as we proceed to the
2580 second panel.

2581 With that, I will swear you in. Let me start by saying
2582 you are aware that the committee is holding an investigative
2583 hearing, and when doing so has had the practice of taking

2584 testimony under oath. Do you have any objection to
2585 testifying under oath?

2586 Dr. {Shuren.} I do not.

2587 Mr. {Stearns.} The chair then advises you that under
2588 the rules of the House and the rules of the committee, you
2589 are entitled to be advised by counsel. Do you desire to be
2590 advised by counsel during your testimony today?

2591 Dr. {Shuren.} I do not.

2592 Mr. {Stearns.} In that case, if you would please rise
2593 and raise your right hand?

2594 [Witness sworn.]

2595 Mr. {Stearns.} You are now under oath and subject to
2596 the penalties set forth in Title XVIII, section 1001 of the
2597 United States Code. You may now give a 5-minute summary.
2598 Your written testimony will be part of the record. Proceed.
2599 Thank you.

|
2600 ^TESTIMONY OF JEFFREY E. SHUREN, M.D., J.D., DIRECTOR, CENTER
2601 FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH), FOOD AND DRUG
2602 ADMINISTRATION

2603 } Dr. {Shuren.} Mr. Chairman and members of the
2604 subcommittee, I am Dr. Jeff Shuren, Director, Center for
2605 Devices and Radiological Health, or CDRH, at the Food and
2606 Drug Administration. Thank you for the opportunity to
2607 testify today, and I would like to thank the participants on
2608 the first panel, who raised many important points that I
2609 agree with.

2610 The mission of the FDA is to protect and promote the
2611 public health, to protect the public health by assuring that
2612 the devices that come on the market are safe and effective,
2613 and to promote the public health by facilitating innovation.
2614 Striking the right balance is challenging but also critical.

2615 In September 2009, soon after I came to CDRH, we
2616 initiated a review of our medical device premarket review
2617 programs in response to concerns expressed by industry and
2618 others. We conducted an honest and frank self-assessment of
2619 these processes including the 510(k). In 2010, we released
2620 two reports which concluded that we had not done as good a
2621 job managing our review programs as we should, and proposed

2622 potential solutions for improvement. The number one problem
2623 we found was that there was insufficient predictability in
2624 our premarket review programs which contributes to
2625 inconsistent decisions and longer terms to market. We
2626 identified several root causes. They including changing,
2627 unnecessary, inappropriate and/or inconsistent data
2628 requirements imposed on device sponsors, insufficient
2629 guidance for industry, insufficient interactions between the
2630 agency and industry, very high reviewer and manager turnover
2631 at CDRH, turnover that is almost double that of FDA's drugs
2632 and biologic centers, insufficient training for reviewers,
2633 insufficient oversight by center managers, CDRH's rapidly
2634 growing workload due to the increasing scientific and
2635 technological complexity of the devices we reviewed and the
2636 number of submissions we received, and poor quality
2637 submissions by industry.

2638 We solicited public comment on these reports from
2639 stakeholders and heard a wide range of perspectives. This
2640 past January, we announced 25 specific actions that CDRH will
2641 take in 2011 to improve the predictability, consistency and
2642 transparency of our premarket review programs, and have since
2643 announced additional actions. For example, we have made a
2644 commitment to develop a range of updated and new guidances to
2645 clarify CDRH requirements for timely and consistent product

2646 review including device-specific guidance in several areas
2647 such as mobile applications and artificial pancreas systems.
2648 We are also working to revamp the guidance development
2649 process to make it more efficient. We are enhancing the
2650 interactive review process and streamlining the review
2651 program for low- to moderate-risk novel devices called the de
2652 novo process. We are streamlining our clinical trial program
2653 to assure that clinical trials can start in a timely manner.
2654 We have already established a new center science council to
2655 help ensure consistency and predictability in our scientific
2656 decision-making, and we are creating a network of experts to
2657 help us resolve complex scientific issues and product
2658 assessment, which we hope will ultimately result in more
2659 timely reviews of device submissions. We are instituting a
2660 reviewer certification program and a pilot experiential
2661 learning program to provide review staff, especially our
2662 newer review staff, with necessary training and real-world
2663 experiences.

2664 These efforts signify our commitment to improving our
2665 premarket review programs to ensure that patients have timely
2666 access to safe and effective devices and the U.S. device
2667 industry remains strong and innovative.

2668 Mr. Chairman, I commend the subcommittee's efforts and I
2669 am pleased to answer any questions the subcommittee may have.

2670 [The prepared statement of Dr. Shuren follows:]

2671 ***** INSERT 8 *****

|
2672 Mr. {Stearns.} I thank you, Dr. Shuren.

2673 Just so there is no lingering uncertainty with respect
2674 to Medtronic Sprint Fidelis approval that was discussed on
2675 the first panel, I think you were here to listen to that, was
2676 the Medtronic device at issue approved as a 510(k) as Dr.
2677 Curfman stated in his testimony?

2678 Dr. {Shuren.} No.

2679 Mr. {Stearns.} Well, then that and other factual
2680 inaccuracies that also included in Dr. Redberg's letter to
2681 Ranking Member Waxman, which is attached to the Democrats'
2682 supplemental memo, throws into serious doubt Dr. Curfman's
2683 and Dr. Redberg's conclusions. I ask the gentlelady, does
2684 the minority still wish to include that supplemental memo in
2685 the record?

2686 Ms. {DeGette.} Yes, it has already been included.

2687 Mr. {Stearns.} Okay. We just wanted to establish that.

2688 Dr. Shuren, you have been at the FDA not just the 2
2689 years in this present position, how many years were you
2690 before that?

2691 Dr. {Shuren.} I first started in 1998 but I also worked
2692 over at the Medicare program, and I came back in 2003 and had
2693 been there since then.

2694 Mr. {Stearns.} So that is 8 years from 2003, and before

2695 that how many years were you there?

2696 Dr. {Shuren.} About--

2697 Mr. {Stearns.} Two?

2698 Dr. {Shuren.} Approximately two.

2699 Mr. {Stearns.} So our records show you actually have
2700 been there 10 years. Would that be a fair statement?

2701 Dr. {Shuren.} That would be a fair statement.

2702 Mr. {Stearns.} Okay. And I think in your opening
2703 statement here, you say that the FDA needs to take steps to
2704 improve predictability, consistency and transparency. So the
2705 question is, since you have been there 2 years, I guess
2706 rhetorical, why hasn't all that been done, and maybe more
2707 specifically, your comment that FDA needs to improve
2708 management oversight and standard operating procedures, and I
2709 guess the question is, since you have been there for 2 years
2710 have you done that?

2711 Dr. {Shuren.} So the answer is yes, we have actually
2712 already started to make improvements. When I first came in,
2713 there were a lot of questions from different sides about were
2714 the programs not working well, were we too risk-averse.
2715 Others were saying we are too risk-permissive. And what we
2716 said we needed to do is a thorough assessment of the programs
2717 first, understand the problems, identify the root causes, and
2718 then determine the appropriate solutions. That is what we

2719 spent much of 2010 doing. We went around the county to hear
2720 from different people, not just asking people to come to us
2721 but our going out to them, and that is what is contained in
2722 our two reports. We put out the recommendations of what we
2723 would do, and we wanted to get public input first to make
2724 sure we were doing what was right before we proceeded, and in
2725 fact, we had heard from industry and even some in Congress,
2726 please don't rush into making changes, we want to make sure
2727 you finish your process first.

2728 So we did that, but we moved quickly so that we could
2729 wrap up and start putting improvements in place, and one of
2730 them already set up is the center science council that I
2731 mentioned. This is a body of our senior managers and
2732 experienced scientists, and to them are brought some of the
2733 important issues to be decided by the center. For example,
2734 where in the past a decision to--

2735 Mr. {Stearns.} Would it be fair to say what you are
2736 talking about is what you intend to do?

2737 Dr. {Shuren.} No, no, no. The center science council
2738 is already set up.

2739 Mr. {Stearns.} Okay. Let us say all the things you
2740 said are good things. You heard Dr. Fischell, didn't you, in
2741 which he said the ``FDA's device center over the past few
2742 years is the worst I have experienced in 42 years,' ' so then

2743 I asked him to narrow it down, is it 4 years ago, 5 years
2744 ago, the last 2 years. He indicated, as you heard, it is
2745 really under your watch. Isn't that what you heard from him?

2746 Dr. {Shuren.} That is what I heard from him but--

2747 Mr. {Stearns.} So we both agree, that is what he said.

2748 So under your watch, here is a very competent inventor of the
2749 United States award 200 patents in Europe and the United
2750 States, he said it is the worst experience he has seen in 2
2751 years. Do you agree with him?

2752 Dr. {Shuren.} No, I don't think we are the worst in
2753 terms of running the center. I do think in terms of
2754 performance, we have seen performance worsen.

2755 Mr. {Stearns.} So performance has worsened in the last
2756 2 years?

2757 Dr. {Shuren.} No, it has but it started before then.
2758 If I could show, actually I can show you the data if you
2759 would like to see it. First off, if you would just go to
2760 chart number 4.

2761 Mr. {Stearns.} So he is saying in his opinion, it is
2762 worse. You are saying in a sense that it has been bad but it
2763 is not the worst.

2764 Dr. {Shuren.} Well, what I--

2765 Mr. {Stearns.} Would you agree the last 2 years are
2766 bad?

2767 Dr. {Shuren.} What I would like to explain is that
2768 performance has gotten--I think some things are actually now
2769 starting to improve. For example, if you look at the chart
2770 here, this is for 510(k)s. When we have deficient
2771 applications or we have questions, we send out what is called
2772 an additional information letter. If you look at the chart
2773 here, the percent of 510(k)s that we are sending letters out
2774 on actually started to increase in 2002. If you next put up
2775 the chart for number two, you actually see our performance on
2776 510(k)s over time, and what I want to lay out for you is that
2777 there have been issues here going on many years that have
2778 been increasing.

2779 So what you will see on the chart here is our average
2780 time for a decision. The top line is what we call total
2781 time. This is the time it takes FDA and the time it takes
2782 industry. The middle line is FDA's performance. The bottom
2783 line is industry time. What you will see here is that
2784 starting in 2005, total time is going up. In fact, if you
2785 overlaid even our first chart, which you don't have to do,
2786 but from 2002 recall those letters going up. Now watch
2787 industry time going up and then followed after it while our
2788 performance started to improve, total time goes up. If you
2789 look at the very end and the numbers at the end are not done
2790 yet, the applications we are looking at the very end shows

2791 2010.

2792 Mr. {Stearns.} So in your opinion, things are changing?

2793 That is what you are arguing?

2794 Dr. {Shuren.} That is what I am trying to say. Things
2795 are starting to change. We have a long way to go.

2796 Mr. {Stearns.} Long way to go, but you do admit that
2797 the last 2 years have been not as, shall we say, competent
2798 and--

2799 Dr. {Shuren.} No, I wouldn't say that. I think for
2800 some indicators in terms of times, those numbers--

2801 Mr. {Stearns.} Let me get to this quote here. Is FDA
2802 Commissioner Hamburg your boss?

2803 Dr. {Shuren.} Yes.

2804 Mr. {Stearns.} You have said that the level of
2805 criticism the device center has received has only compounded
2806 the problem. FDA Commissioner Hamburg, however, acknowledged
2807 last week that ``much of the criticism was deserved.'' Has
2808 Commissioner Hamburg expressed this concern to you? Yes or
2809 no.

2810 Dr. {Shuren.} Yes.

2811 Mr. {Stearns.} If so, when did she give you that
2812 criticism to you?

2813 Dr. {Shuren.} For over the past year, we have been
2814 aware of--

2815 Mr. {Stearns.} So she has criticized for the last year
2816 to you. Is that correct?

2817 Dr. {Shuren.} What she is conveying is the criticism
2818 she has heard from others and that she and I both agree with,
2819 that many of the concerns raised are accurate.

2820 Mr. {Stearns.} Did she specifically tell you to do
2821 something about it after she gave this criticism to you?

2822 Dr. {Shuren.} I started to do something about it from
2823 the day I hit the center. I had heard of these and known
2824 about the problems before I ever took on my job, and one of
2825 the very first things I did when I started was to announce,
2826 we need to look at this. In fact, when I first started the
2827 job, I was acting. I didn't know I would be permanent, and I
2828 told the commissioner, look, if you are going to give me this
2829 job, I am not going to be here and just be a guardian, there
2830 are things we need to do and this is one of the things we
2831 need to do, we need to get to the bottom of what the problems
2832 are, and I asked permission to do that and was told yes, you
2833 can proceed--

2834 Mr. {Stearns.} I think my only concluding comment is
2835 that from our perspective, it looks like you are on the go
2836 right now but you weren't necessarily on the go 2 years ago,
2837 and we have this lag of which Dr. Fischell has talked about
2838 and which a lot of our people in the first panel just

2839 complained about, and so you heard them. So my time is
2840 expired.

2841 The gentlelady from Colorado is recognized for 5
2842 minutes.

2843 Ms. {DeGette.} Dr. Shuren, thank you very much, from my
2844 perspective, for your patience today with the very, very long
2845 day we have had. In my short time, I have a lot of ground to
2846 cover so I want to try to keep this flowing as much as
2847 possible.

2848 It looks to me from the two charts that you put up that
2849 the number of device applications is increasing. Is that
2850 correct?

2851 Dr. {Shuren.} The number of device applications has
2852 been increasing. In fact, since 2004, it has increased
2853 through 2010 about 26 percent.

2854 Ms. {DeGette.} And has the staff in your division of
2855 the FDA increased to keep pace with that?

2856 Dr. {Shuren.} It hasn't kept pace with the increase in
2857 our workload. If you look from 2007 to 2010, and actually we
2858 have a chart, number six, it will show the increase in
2859 workload is about 27 percent but we have not had the staff
2860 increase for premarket review to handle all that work.

2861 Ms. {DeGette.} And that is even including the user fees
2862 or the PDUFA fees that are coming up, right?

2863 Dr. {Shuren.} That is correct.

2864 Ms. {DeGette.} Okay. Now, you said that the 510(k)
2865 letters are going up. Why is that? Is that because of
2866 insufficient applications or the increase in applications, or
2867 both?

2868 Dr. {Shuren.} So we did an analysis of the letters we
2869 sent out in 2010. We looked at about 100 of them and then we
2870 looked at follow-up letters if the manufacturer didn't
2871 respond to all of the deficiencies. The causes for those
2872 letters are multifactorial. In some cases, it is our fault.
2873 We found that 8 percent of the time when we sent out letters,
2874 we asked for--

2875 Ms. {DeGette.} I don't mean to stop you, so there are a
2876 lot of reasons why the number of letters are going up?

2877 Dr. {Shuren.} Sometimes we ask for things we shouldn't.
2878 Other times companies didn't provide information they knew
2879 they should have provided.

2880 Ms. {DeGette.} Okay. Now, you heard me say, and you
2881 knew this, I am the chair of the Diabetes Caucus, and I know
2882 that you are aware of the guidance that the FDA is working on
2883 towards artificial pancreas and also towards these low-
2884 glucose suspending systems that Ms. Sagan was talking about.
2885 Are you familiar with that?

2886 Dr. {Shuren.} Yes, I am.

2887 Ms. {DeGette.} Is the agency still on target to have
2888 the guidance on the artificial pancreas approved by December?

2889 Dr. {Shuren.} Yes.

2890 Ms. {DeGette.} And can you tell me how the agency is
2891 going to be working with the manufacturers of both the
2892 artificial pancreas and also the pump and glucose monitor
2893 combinations on both of these systems, the artificial
2894 pancreas and the low-glucose suspend systems? How are you
2895 going to be working with manufacturers so we can move these
2896 issues along?

2897 Dr. {Shuren.} So we allow for meetings with the
2898 companies before they are even at a point to actually--

2899 Ms. {DeGette.} Is that happening?

2900 Dr. {Shuren.} Yes.

2901 Ms. {DeGette.} Okay.

2902 Dr. {Shuren.} We do meet with companies, and when we
2903 actually deal with the clinical trial, we have set out for an
2904 interactive review so there is a rapid turnaround. In fact,
2905 one company right now, I just got told by the head of my
2906 artificial pancreas group, he has spoken with the company
2907 five times this week.

2908 Ms. {DeGette.} Okay. Good. So you feel like we are on
2909 track with all of those systems. Because that is important
2910 to a lot of us.

2911 Now, beyond diabetes devices, I want to ask you more
2912 generally, because all of us on this committee on both sides
2913 of the aisle are concerned. You know, you heard the first
2914 panel, we are concerned about all these devices. What other
2915 actions is the FDA taking to improve device review and
2916 safety?

2917 Dr. {Shuren.} So to get the program back on track, we
2918 need to have clearer policies. We need to put clarification
2919 of what companies need to do and our expectations. We need
2920 to train our people and to have training to industry. We
2921 need to have the procedures in place in our center to make
2922 sure that the decisions are made at the right level so that
2923 we make the right call.

2924 Ms. {DeGette.} And do you think that your staff has
2925 sufficient training or could they need more?

2926 Dr. {Shuren.} Oh, they do need more.

2927 Ms. {DeGette.} And is that going to require adequate
2928 funding?

2929 Dr. {Shuren.} We will need to have sufficient funding,
2930 not just to have the training but for the people to take the
2931 time from not doing premarket review so that they can go off
2932 and do the training, and one of the challenges when you have
2933 limited capacity in your staff is that they have to pick and
2934 choose between do I do the training but it is going to take

2935 longer on the premarket review and we would like to have
2936 sufficient number of staff to do the work and ensure people
2937 can do the training and ensure that they can develop the
2938 guidance documents which are so helpful to industry.

2939 Ms. {DeGette.} Now, you heard Dr. Fischell's idea on
2940 the first panel of just having peer review by people in the
2941 field like putting three people on. What is the FDA's
2942 position on that?

2943 Dr. {Shuren.} I think the FDA still has responsibility
2944 to review those applications but we need to make far better
2945 use of outside experts, which is why we are setting up four
2946 of these networks of experts so we can go out to people who
2947 understand the new technology, experts in the field, and try
2948 to answer important scientific questions. We will never and
2949 can never and should not expect to have all the expertise in
2950 house but we need to have sufficient expertise in-house so we
2951 can reach outside and have the right kind of conversations to
2952 learn from those outside experts. I am a neurologist. I can
2953 talk to another neurologist. You are not going to send me
2954 out to talk to an orthopedist

2955 Ms. {DeGette.} Okay. Thank you, Doctor.

2956 Mr. {Stearns.} Dr. Burgess is recognized for 5 minutes.

2957 Dr. {Burgess.} Submit for the record that no one can
2958 talk to an orthopedist.

2959 Dr. {Shuren.} My brother is an orthopedist, and I agree
2960 with you.

2961 Dr. {Burgess.} Dr. Shuren, you have been very good to
2962 speak to me several occasions about some of these problems,
2963 and we have talked about some of the issues regarding the
2964 FDA's regulation, your regulation of laboratory-developed
2965 tests. Of course, we already have the CLIA structure in
2966 place that does that regulation currently. If we are going
2967 to talk about improved safety standards, about thousands of
2968 new tests and many more coming down the pipeline, how do you
2969 propose that FDA, if it going to take on this task and take
2970 it away from CLIA, how do you propose to be able to do that
2971 with all the other stuff that you have got to do?

2972 Dr. {Shuren.} Well, first off, CLIA doesn't get to the
2973 oversight of the tests, it gets more to the quality of the
2974 laboratory and the ability of a laboratory to perform those
2975 tests, whereas the FDA handles the safety and effectiveness
2976 of the tests. We have been looking at how could we handle
2977 that workload if it were to come in, and that is why any
2978 policy we would put out would be phased in over time to try
2979 to address incoming workload. Secondly, we would be looking
2980 at leveraging our third-party review program we already have
2981 to help on reviewing some of the lower-risk devices, and in
2982 addition, we look at some of the tests to say with

2983 experience, maybe we don't need to look at them premarket, we
2984 can down-classify them, and in fact, just the other week, we
2985 down-classified 30 devices that we no longer will be asking
2986 for premarket review on.

2987 Dr. {Burgess.} I appreciate you being here while we
2988 heard the testimony from all the panelists because I do think
2989 it was important that you hear that. I mean, this is the
2990 type of thing that we hear in our offices or I hear in my
2991 office week in and week out--we have got this thing, we have
2992 got this stuff, we have got this test and it has been in the
2993 pipeline for 3 years, 5 years, 17 years and we are no closer
2994 today than we were when we started. So I think it was
2995 important that you heard and felt some of that frustration.
2996 And you and I have talked about some of these things
2997 specifically in the past. At some point I would like to know
2998 what we have done at the FDA to improve that process, but can
2999 you give us any idea of the volume of work that is there
3000 bottled up at the FDA right now?

3001 Dr. {Shuren.} Well--

3002 Dr. {Burgess.} If you put everybody at every desk and
3003 said no holidays, you don't even get to go home at night
3004 until all this work is finished, would you be able to get
3005 that done?

3006 Dr. {Shuren.} No. Actually--

3007 Dr. {Burgess.} Since the trial lawyer next to me
3008 brought it up, if this were a plaintiff's firm and this were
3009 a product liability suit or a class action suit, they would
3010 have no trouble sifting through a whole basement full of
3011 data, digitizing it and getting it available to their
3012 attorneys in a relatively short period of time. They would
3013 hire enough people to get that done because it would be
3014 important to them, and what it suggests to me is, this is not
3015 important to the FDA.

3016 Dr. {Shuren.} No, it is important to us, and if I had
3017 the ability to hire more people, I would do so. And we can
3018 push our people, I can chain my people to their desks 24/7,
3019 but it is not like I have one case before me. I have a
3020 growing workload and it doesn't go away.

3021 Dr. {Burgess.} Now, Mr. Waxman brought up the issue of
3022 funding but it looks like from the information that we have
3023 with the user fee tax that it out there that your funding has
3024 significantly increased over time. So Dr. Sharfstein said he
3025 had plenty of money when I asked him that question a year
3026 ago. Are you telling us differently today?

3027 Dr. {Shuren.} I think--and I am very happy to go back
3028 to the record. I think what Dr. Sharfstein was saying is
3029 that resources along was not enough to handle it, and I think
3030 it was the context of globalization, but we do need adequate

3031 resources, but let me be clear. Resources are not the only
3032 thing at issue. There are a lot of things at the center that
3033 need to be fixed. We know what the problems are, we know
3034 what to do, and we are on it. We are already making changes.
3035 There are some things we have to work with with industry on.
3036 We need to get the data that they are supposed to send to us,
3037 and we are already in discussions with industry about that.
3038 In fact--

3039 Dr. {Burgess.} I am going to have to interrupt you
3040 because I am going to run out of time, but I don't think
3041 there is any question the device times have significantly
3042 increased, the approval times have significantly increased.
3043 I am glad to hear you say it is not just solely due to
3044 funding, but we have to improve.

3045 Now, Michael Mandel was here on our panel earlier. He
3046 was from the Progressive Policy Institute, and he had a story
3047 to tell about this MelaFind, and do you think that the FDA
3048 was impeding the implementation of being able to use this
3049 device that he was describing?

3050 Dr. {Shuren.} I think in the case, there were issues
3051 with the data that was sent to us. What we are doing now is
3052 going through the data provided, and keep in mind, the
3053 manufacturer then more recently a few months ago changed the
3054 indication they were looking for. We are trying to see, does

3055 the data support what the manufacturer would like to do or
3056 something close to it, and if so, then we would approve that
3057 device.

3058 Dr. {Burgess.} But the fact remains that it has taken
3059 so long, and the rules seem to be changing. Is the FDA
3060 causing us to lose our edge in the development of these new
3061 devices?

3062 Dr. {Shuren.} I think the FDA needs to do a better job
3063 to ensure that we keep our edge as the world's leader in
3064 medical device innovation.

3065 Dr. {Burgess.} Thank you, Mr. Chairman. I will yield
3066 back.

3067 Mr. {Stearns.} He asked you, do you think we are losing
3068 our edge. Just yes or no.

3069 Dr. {Shuren.} I don't think we have lost our edge. I
3070 think if there are steps we don't take, we are at risk for
3071 losing it in the future.

3072 Mr. {Stearns.} Thank you. And the gentleman from
3073 California, Mr. Waxman, is recognized for 5 minutes.

3074 Mr. {Waxman.} Thank you very much.

3075 Dr. Shuren, I want to ask you about a statement that
3076 Advanced Medical Technology Association, known as AdvaMed,
3077 the medical device industry trade association, issued today.
3078 I would like to ask that this statement be made part of the

3079 hearing record, Mr. Chairman.

3080 AdvaMed is the leading device industry trade group.
3081 According to their website, their members produce 90 percent
3082 of the medical devices sold in the United States. Here is
3083 what AdvaMed had to say: ``The medical technology industry
3084 has long recognized that a strong and well-functioning FDA is
3085 vital to maintaining America's preeminence in the medical
3086 technology innovation and we support the current regulatory
3087 framework in the United States.'' Do you have any reaction
3088 to this statement?

3089 Dr. {Shuren.} I am glad to hear it. Actually, recently
3090 I was in a meeting with senior officials from AdvaMed and
3091 they had said to me that they support the current approval
3092 and clearance standards for the United States.

3093 Mr. {Waxman.} Well, their press release says that ``we
3094 believe that any steps necessary to address the situation can
3095 be taken without changing the current robust statutory
3096 standards for clearance and approval of medical devices.'' Earlier today, we were hearing from member after member on
3097 the Republican side insisting that the FDA and the regulatory
3098 standards required by the agency for device approval are
3099 destroying innovation and causing device manufacturers to
3100 move overseas. But the leading device manufacturer trade
3101 group puts out a press release that says the best way to
3102

3103 maintain America's preeminence in this area is, and I quote,
3104 ``a strong and well-functioning FDA requiring industry to
3105 comply with robust statutory standards for clearance.'' Now,
3106 I assume they don't want the statutory requirements changed,
3107 but when they talk about a robust FDA, I am sure they are
3108 talking about a well-funded one.

3109 I must take exception to the comment that was made if
3110 FDA really cared, they would hire more people. You are
3111 hiring as many people, I presume, as you can afford. Isn't
3112 that correct?

3113 Dr. {Shuren.} That is correct, and we also suffer from
3114 a high turnover rate, which makes it so much harder to try to
3115 keep up with our losses.

3116 Mr. {Waxman.} Well, if the Republican budget as
3117 proposed passes, it would provide a 10 percent cut over \$200
3118 million in the FDA budgets. Cut of this magnitude would
3119 affect every facet of FDA operations. You have a tough job
3120 to do, balancing the desire of manufacturers and patients to
3121 get quick approval for devices with your statutory
3122 requirements to make sure they are safe and effective. I
3123 think this is shortsighted to make these kind of budget cuts.
3124 Do you differ with me on that?

3125 Dr. {Shuren.} I am deeply concerned that budget cuts
3126 would cause us to not only lose people but our performance

3127 will worsen, and that will not be in the best interest of
3128 industry, it won't be in the best interest of patients.

3129 Mr. {Waxman.} Do you have difficulty attracting the
3130 best people?

3131 Dr. {Shuren.} We do have a challenge attracting the
3132 best people. The circumstances are, it is a high workload
3133 for people. People get burned out. And the pay for our
3134 people, particularly our frontline managers, doesn't compare
3135 to what they get in industry. In fact, in some respects, it
3136 is not necessarily even the same for other parts in the
3137 agency and so we have a very high turnover rate.

3138 Mr. {Waxman.} So you have a high turnover rate, you
3139 have got a difficult balancing job to do. You recognize
3140 other internal problems that you are trying to deal with in
3141 the medical device area in terms of, I will say it, culture
3142 or inability to move as quickly as we would hope they would,
3143 and you are trying to address those issues?

3144 Dr. {Shuren.} I am. And in fact, these same problems
3145 were seen in the drug program 10 years ago, same thing in
3146 PDUFA where they had high turnover rate, there were concerns
3147 about slow review times, and the drug program was able to get
3148 on top of it. I think people may have heard Dr. Woodcock the
3149 other week testify, talk about how now they are so much
3150 faster than Europe and there was a health affairs article out

3151 about it recently and what made it, they had to make some
3152 internal changes but ultimately the drug industry got behind
3153 the program. They provided additional funding and that
3154 program took off. In fact, right now the drug program, and I
3155 am not saying it should be the same size but it is three
3156 times the size of the device program. They have five times
3157 as many medical officers. They get 10 times the amount in
3158 user fees, and in fact, 60 percent of their larger program is
3159 supporter by user fees whereas 20 percent of my smaller
3160 program is supported by user fees, and that ultimately made a
3161 big difference in being successful. I hope ultimately our
3162 program is much more successful like the drug program.

3163 Mr. {Waxman.} Well, we hope so too, and I hope this
3164 hearing will lead to a very constructive approach by a
3165 Congress that has not very well performed so far this year.
3166 We have done practically nothing. We may not even raise the
3167 debt ceiling and allow our economy to go over the cliff, and
3168 we are telling you how to run an agency, but I hope as we do
3169 our job and improve in our job performance that we can help
3170 you, not cause more problems for you.

3171 I see my time is expired and I yield back, Mr. Chairman.

3172 Mr. {Stearns.} The gentleman's time has expired. The
3173 gentleman from Nebraska is recognized for 5 minutes.

3174 Mr. {Terry.} Thank you, Dr. Shuren, and I appreciate

3175 that you have outlined some of the areas that you have
3176 identified as needing improvement, so I appreciate that you
3177 are willing to do that. Lisa Jackson is much more fun than
3178 you are, frankly, up here. At least she fights with us
3179 instead of coming and recognizing that there are issues and
3180 problems that need fixing.

3181 Dr. {Shuren.} I save it for my wife.

3182 Mr. {Terry.} We share something.

3183 But on the money part, let us start with that, and then
3184 I want to tag along on what Diana was talking about with some
3185 of the artificial pancreas and how we can work through it
3186 maybe even faster, but as I understand from a Congressional
3187 Research Service report, funding from 2008 to 2010 increased
3188 35 percent for the medical device review process. So it has
3189 gone from in 2008 \$275 million to \$368 million. So I find it
3190 hard to really grasp that the 2-year period that we are
3191 talking about, funding was increased, delays increased,
3192 problems occurred and it is all related to the lack of money.
3193 So my question to you is, the 2 years you have served there,
3194 there has been an increased of dollars, you have had a
3195 turnover. Is the turnover related to pay?

3196 Dr. {Shuren.} Turnover is related to pay and to
3197 workload. I will say in terms of the funding we got--and I
3198 haven't seen that report to look at percentages--but we did

3199 get increased appropriations from Congress. Congress also
3200 tells us how that money should be used, and that money
3201 predominantly was directed towards postmarket safety and
3202 globalization, some science. We really didn't get the big
3203 boost for premarket review. We did get an increase in user
3204 fees, which we focused on premarket review, and if you are
3205 talking about the years 2008 to 2010, the enacted user fees
3206 that we can get in 2008 were for my center, \$26.6 million,
3207 and they went up to \$32.8 million in 2010. So between those
3208 two years, I had about an increase in \$6 million in user
3209 fees, enacted user fees, and those while I have been on the
3210 job, and recall, I came in in late 2009, so I am dealing with
3211 money coming in for 2010, I tried to direct more money to
3212 premarket review. Twenty eleven was a bit of a challenge
3213 because, as you know, I understand the challenges you all go
3214 through.

3215 Mr. {Terry.} Oh, that is right. We did pass a budget,
3216 didn't we? It is the Senate that hasn't.

3217 Let me get to the low-glucose suspend systems and
3218 artificial pancreas. Do you know how long those have been
3219 before the FDA medical devices for approval?

3220 Dr. {Shuren.} Well, there is no true artificial
3221 pancreas. No one has developed it. There is nothing
3222 commercial. The low-glucose suspend, the company has come to

3223 us, I believe, and this is my understanding from my staff,
3224 but I believe it is just been in the past year, and we have
3225 been working with them to get up to do the studies they need
3226 and ultimately, hopefully if things turn out right, then
3227 approve it and have it on the market.

3228 Mr. {Terry.} And the process that has been there for a
3229 year, what information is required at this stage?

3230 Dr. {Shuren.} So at this stage is to show it is safe
3231 and effective. The device is available in other countries,
3232 but from what we were able to see and particularly in Europe,
3233 it wasn't approved for the low-glucose suspend. It has that
3234 as a feature but it is not in its indications for use, and
3235 then we asked, did you do any of the prospective clinical
3236 studies to show that that feature works, and they hadn't.
3237 They didn't need to do that for Europe, so that is what we
3238 are asking for here in the United States.

3239 Mr. {Terry.} All right.

3240 Dr. {Shuren.} And I would like to see such a device out
3241 there, and I will tell you, the head of my artificial
3242 pancreas group, he is a type 1 diabetic. He has said to me,
3243 if we have something out there that worked that was safe and
3244 effective, he would use it.

3245 Mr. {Terry.} In my last 30 seconds, what do we need to
3246 do to get this done? You have got the JDRF out here, others

3247 that are listening. What is necessary right now?

3248 Dr. {Shuren.} So right now, we need to get the next
3249 guidance out there. We need to finalize the one we put out
3250 on low-glucose suspend. We need to get the next one out on
3251 artificial pancreas. That will be out on December 1. In the
3252 best of all possible words, I would be able to beef up and
3253 have a stronger staff to focus on this. We deal with so many
3254 disease disciplines that we don't have enough of the people
3255 to do all of that work, and I will tell you in the case of
3256 this guidance that we just put out, I actually pulled
3257 endocrinologists from my other centers and asked them, would
3258 you be willing to give up your time on reviewing drugs and
3259 biologics to help us out on this just so we have the
3260 capability to get it done as soon as possible.

3261 Mr. {Terry.} My time is up.

3262 Mr. {Stearns.} The gentleman's time is expired. The
3263 gentleman from Michigan, Mr. Dingell, is recognized for 5
3264 minutes.

3265 Mr. {Dingell.} Mr. Chairman, I thank you.

3266 Would you please submit us a list of measures you are
3267 taking to improve the consistency of the review process,
3268 please?

3269 Dr. {Shuren.} Yes.

3270 Mr. {Dingell.} How many FTEs in your center work on

3271 device review?

3272 Dr. {Shuren.} The device review process under our user
3273 fee program is 949 FTEs as of 2010.

3274 Mr. {Dingell.} In your tenure at the center, have you
3275 witnessed a high turnover among the review staff? Yes or no.

3276 Dr. {Shuren.} Yes.

3277 Mr. {Dingell.} What is your turnover rate? Would you
3278 submit that for the record, please?

3279 Dr. {Shuren.} Yes.

3280 Mr. {Dingell.} Amongst the review staff currently
3281 employed by FDA, what is their average tenure in that
3282 position? Please submit that to the record.

3283 Dr. {Shuren.} Yes.

3284 Mr. {Dingell.} Now, as I am sure you are well aware,
3285 the House recently passed H.R. 2112, the fiscal year 2112
3286 agriculture appropriations bill, which would cut the FDA
3287 budget by roughly 11 percent, or \$285 million. Please submit
3288 for the record what is the result of that on your efforts to
3289 improve the handling of new permits for the devices that we
3290 are talking about. Would you do that, please?

3291 Dr. {Shuren.} Yes.

3292 Mr. {Dingell.} Now, if the proposed cuts to the FDA
3293 budget included in H.R. 2112 are enacted, will FDA have to
3294 lay off employees? Yes or no.

3295 Dr. {Shuren.} Yes, there is a likelihood we may have to
3296 lay off employees.

3297 Mr. {Dingell.} How many will have to be laid off? Will
3298 you submit that for the record, please?

3299 Dr. {Shuren.} Yes.

3300 Mr. {Dingell.} And I want that. I don't want it
3301 strained through OMB. I want that delivered to this
3302 committee.

3303 Now, will the proposed cut jeopardize the number of
3304 review staff that FDA is able to employ at the center? Yes
3305 or no.

3306 Dr. {Shuren.} Yes.

3307 Mr. {Dingell.} By what order of magnitude? Submit that
3308 for the record, please.

3309 Dr. {Shuren.} Yes.

3310 Mr. {Dingell.} Will the proposed cut have a detrimental
3311 impact on any efforts to improve reviewer training at the
3312 center?

3313 Dr. {Shuren.} Yes.

3314 Mr. {Dingell.} Now, I would note that one of the
3315 complaints that my office consistently receives is that
3316 medical device approval process has a certain inconsistency
3317 from reviewers at the Center for Devices and Radiological
3318 Health. Have you taken steps to improve reviewer training?

3319 Yes or no.

3320 Dr. {Shuren.} Yes.

3321 Mr. {Dingell.} Would you please define what those are
3322 for the purposes of the record?

3323 Dr. {Shuren.} Yes.

3324 Mr. {Dingell.} And would you also submit to us, please,
3325 what steps you are taking to improve the capability of your
3326 reviewers there?

3327 Dr. {Shuren.} Yes.

3328 Mr. {Dingell.} Now, there are some areas of improvement
3329 in the current medical device approval process but I would
3330 ask my colleagues here, does anybody remember the Dalkon
3331 Shield? Anybody around here? Well, 3 million American women
3332 used that device. They were assured it was safe in the early
3333 1970s. Yet the result was widespread cases of pelvic
3334 inflammatory disease, spontaneous abortions, ectopic
3335 pregnancies and infertility. I was here when this committee
3336 created a medical device law in 1976 at the urging of my good
3337 friend, now deceased, President Ford, a Republican.

3338 So is there anybody around here that wants to return to
3339 what President Ford called the horse and buggy days of device
3340 regulation? Do you want to do that?

3341 Dr. {Shuren.} No.

3342 Mr. {Dingell.} Now, I want to remind everybody here

3343 that first of all, we face huge risks. We talked earlier
3344 about pharmaceuticals that kill people and cause children to
3345 be born with flippers, but I would like to have you tell us
3346 what you have found to be your experience with the money that
3347 you have gotten in terms of having your staff financed in
3348 good part by the funding of your agreements with industry for
3349 paying for the cost of that. Would you submit that for the
3350 record, please?

3351 Dr. {Shuren.} Yes.

3352 Mr. {Dingell.} And I would ask you to just tell us yes
3353 or no, are you more able to provide the services that you
3354 need to do now that you have that particular program?

3355 Dr. {Shuren.} Yes.

3356 Mr. {Dingell.} And of course, that is true in the case
3357 of pharmaceuticals, is it not?

3358 Dr. {Shuren.} Yes.

3359 Mr. {Dingell.} Mr. Chairman, I thank you.

3360 Mr. {Terry.} [Presiding] Thank you, Mr. Dingell.

3361 Mr. Bilbray, you are recognized for 5 minutes.

3362 Mr. {Bilbray.} Doctor, the gentleman from California
3363 was pointing out that, you know, you could have been facing a
3364 10 percent cut in your budget. Are you aware that venture
3365 capital in medical device research is down almost 40 percent?
3366 That is about 30 percent more than the reduction of other

3367 venture capital in high tech.

3368 Dr. {Shuren.} I don't know the actual figure right now
3369 for investment.

3370 Mr. {Bilbray.} Would you have any explanation of why
3371 those investors who traditionally went to research in medical
3372 devices would have such a large reduction in proportion to
3373 maybe those who are investing in other high-tech devices that
3374 don't relate to medical?

3375 Dr. {Shuren.} What I can say in terms of what I have
3376 been told, and told by industry or industry reports, it is
3377 multifactorial. I mean, one is with the global recession,
3378 venture capital investment went down across the board, and
3379 the VCs have become more risk-averse. They are looking for
3380 investing in technologies that are further along in
3381 development. At the same time, there are some things on our
3382 end.

3383 Mr. {Bilbray.} Okay. What--

3384 Dr. {Shuren.} Insufficient--

3385 Mr. {Bilbray.} Go ahead.

3386 Dr. {Shuren.} I was going to say, insufficient
3387 predictability from FDA is something that can also--

3388 Mr. {Bilbray.} Because that is a huge gap, 30 percent
3389 between venture capital for an iPhone as opposed to venture
3390 capital for a melanoma scanner is a huge gap, and you do say

3391 that you think that the regulatory oversight is one of the
3392 major--or a major problem that we need to address with that
3393 discrepancy?

3394 Dr. {Shuren.} Well, I think having sufficient
3395 predictability is an issue we need to address regardless. I
3396 mean, when I looked at VC investment, and like I said, it was
3397 down, some of the figures from 2010 showed that devices were
3398 still the fourth leading area for investment and had held
3399 that way, but I do understand from the VCs and I do take this
3400 seriously that if we can improve predictability, we can lead
3401 to more investment in device technology.

3402 Mr. {Bilbray.} Okay. Let us talk about a device that
3403 was brought up in the testimony and, you know, there is a lot
3404 of people that don't want their devices or their items
3405 brought up because they are concerned about it affecting
3406 their review process, which I think is a concern in itself,
3407 but we are not here to talk about that. We are talking about
3408 something that was brought up in the first panel, and that is
3409 this remote scanner for melanoma. When we are facing a
3410 situation with 3 percent annual increase, annual increase on
3411 child melanomas, 8,700 people die a year from this, that we
3412 have a device that may be practical for a general
3413 practitioner to use to detect melanomas that may not be
3414 following the regular description, why was that device

3415 basically denied the ability to go through a review process,
3416 a review panel?

3417 Dr. {Shuren.} The decision the first time around not to
3418 have the device go to the advisory panel was wrong. The
3419 staff made the wrong call. It should have been allowed to go
3420 to the advisory panel. It eventually was. It was supported.
3421 It was a very slim margin. It was 8-7. We went back--

3422 Mr. {Bilbray.} How much of a delay did that put in?

3423 Dr. {Shuren.} I don't know.

3424 Mr. {Bilbray.} Let me just say this. And I don't blame
3425 you. I just blame that--I hope both sides of the aisle
3426 understand that some of us that have worked in government
3427 long enough understand, there is an inherent problem with
3428 bureaucracy, and just accept it. It is just one of those
3429 things. There is a problem with capitalism but there is a
3430 problem with government bureaucracy, and that is, it is too
3431 comfortable to say no. It is too comfortable to show up to
3432 the office and go through basically review stuff, and there
3433 is not the push or the uncomfortable getting something done
3434 that you may get at a different angle, and Doctor, the
3435 challenge is, what is the accountability to the people who
3436 said no and how long was this delay, and I will say this. If
3437 you take how many months, and I will challenge how many
3438 months, that this device was slowed down, how many people

3439 died during that period in the United States from melanoma
3440 that could have been avoided possibly if not just
3441 dermatologists but general practitioners had the ability to
3442 detect this down the line, and how do we get the bureaucracy
3443 to understand, this is not about time and it is not about
3444 money, it is about people's lives.

3445 There was a comment made this morning about the delay.
3446 Who was the doctor who was over in the corner, Mr. Chairman?
3447 Fischell. He made the comment that the delay of a few months
3448 is not that big a deal when you consider the life span of a
3449 drug or a device, okay? Would you agree with that statement?

3450 Dr. {Shuren.} Yes, I do.

3451 Mr. {Bilbray.} See, my problem is, the people down the
3452 aisle were saying the life span of a device, how about the
3453 life span of a patient, and a couple months, 10 months, 12
3454 months delay, when you talk about a 12-month delay, how many?
3455 Is there 8,700 people that are not going to be detected in
3456 this country because we didn't get a device out to the
3457 general practitioners that might have been able to use it?
3458 That is the kind of concern I would like you to transfer to
3459 your rank and file that every day they say no, every day they
3460 say let us study it a little more, that may be the cause of
3461 people dying because there are two ways of killing somebody
3462 in medicine: improper triage and denying proper triage. And

3463 the people that say no are just as liable, but you don't read
3464 about it, and I will just close with this.

3465 You don't read about those things, you read about the
3466 chairman emeritus talking about a morning sickness medicine
3467 in the 1950s that caused birth defects, and we all talk about
3468 that. We don't talk about in the 1980s when there was a
3469 morning sickness medicine driven off the market and people
3470 died because that was driven off. Nobody hears about those
3471 people that died from not having access to a product. We
3472 only hear about those that die because of inappropriate, and
3473 the balance needs to be there, Dr. Shuren.

3474 Dr. {Shuren.} And let me say first off from my people,
3475 they will actually get more grief for taking too long, being
3476 too conservative. We are looking at review times, and quite
3477 frankly, if things are moving along quickly, there aren't
3478 issues. When they are moving slowly, that is when management
3479 is coming back and saying we have a problem, and that is when
3480 staff get more grief actually. And in terms--

3481 Mr. {Terry.} Thank you.

3482 Dr. Green--Dr. Green? I just assumed.

3483 Mr. {Green.} I am just an old city lawyer.

3484 Mr. {Terry.} Juris doctorate, the best kind. Right,
3485 Mr. Burgess? The gentleman from Texas, you are recognized
3486 for 5 minutes.

3487 Mr. {Green.} Thank you, Mr. Chairman.

3488 First of all, I want to reiterate and associate myself
3489 with the comments that our ranking member on the studies and
3490 how important the work on the artificial pancreas is, and
3491 hopefully the time frame that I am seeing will be met by
3492 December, and 245 Members of Congress actually urged the
3493 agency to consider the draft guidance, so hopefully we will
3494 meet those deadlines.

3495 Dr. Shuren, I note that in testimony at other hearings
3496 on the same topic, you stated that delays in the device
3497 reviews and declines in FDA performance are due to poor
3498 quality submissions from the medical device industry. While
3499 I agree with you that not every submission is created equal
3500 and there are certainly some variations in quality, I find it
3501 hard to believe that the dramatic growth we have seen in
3502 review times for both PMA devices and 510(k) devices can be
3503 fully explained by the sudden decline of the quality in
3504 submissions. What other factors explain the dramatic
3505 increase in the review times?

3506 Dr. {Shuren.} So I agree, that is not the explanation,
3507 complete explanation for everything. Some of it is fault on
3508 our end, when we ask for things we shouldn't ask for, and as
3509 I mentioned, that is about 8 percent of those letters we send
3510 out, so about 5 to 6 percent of the 510(k)s we are asking for

3511 things we shouldn't ask for, so we are putting in procedures
3512 to actually make sure that doesn't happen because it should
3513 never happen, but we do have companies who are submitting
3514 applications that are deficient. I am talking about big
3515 concerns where we put out guidance document, it has been out
3516 for years, and says exactly what to do, and the company
3517 doesn't do it and doesn't provide a justification not to do
3518 it.

3519 At the same time, we also need to have better clarity on
3520 expectations. I would like to have more guidance out there.
3521 We know when there is guidance, you are more likely to get
3522 your device cleared and cleared quickly, but we need the
3523 capability to do that. I need a core team of writers and I
3524 need sufficient number of experts to do the reviews and do
3525 the guidances and get them out quickly. That can make a big
3526 difference.

3527 Mr. {Green.} And you don't have that ability right now?

3528 Dr. {Shuren.} We do not have sufficient ability.

3529 Mr. {Green.} Is it just based on funding? I know
3530 others members have asked questions about that.

3531 Dr. {Shuren.} It is funding. To the extent we can make
3532 our own systems more efficient, we are doing that. We are
3533 doing what we can with what we have. We can do more if we
3534 have more, and we can do it right.

3535 Mr. {Green.} What some of us are hearing, particularly
3536 medical device companies are saying there is a lack of
3537 consistency and predictability in the process and sometimes
3538 the rules change in mid-game, and believe me, the FDA would
3539 not be the only federal agency that does that. I can talk
3540 about a lot of agencies. Certainly it is hard to put a
3541 quality submission together, but is that also a problem that
3542 sometimes once a submission is made, like you said, you may
3543 be requesting information that you don't really need or do
3544 the rules actually change once somebody submits?

3545 Dr. {Shuren.} Sometimes the rules change and it is
3546 justified, there is a new safety concern and we go back to
3547 the company and say we have new information and based upon
3548 that we need additional information, or based on the
3549 company's own data, we have found a problem and we send them
3550 back. What we are now instituting is, when the rules of the
3551 road change and they need to change quickly where we can't
3552 take time to get public comment because of major public
3553 health concerns, we are now going to put out a notice to
3554 industry to say things are changing, here is why and get it
3555 out quickly, where before companies wouldn't find out until
3556 they came in the door with their submission and they wasted
3557 their time and effort when they could have been notified
3558 earlier, and we are fixing that.

3559 Mr. {Green.} I guess just the certainty and
3560 consistency, that is what anybody wants.

3561 I have heard you say previously that the FDA is meeting
3562 its user fee goals for 95 percent of the submissions. When I
3563 looked at the charts from the most recent quarterly update on
3564 the medical device performance goals, there was an awful lot
3565 more goals in the 5 percent that were not being met, and I
3566 know that the 510(k) submissions account for about 95 percent
3567 of the device reviews that FDA does each year but all these
3568 red boxes where the FDA is not meeting its user fee goals are
3569 concerning to me. I also note that goals aren't being made,
3570 largely the PMA goals. In the previous panel, we heard from
3571 patients who could not access these breakthrough technologies
3572 and had to leave the country to get access. What are you
3573 doing right now to rectify that situation and what steps is
3574 FDA taking to ensure that patients have access to this
3575 cutting-edge medical technology?

3576 Dr. {Shuren.} So in addition to the actions I already
3577 mentioned about making these systems more predictable, more
3578 consistent and more efficient, the other things we are doing
3579 are, we need to adjust clinical trials in the United States.
3580 If we can start clinical trials earlier here, we get the
3581 technology earlier here, companies then keep the technology
3582 with our doctors, so we are going to putting out a policy

3583 soon to actually allow for the first time you give it to a
3584 patient, to let those studies start earlier than we did in
3585 the past and to allow for the manufacturer to make changes,
3586 to innovate and test without necessarily coming back to the
3587 FDA. We heard this is a big deal for the VCs, it is a big
3588 deal for the companies. We will putting out that policy.

3589 The other is being very clear about the factors we take
3590 into account when we make benefit risk determinations. We
3591 had been inconsistent in some cases when we do that. We are
3592 for the very first time going to put out what those factors
3593 are. We are going to get public comment on it, things like
3594 taking into account a patient's tolerance for risk. Serious
3595 disease patients are going to be willing to tolerate more
3596 risk. Serious disease, we may allow for a treatment,
3597 particularly if there is not an alternative out there. That
3598 guidance will go out. We will require that our viewers go
3599 through those factors. They lay out what the answers are and
3600 they put in the record. I consider that so important that
3601 actually I chair that working group personally.

3602 Mr. {Green.} One quick question. I would like to know,
3603 we have heard a lot of comparisons to the European system and
3604 ours. If there is a device in Europe that has been approved
3605 even with those 74 or whatever they do, can the FDA assess
3606 the success or failure of that device in Europe and do you

3607 give any substance to the quality of any studies that come
3608 out of those that are actually being used in Europe?

3609 Dr. {Shuren.} So we absolutely will use data from
3610 Europe or from other countries. We do use that data all the
3611 time. In some cases, we have even approved devices that are
3612 based predominantly or, to my understanding, completely on
3613 data outside the United States, but it has to be the data
3614 that actually answers the question, and one of the challenges
3615 with Europe and other countries is, they will let a device on
3616 the market without showing it is effective. So they actually
3617 never generated the data to show it is effective to meet the
3618 U.S. standards, and a lot of those studies are not so robust.
3619 In fact, the British medical journal in a series of
3620 investigative articles, the European Society of Cardiology, a
3621 group of European health technology assessment agencies all
3622 came out and said for high-risk devices, you should be more
3623 like the United States. You should show you are effective.
3624 You need to have more robust clinical studies like the United
3625 States. You need to be transparent like the United States.
3626 Tell doctors and patients the basis of those decisions and
3627 put out more guidance explaining what you need to do. As
3628 much as we need to do more guidance, the EU puts out nothing
3629 near what we do to clarify what kind of studies you have to
3630 perform.

3631 Mr. {Green.} Thank you for your patience.

3632 Mr. {Terry.} Mr. Scalise, or is it Dr. Scalise?

3633 Mr. {Scalise.} I am not a--

3634 Mr. {Terry.} You are recognized for 5 minutes.

3635 Mr. {Scalise.} --juris doctor or a medical doctor. I

3636 just play a Congressman on C-SPAN occasionally here.

3637 I do want to ask a few questions going back to your
3638 testimony, and in a few different sports you talk about the
3639 success of the FDA, and specifically in relation to what is
3640 happening in Europe, and of course, we had a full panel this
3641 morning that was giving I think some very eye-opening,
3642 riveting and not real positive glowing endorsements of FDA's
3643 performance, especially compared to Europe, and you say here
3644 ``In terms of time to market, data shows that the United
3645 States is performing as well or better than the European
3646 Union,'' and then you go on to say, ``The EU typically
3647 approves higher risk devices faster than the United States
3648 because unlike in the United States, the EU does not require
3649 the manufacturer to demonstrate that the device actually
3650 benefits patients.'' You had a whole panel of patients
3651 sitting here at this table talking about devices they have
3652 access to in Europe that they would have to go to Europe to
3653 get that would actually improve their lives. Some actually
3654 did it. They went to Europe to get the device. You had Dr.

3655 Fischell sitting right there with a device sitting in front
3656 of him that has been waiting on FDA approval for years that
3657 relieves migraine headaches and yet there is data, there is
3658 devices, there is real testing, there are patients that use
3659 it and there are people that are using it in Europe, and you
3660 are implying that Europe has just got some of Wild West
3661 mentality that they are just giving out approval for things
3662 when in fact you have got Americans that right now have to go
3663 to Europe to get the treatment that actually would and has in
3664 some cases improved the lives of those patients. So how can
3665 you make those comments, especially after you sat here and
3666 heard the statements from these patients and the mother of a
3667 patient?

3668 Dr. {Shuren.} So I can have chart 3, first of all, I
3669 empathize with the patients. I am a physician and a patient
3670 myself. I have loved ones who are patients. I want to get
3671 safe and effective devices but emphasis on safe and effective
3672 devices to patients, patients even like myself.

3673 You asked in terms of the data for performance. This
3674 isn't my study, this is an industry study. They looked at
3675 the 510(k)s without clinical data. That is about 80 percent
3676 of the devices that we review, and the products came on the
3677 market first in the United States as often or more often in
3678 the United States than they did in the EU, and in fact, if

3679 you looked at the top chart, the performance, the likelihood
3680 of coming on the U.S. market first actually has improved more
3681 recently in time.

3682 Now, for the smaller group of high-risk devices, they
3683 have come on the market first in other countries for years.
3684 We can do better on that. We can get a lot closer. But we
3685 will never be completely as fast because of that difference
3686 in effectiveness. Does it have ramifications? Yes, because
3687 you do put on the market devices that don't benefit patients,
3688 patients get in some cases when they have alternative that
3689 works so they missed out on good therapy. The health care
3690 system paid for ineffective treatments. And in fact--

3691 Mr. {Scalise.} I want to go back to something, though,
3692 because again, we had testimony not just from patients but
3693 from doctors who have actually invented devices. I mean, Dr.
3694 Fischell, this is somebody who has been inventing devices for
3695 decades, has been nationally recognized, inventor of the
3696 year, has put out more devices than most doctors in this
3697 country, and he first talked about the change he has seen in
3698 the attitude in the FDA is the last 2 years is the worst he
3699 has seen in his 42 years of inventing, and then he further
3700 went on to say there is a different attitude at the FDA than
3701 we have ever seen before. This isn't--you know, you can show
3702 metrics all day long but instead you have patients who are

3703 sitting here and you have got inventors who are sitting here
3704 saying the problem they are seeing in the last 2 years isn't
3705 something that they have seen before at the FDA, and they
3706 surely aren't agreeing with your glowing metrics that you can
3707 go find somebody to say how great you are doing when you have
3708 got real inventors, real patients sitting here saying the job
3709 is not getting done. You know, they will tell you if you
3710 want to look at data and compare it to Europe and say what
3711 Europe has or doesn't have. They will say that firms are
3712 willing to submit whatever data you want but they can't get
3713 the certainty in the regulatory process from your agency.
3714 They want to know how to comply. They can't even get the
3715 certainty from you to know how to comply.

3716 And so you can sit here and talk about all the data you
3717 are not getting and all the money you are not getting and all
3718 the turnover you have got. I can tell you, I mean, I have
3719 looked at your budget. Congressional Research Service
3720 actually issued a finding that the medical device review
3721 process funding in your agency has increased 35 percent in
3722 the last 2 years. You show me a family out there as families
3723 are cutting back you have got a 35 percent and you have the
3724 nerve to sit here and say you are not getting enough money
3725 and the reason you can't move things fast enough is because
3726 you all have too much turnover. Let me tell you, I have

3727 looked at agencies and especially if you talk to people in
3728 the private sector, they will tell you, if you have got
3729 turnover problems, that is a management problem. You can't
3730 blame that on somebody else. You can't say you are not
3731 getting enough money. You got a 35 percent increase over the
3732 last 2 years, and oh, by the way, during that time, the
3733 average review time increased by 43 percent. So maybe
3734 cutting back to what you were at when you were actually
3735 getting some things done might be the most prudent approach
3736 as some of the patients here said, and so to say that you
3737 don't get enough money, you got a 35 percent increase. The
3738 delays are increased. You have got some management problems I
3739 think you have to recognize before you blame the patients and
3740 the inventors who are sitting here and some have to go to
3741 Europe to get the relief that they have gotten. They
3742 actually went to Europe and got the relief and you still
3743 haven't approved the devices here.

3744 So real changes have to occur and you can't just show
3745 metrics that say how great you are doing or say you need more
3746 money. I mean, you know the environment here. We are broke.
3747 We are trying to figure out how to do more with less because
3748 we don't have the money. We can't borrow it from China
3749 anymore and, you know, there has got to be real changes. But
3750 you can't blame other people either.

3751 Mr. {Terry.} Thank you.

3752 Mr. {Scalise.} I will yield back the balance of my
3753 time, whatever that balance is, Mr. Chairman.

3754 Mr. {Terry.} Dr. Christensen, you are recognized for 5
3755 minutes.

3756 Dr. {Christensen.} Thank you, Mr. Chairman, and Dr.
3757 Shuren, thanks for your patience today.

3758 Let me at least try to help you answer the question
3759 about what is happening with venture capital because the
3760 ranking member earlier reported that Bloomberg News today
3761 reported that in the first quarter of this year, venture
3762 capital for medical device and equipment makers went up 20
3763 percent. That was \$841 million in 90 deals, so the first
3764 quarter it went up.

3765 But let me try to ask you a question about some other
3766 things that have been discussed today. In this hearing and
3767 in previous hearings before the committee, we have heard from
3768 a variety of industry sources and supporters of weaker or
3769 less rigid regulation about a flawed FDA regulatory process
3770 for medical devices. We have heard a lot about two industry-
3771 funded studies in particular, one by Dr. Josh Makower and one
3772 by the California Healthcare Institute. These studies were
3773 critical of your agency, purporting to show that the FDA
3774 process causes undue delay in approvals. We asked leading

3775 medical experts to provide us with their views on the
3776 methodology of these studies, and we asked FDA to provide the
3777 views of the agency. So Dr. Shuren, first, can you tell us
3778 about the FDA's views on the findings of the Makower and the
3779 California Healthcare Institute studies?

3780 Dr. {Shuren.} So we did have concerns about the
3781 methodologies that were used. For example, in the Makower
3782 study, he sent out a survey to 1,000 companies, not to the
3783 full industry. Of that, he got 204 who responded, and then
3784 on particular questions trying to compare the United States
3785 to the EU, at most, the number of people who could actually
3786 had a device in both might have been 60 to 80. So very
3787 underreporting, and in those cases, we know the people who
3788 are most dissatisfied, that is who reports. Most of these
3789 companies did not have much experience with the FDA. Only 55
3790 percent brought a 510(k) through the process, only 32 percent
3791 a PMA.

3792 Much of the methodology to compare time frames was
3793 apples to oranges. They didn't look at the same point in
3794 time between the EU and the United States. They compared a
3795 first communication with the United States which could occur
3796 before you even do a clinical study where in the EU your
3797 first communication may be before you actually submit the
3798 application. And therefore I could reduce those times

3799 dramatically if I didn't meet with companies and just say
3800 give me the submission and our times would dramatically
3801 improve. In fact, the best way to compare is, if we had the
3802 data from the EU and comparable times for reviews, and in
3803 fact it doesn't exist because the EU doesn't keep it and
3804 doesn't report it.

3805 Dr. {Christensen.} Thanks. Well, your views are really
3806 similar to the views of the outside experts that are
3807 described in the supplemental memo that was shared today.
3808 These experts also identified a variety of problems. One
3809 reviewer concluded that there so many flaws in the design and
3810 execution that the author's conclusions are rendered
3811 essentially meaningless. Another reviewer concluded that the
3812 CHI study reflects little or no understanding of the
3813 complexity of medical devices. All reviewers indicated that
3814 these studies would not stand up to basic scientific peer
3815 review.

3816 So Dr. Shuren, would you agree that these industry
3817 studies are so flawed that they should not be used as the
3818 basis to justify a radical change to the FDA device safety
3819 standards?

3820 Dr. {Shuren.} I would not be using them in terms of the
3821 actual numbers and data behind them, and that is why we tried
3822 to actually go and pull what the real numbers look like. On

3823 the flip side, in some of the studies that have come out,
3824 they raised what concerns are and some of the problems that
3825 are raised like high turnover rate, insufficient guidance,
3826 those are issues that we agree need to be addressed. That is
3827 why we are taking the steps that we are taking, but we
3828 shouldn't base decisions based on flawed data. That doesn't
3829 serve anyone well.

3830 Dr. {Christensen.} I agree.

3831 Mr. Chairman, we have important decisions to make on
3832 this committee as we work towards reauthorizing the Medical
3833 Device User Fee Act, and we can't really afford to base these
3834 decisions on fatally flawed and biased studies.

3835 Dr. {Shuren.} If I may just say quickly, by the way,
3836 that chart is from one of the flawed studies, and I put it up
3837 because, you know, if you put it out there, it is out there.
3838 It is not my data, that even industry in their own study
3839 reported what comparisons between the United States and the
3840 EU, so just that is on the record.

3841 Dr. {Christensen.} I am just curious. I understand
3842 that Europe might be forming some kind of unified committee
3843 to more standardize their review of their medical devices and
3844 probably medication. Do you know anything about that and how
3845 close they are, and might that not make a difference in how
3846 FDA might accept some of the data?

3847 Dr. {Shuren.} Ultimately, I don't know what the EU will
3848 decide. We should find out in 2012. But they have been
3849 going through a whole process to review their own system
3850 because of complaints that were about it, about not uniform,
3851 inconsistent, not providing adequate patient protections. In
3852 fact, the clinical director for the UK counterpart to my
3853 agency just last year said I am appalled at how many devices
3854 are brought to market with a lack of appropriate clinical
3855 data. The fact that much more clinical data and evaluation
3856 is needed and the notified bodies, there are over 70 private
3857 companies, do not know how to adequately assess or challenge
3858 clinical data or tell those companies relying on equivalents
3859 that they actually need to do a clinical investigation.
3860 These are commercial organizations, many of whom are
3861 reluctant to challenge because they fear losing their clients
3862 and for their survival, and these are one of the things
3863 leading to that review in the EU and maybe potentially
3864 changes over there, and that is the call you heard from the
3865 European Society of Cardiology and the British medical
3866 journal to actually in some respects make some things more
3867 like the United States.

3868 Dr. {Christensen.} Thank you. Thank you, Mr. Chairman.

3869 Mr. {Stearns.} The gentleman from Virginia, Mr.
3870 Griffith, is recognized for 5 minutes.

3871 Mr. {Griffith.} Thank you, Mr. Chairman.

3872 I was pleased to hear you talk about tolerance for risk,
3873 and if you have a high-risk patient, they are more willing to
3874 take--you know, the patient who has got a serious illness
3875 willing to take some risk. I am wondering if the reverse is
3876 true in relationship to the treatment, and it sounds like it
3877 isn't, because I heard you talk about the European and some
3878 of the doctors said on a high-risk device they wish it was
3879 more like the American systems. But I am thinking about low-
3880 risk devices. I am thinking about Ms. Sagan's testimony when
3881 I say this, because, you know, as long as there is a caveat
3882 or a statement that says, you know, this hasn't been through
3883 50 years of marketing or testing on humans, her daughter
3884 would be in a much better shape to have something that would
3885 shut off the insulin pump and the daughter would know and her
3886 mom would know that, you know, even if it doesn't work, it is
3887 better than what they have got right now. Even if it doesn't
3888 work 100 percent, it is better than what they have right now.

3889 Every human being is different, and I would point that
3890 out to you because we had testimony from the other lady that
3891 she had the migraine fix for her 5 years ago, if I remember
3892 correctly--I may be off on the number of years--but years ago
3893 because she was part of a trial, and for 9 months she had a
3894 normal life, and it sounds like in listening to that

3895 testimony this morning that that was a fairly low-risk
3896 medical device that could have been brought to bear, and
3897 everything isn't going to work for everybody, and having a
3898 huge study that says it is effective for 99 percent of the
3899 population isn't always going to be the way to go.

3900 I did a little data research, you know, on accidents in
3901 ambulances, and I am not going to ambush you with it but I
3902 will just tell you about it. Because if you take the theory
3903 that I was hearing this morning that we have a certain number
3904 of deaths, we had 300 deaths in an 11-year period in
3905 automobile accidents while people were in ambulances. We had
3906 24 deaths in a single year with med-evac. Well, if you took
3907 that and applied it to what the FDA has been doing from what
3908 I heard in testimony today, that means you wouldn't allow the
3909 med-evacs or the ambulances to be out there because
3910 notwithstanding the fact that it might help thousands of
3911 people, some people died. And I understand that you have to
3912 be careful but you have to take that into account. And so I
3913 would have to say to you that you might want to look at a
3914 risk-versus-benefit analysis and if the risk is low and the
3915 benefit might be great, get that thing out there quicker
3916 because, you know, we heard testimony from people who are
3917 suffering who could really use some help, and I understand,
3918 if you are putting something inside somebody's body that is

3919 going to be there for hopefully 20 years, that is a different
3920 situation. I understand what the Europeans are saying about
3921 high-risk devices. But we were hearing testimony this
3922 morning about devices that sounded like to me--now, I am a
3923 lawyer, not a doctor, and maybe I wrong, but it sure didn't
3924 sound like they were high-risk devices to me, that it seemed
3925 more high risk not to have, for Ms. Sagan's daughter not to
3926 have something that at least--you know, even if it worked
3927 most of the time would shut that insulin off. That doesn't
3928 mean she still wouldn't have risk because she is diabetic but
3929 it would seem to me that that would be the better course, and
3930 I don't know how you fix that, and if you need us to help,
3931 come see me, I will do what I can.

3932 That being said, I would also say in regard to venture
3933 capital that Chris Coburn, the head of the Cleveland Clinic
3934 Innovation, stated last week raising capital is harder, given
3935 the current economy and health care reform creates a lot of
3936 unknowns. Raising capital is harder. Health care reform
3937 creates a lot of unknowns in the current timeline. You add
3938 in regulatory delays and all of a sudden the arithmetic of
3939 developing products domestically starts to break down. So it
3940 is not just folks coming in here with some kind of a
3941 political agenda, this was just a talk that he was giving
3942 somewhere, and I am just wondering if you would submit them

3943 later because my time is almost up what steps you might be
3944 taking on all of these things that I have mentioned.

3945 And then also I would say apparently at a recent hearing
3946 of the Committee on Oversight and Government Reform, you
3947 mentioned that sometimes reviewers ask for data that might
3948 not be necessary, and I am wondering what you are doing about
3949 that because the industry indicates that is a relatively
3950 recent phenomenon. We heard testimony this morning that one
3951 of the parts on the migraine invention that Dr. Fischell was
3952 talking about, he said he had a plastic valve he showed us,
3953 and he said this is already used in all kinds of different
3954 devices but now I have to show them it works again, even
3955 though it has already been approved in other devices, just
3956 that valve, and I am just wondering what steps you are taking
3957 to correct that. Where would people have gotten the idea
3958 that asking questions like that is acceptable, and do you
3959 have a process in your industry if you have different teams
3960 looking at different things to say well, wait a minute, team
3961 A already approved this valve and it looks like it is pretty
3962 good.

3963 So I would ask you to submit those to us for the record
3964 and so that I can review those as well, and I know I fired a
3965 lot at you and I only have 19 seconds for you to respond, but
3966 anything you want, you can say.

3967 Dr. {Shuren.} Well, I will give you an example of some
3968 of the things we are doing to ensure we make the right
3969 decision and consistent. So if you are going to the review
3970 team says we want to ask for a new kind of study for a type
3971 of device, that is being brought to this new center science
3972 council so rather than a decision made low down in the
3973 organization, it is coming up to the senior managers and
3974 experienced scientists and medical officers to review to make
3975 a call as to whether or not that is right. That allows for
3976 looking over the program for consistency, to make sure that
3977 decision is well informed because we may turn around and say
3978 we disagree. Those are the kinds of changes we are putting
3979 in place that if you are going to make a change, it has to be
3980 made at the right level in the organization. I still want to
3981 give my reviewers flexibility, but when big decisions are
3982 being made, I need the right people to be involved in making
3983 that call.

3984 Mr. {Griffith.} Thank you, Mr. Chairman.

3985 Mr. {Stearns.} All right. The gentleman's time is
3986 expired. I think we are going to do a second round and then
3987 you are free to go, so we appreciate your waiting here.

3988 Just to be clear, you are citing what appears to us as a
3989 flawed study in your testimony, what you said in your opinion
3990 in your testimony and on the report here. Is that right?

3991 Does that make sense to you?

3992 Dr. {Shuren.} Oh, yes, for the California Healthcare
3993 Institute?

3994 Mr. {Stearns.} Right.

3995 Dr. {Shuren.} Yes, I do think there are parts in terms
3996 of some of the data they provided that I would disagree with
3997 and how it is presented.

3998 Mr. {Stearns.} Okay. I just wanted to put that on the
3999 record.

4000 The gentleman from Texas, Dr. Burgess.

4001 Dr. {Burgess.} Thank you, Mr. Chairman.

4002 Dr. Shuren, thank you for staying with us so long. Part
4003 of the review of the 510(k) process, the FDA allocated \$1.3
4004 million to the Institute of Medicine to convene a committee
4005 to evaluate the 510(k) effect on patient safety and
4006 innovation. The IOM committee will have a very influential
4007 role including reviewing seven of the FDA's most
4008 controversial recommendations. Now, in February of this year
4009 at a Health Subcommittee hearing, you seemed to have some
4010 concern that the IOM committee itself would lack the patient
4011 advocates, innovators and inventors who are familiar with the
4012 510(k) system. Critical omissions raise questions as to
4013 credibility of the IOM recommendations and why the FDA would
4014 pay \$1.3 million in taxpayer money for such recommendations.

4015 Is that a fair observation?

4016 Dr. {Shuren.} I don't think I had raised concerns about
4017 it. I think some of the members were raising concerns in
4018 terms of the panel makeup. And what I did try to put out at
4019 the time is--

4020 Dr. {Burgess.} Are not our concerns your concerns?

4021 Dr. {Shuren.} Concerns by the members, some of the
4022 members who are on the committee.

4023 Dr. {Burgess.} They should be your concerns. If they
4024 are our concerns--

4025 Dr. {Shuren.} Well, I understand, and what I tried to
4026 say too is, we contract with the IOM. We don't make a
4027 decision in terms of who are on the panels or what they look
4028 at. I will tell you, though, that, what comes back from them
4029 are recommendations. They are not making a decision; they
4030 are recommendations. And if they make a recommendation, if
4031 we are thinking of adopting it and it would have an impact, a
4032 big impact on industry or others, we will go out and seek
4033 public comment first. If it is a recommendation that
4034 pertains to legislation, that is not our call.

4035 Dr. {Burgess.} Have they made recommendations to the
4036 FDA?

4037 Dr. {Shuren.} No, I have not seen anything from the IOM
4038 yet.

4039 Dr. {Burgess.} Now, there is a lawyer from the
4040 University of Minnesota named Ralph Hall who has concerns
4041 that the IOM committee violates the Federal Advisory
4042 Committee Act. Are you aware of that opinion from Dr. Hall?

4043 Dr. {Shuren.} Yes.

4044 Dr. {Burgess.} And if that is the case, it would be
4045 illegal for you to implement the recommendations of the IOM
4046 committee that violated the Federal Advisory Committee Act,
4047 correct?

4048 Dr. {Shuren.} I think he raised the concern of, is the
4049 committee fairly balanced, and there are people on that
4050 committee who have experienced developing 510(k)s to come to
4051 the agency, there are people with experience dealing with
4052 510(k)s within the agency.

4053 Dr. {Burgess.} Did the IOM committee certify that it
4054 had complied with section 15 of the Federal Advisory
4055 Committee Act?

4056 Dr. {Shuren.} I don't know if they certified.

4057 Dr. {Burgess.} Well, but you are telling us today that
4058 you will not institute any of the IOM committee
4059 recommendations until some of these questions are resolved?

4060 Dr. {Shuren.} I will not implement any of the
4061 recommendations if we wanted to adopt, there would be
4062 recommendations we may decide we are not going to adopt. But

4063 if there are recommendations that would have a big impact on
4064 industry or others, we would seek public comment before we
4065 would proceed.

4066 Dr. {Burgess.} But why spent \$1.3 million to a
4067 committee that doesn't have patients and doesn't have anyone
4068 with any medical device-related experience, especially
4069 innovators?

4070 Dr. {Shuren.} The Institute of Medicine is a well-
4071 respected, well-regarded organization that government has
4072 turned to, Congress has turned to many times for outside--

4073 Dr. {Burgess.} But shouldn't they have at least one
4074 patient representative on those committees?

4075 Dr. {Shuren.} I would direct to the Institute of
4076 Medicine in terms of the decisions made.

4077 Dr. {Burgess.} And again, I would direct your attention
4078 to the overall legality of whether or not they complied with
4079 section 15 of the Federal Advisory Committee Act.

4080 Let me ask you this. There are complaints that the FDA
4081 has not communicated with companies what is needed in the
4082 submissions. The FDA is not telling companies in advance,
4083 and what will happen is, 50 to 75 days later after the
4084 submission you all will come back with what was needed in the
4085 submission, so obviously that upsets and frustrates the
4086 companies because of the added time, and I think we heard Mr.

4087 Bilbray comment on that fact. What are you doing to ensure
4088 that companies are notified in advance about what is needed
4089 and then thereby included in the submitted applications?

4090 Dr. {Shuren.} First, I would say there are other
4091 occasions where companies know what to do, we have told them
4092 what to do, and they don't do it, and I appreciate the fact
4093 of hearing that companies will provide us what we need to
4094 receive, and I have heard that before, but we have companies
4095 that actually don't do that. They don't give us, even in
4096 spite of laying out what they need to do. I will give you a
4097 very quick example, something called the pulse oximeter that
4098 actually--

4099 Dr. {Burgess.} I know what it is.

4100 Dr. {Shuren.} And you know what it is, just for the
4101 other members. It is a sensor you can put on your finger and
4102 it will tell you how much oxygen is in the blood. We have
4103 had guidance since, I believe, 1992. We updated it in 2007.
4104 It said you need to do a very simple clinical study. It is
4105 sort of you use this and you measure from the blood and see
4106 if it is accurate. We recently had a company come in, didn't
4107 send us any clinical data, and we go back to them, why not,
4108 and we ask again, where is the clinical data, we have laid
4109 this out for years. We do deal with those circumstances, so
4110 it goes back and forth.

4111 For the cases where we can provide more clarity, I would
4112 like to be able to put out more guidance for industry and to
4113 update our guidances more quickly. I would like to have the
4114 capacity to go ahead and do that.

4115 Dr. {Burgess.} And I think we would like for you to do
4116 that. I would like the assurance that a company comes to you
4117 with a novel device and says what are we going to need to do
4118 to comply with your guidelines to get the submission
4119 completed in a timely fashion. I would like to be certain
4120 that they are getting that information upfront the first time
4121 and it doesn't change throughout the submission of that
4122 application.

4123 Dr. {Shuren.} Well, one of the things we are doing are
4124 what we call pre-submission meetings if you come in, let us
4125 say, before you are going to do a clinical trial or before
4126 you submit your application. We are going to be putting out
4127 guidance probably by November that now for the first time it
4128 lays out here are the expectations for company, what they
4129 have to give to us, here are the expectations of what you can
4130 expect to see from the agency, and that includes our putting
4131 down what is our advice, and then standing behind it,
4132 assuming that device doesn't change in an important--you
4133 change what the use is for, you change the technological
4134 characteristics that may have been. But if not, then we

4135 should be standing behind it and that is going to be put out
4136 in our guidance later this year.

4137 Dr. {Burgess.} And on your website?

4138 Dr. {Shuren.} The guidance will be on our website. In
4139 fact, it will be out for public comment before we finalize
4140 it. All the things I am talking about from guidance, all go
4141 for public comment. In fact, some of the things we don't
4142 normally put out for public comment we are doing like that
4143 notice to industry letters, which is an internal action, we
4144 put out standard operating procedures of what we would do and
4145 when, we asked for public comment on it. It is out right now
4146 for folks to weigh in.

4147 Mr. {Stearns.} The gentleman's time is expired.

4148 The gentlelady from Colorado is recognized for 5
4149 minutes.

4150 Ms. {DeGette.} Thank you very much, Mr. Chairman.

4151 I just want to ask you a couple of follow-up questions,
4152 Dr. Shuren. The first one is, the question about the funding
4153 levels because the chairman had said in April 2010 there was
4154 a CRS report that said the medical device review process
4155 funding increased from \$275 million in fiscal year 2008 to
4156 \$368 million in fiscal year 2010, but that funding as I
4157 understand it includes user fees. Is that correct?

4158 Dr. {Shuren.} Yes, and I believe that is more than for

4159 my center because my numbers for my center are a little bit
4160 lower.

4161 Ms. {DeGette.} What are your numbers?

4162 Dr. {Shuren.} What I have from my enacted and my total
4163 budget for 2008 is \$225 million, and this is what I am given
4164 from my budget people, and from 2010, it is \$272.7 million,
4165 and that is comprised of appropriations and user fees.

4166 Ms. {DeGette.} How much of that is user fees? Do you
4167 know?

4168 Dr. {Shuren.} So in 2008, the enacted amount is \$26.6
4169 million, and the amount in 2010 is \$32.8 million. And I say
4170 enacted because under the law, if we collect more than we are
4171 supposed to in the first 4 years, we have to give it back by
4172 lowering our fees in 2012, and in fact we are going to be
4173 doing that. Fees will go down in 2012.

4174 Ms. {DeGette.} Now, when we enacted the user fees in
4175 the MDUFA legislation in 2002, that allowed the funding to
4176 increase in better proportion to the costs of the agency. Is
4177 that right?

4178 Dr. {Shuren.} That is correct. There was an adjustment
4179 factor after our workload went up we could increase
4180 accordingly. That was taken out in I think 2005, 2006. It
4181 remains in for the drug program. They can adjust
4182 accordingly.

4183 Ms. {DeGette.} Would that be something that would be
4184 worth having the larger committee look at when we go towards
4185 the reauthorization next year?

4186 Dr. {Shuren.} We should look at how to account for
4187 increasing workload. I would like to provide user fees
4188 predictability for industry. I know that is important. But
4189 we also need to make sure that if our workload goes up, we
4190 get the sufficient resources to meet the workload. Otherwise
4191 we are not going to be able to meet our timeframes.

4192 Ms. {DeGette.} So a lot of the device companies have
4193 expressed to me concern that if the user fees are too high
4194 and if we--and this is same thing actually the drug people
4195 say is--if they are too high, that that freezes out a lot of
4196 innovation and a lot of the kinds of creative devices that we
4197 might really want to see. What is your reaction to that?

4198 Dr. {Shuren.} Well, you have the ability to actually
4199 adjust the fees accordingly, dependent upon even for the type
4200 of company. I will tell for a 510(k), full fee right now is
4201 about \$4,300. For a small business, and a small business is
4202 \$100 million or less in annual sales receipts, it is about
4203 \$2,100 for a 510(k).

4204 Ms. {DeGette.} So that is not really an onerous fee.

4205 Dr. {Shuren.} PMA is higher. It is about \$236,000 for
4206 full. For a small company, it is \$59,000. A lot of the PMAs

4207 tend to come from the bigger companies. More of the 510(k)s
4208 come from the smaller companies.

4209 Ms. {DeGette.} Okay.

4210 Dr. {Shuren.} Which is why we developed the fees as we
4211 did. That is what we worked out with industry to spread that
4212 cost.

4213 Ms. {DeGette.} Now, in the budget that some of my
4214 colleagues were talking about that was approved by the House
4215 and not the Senate earlier this year, the overall FDA was cut
4216 by about 10 percent under H.R. 1. Were you given any
4217 indication if that budget went through how much of those cuts
4218 would go to your agency?

4219 Dr. {Shuren.} For my center, my understanding is that
4220 if you take how much would be cut plus not getting the
4221 increases for a fixed cost like my rent goes up every year
4222 that I have to pay but it is out of my control, it is about
4223 12-1/2 percent.

4224 Ms. {DeGette.} You would be cut by 12-1/2 percent. Do
4225 you think this would have an effect even with some of these
4226 user fees on your ability to expedite some of these
4227 applications?

4228 Dr. {Shuren.} Yes, it would have an impact on our
4229 ability to do reviews. I mean, we can cut the funding. We
4230 cannot increase user fees but then people have to manage

4231 their expectations as to what kind of device program they are
4232 going to get. The drug industry said you know what, it is
4233 worth it to us. A robust FDA gets us better performance and
4234 we can see that today.

4235 Ms. {DeGette.} And that was proven to be correct,
4236 right?

4237 Dr. {Shuren.} That was proven to be correct, and I
4238 understand the unique circumstances of the device industry.
4239 I honestly do. But then we have to figure out some way to
4240 have the right program, and if it is not there, then people
4241 need to understand, you know, what you get in return.

4242 We need to do a better job at the FDA. We know that.
4243 We are doing it. That is what I am talking about today.
4244 There are some things we need industry to work on and then we
4245 need adequate resources to do it right. That is good for
4246 companies. It is ultimately good for patients, and that is
4247 what this is all about.

4248 Ms. {DeGette.} I think that is kind of a good place to
4249 end it, Mr. Chairman.

4250 Dr. Shuren, I appreciate your candor with this committee
4251 and your ability and willingness to discuss the deficiencies
4252 at the agency, and I think all of us really need to sit down
4253 with you as we move towards the reauthorization next year of
4254 the user fees to talk about what we really need to do to make

4255 it work because there are a lot of devices out there that can
4256 save lives and we want to make sure that they are reviewed
4257 quickly, that they are reviewed thoroughly, that they are
4258 safe and they are approved. So thank you very much.

4259 Dr. {Shuren.} I appreciate that, and I would like to
4260 have the ability to work with you all, and I also hope that
4261 if the things we are talking about are right, to also have
4262 your support as we move forward.

4263 Mr. {Stearns.} Dr. Shuren, I would expect, you know,
4264 maybe we will have another hearing sometime in the future
4265 just to follow up with all these things you are saying. You
4266 know, obviously you mentioned all these things you are doing,
4267 and I think the turnover rate is something you have to figure
4268 out too because I think lots of times organizations where you
4269 work, turnover rate is low even though they are not paid a
4270 lot of money because of esprit de corps, because of the
4271 mission and the patriotism and whatever else, leadership is
4272 involved, so--

4273 Dr. {Shuren.} Well, we actually did an assessment in my
4274 center. The esprit de corps is actually off the charts
4275 compared to the rest of my government. My people are very
4276 committed.

4277 Mr. {Stearns.} I don't know if that is good or bad.

4278 Dr. {Shuren.} It is good in the right way. I will say,

4279 we have the same problem in the drug program. They had a
4280 high turnover rate. They were able to cut it and they have
4281 been able to maintain it low, and they did it with targeted
4282 retention allowances, by having enough staff to do the work,
4283 get away from a sweatshop mentality and have enough managers
4284 and project managers to run that program.

4285 Mr. {Stearns.} Are all the guidances on FDA's website
4286 the current state of the thinking at FDA staff? If we go to
4287 that site, will we find the latest and the greatest state of
4288 thinking?

4289 Dr. {Shuren.} I would not be surprised if we have
4290 guidances that are probably not fully up to date.

4291 Mr. {Stearns.} So your website is not up to date?

4292 Dr. {Shuren.} No, the website is up to date as to the
4293 current guidance. I will say that we do run into cases where
4294 our thinking for that kind of device may change and the
4295 guidance hasn't gotten updated in time.

4296 Mr. {Stearns.} All right.

4297 Ms. {DeGette.} Mr. Chairman, just before we adjourn,
4298 some housekeeping. You had asked unanimous consent to put
4299 this Medtronic case into the record. Mr. Waxman had asked UC
4300 for this AdvaMed press release, and then we had asked UC for
4301 Dr. Shuren's slides. Are those all agreed to?

4302 Mr. {Stearns.} By unanimous consent, so ordered.

4303 [The information follows:]

4304 ***** COMMITTEE INSERT *****

|
4305 Ms. {DeGette.} Thank you.

4306 Dr. {Shuren.} May I just clarify one thing?

4307 Mr. {Stearns.} Yes.

4308 Dr. {Shuren.} But if the thinking has changed with the
4309 guidance, what we are trying to do is update the guidance
4310 first so people know but if not and we need to make a quick
4311 change because there is new information, there really is a
4312 risk you have to deal with, then we are going to these notice
4313 to industry letters, so that--

4314 Mr. {Stearns.} You have heard a lot of our panel today.
4315 I would think they would help you, and you are going to go to
4316 private industry first too. You are going to go there too,
4317 right?

4318 Dr. {Shuren.} For feedback on the process?

4319 Mr. {Stearns.} Yes.

4320 Dr. {Shuren.} We have already--it is out for anybody to
4321 comment on.

4322 Mr. {Griffith.} Mr. Chairman?

4323 Mr. {Stearns.} Congressman Griffith.

4324 Mr. {Griffith.} I was wondering if I could have just a
4325 minute to ask a question.

4326 Mr. {Stearns.} Sure, sure.

4327 Dr. {Burgess.} But before you do, because I have got--I

4328 just wanted to ask unanimous consent to put these two letters
4329 from Senator Kerry and the Massachusetts delegation into the
4330 record on the IOM study of the 510(k) process.

4331 Mr. {Stearns.} While you are looking from that, the
4332 gentleman from Virginia for 1 minute.

4333 Mr. {Griffith.} I heard you talk about your lease, so I
4334 am switching gears on you into something I am a little more
4335 comfortable with than medical devices, and I guess my
4336 question is, you said your rent goes up every year. I was
4337 wondering how long your lease was for and when was the last
4338 time you went and renegotiated with your landlord. Because I
4339 think it is something the federal government doesn't do. I
4340 am not picking on you all. I don't have any idea.

4341 But a lot of times they just got locked into a lease and
4342 circumstances in the economy have changed, and when I took
4343 office I was able to cut the lease cost of actually more
4344 square footage, not as pretty but more square footage for
4345 about half the cost, and I am just wondering as your costs
4346 are going up, you might want to take a look at your lease and
4347 see if you can't renegotiate. Even if you are locked into a
4348 multi-year lease, you might be able to renegotiate.

4349 Mr. {Stearns.} That is good. That is experience
4350 talking.

4351 We will put this in by unanimous consent.

4352 [The information follows:]

4353 ***** COMMITTEE INSERT *****

|

4354 Mr. {Stearns.} Thank you very much for your patience.

4355 The subcommittee is adjourned.

4356 [Whereupon, at 6:08 p.m., the subcommittee was

4357 adjourned.]