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2 HIF103.020

3 HEARING ON ``IMPORT SAFETY: STATUS OF FDA'S SCREENING

4 EFFORTS AT THE BORDER''

5 WEDNESDAY, APRIL 13, 2011

6 House of Representatives,

7 Subcommittee on Oversight and Investigation

8 Committee on Energy and Commerce

9 Washington, D.C.

10 The Subcommittee met, pursuant to call, at 10:34 a.m.,  
11 in Room 2123 of the Rayburn House Office Building, Hon. Cliff  
12 Stearns [Chairman of the Subcommittee] presiding.

13 Members present: Representatives Stearns, Murphy,  
14 Burgess, Blackburn, Myrick, Bilbray, Gingrey, Barton,  
15 DeGette, Schakowsky, Christensen, Dingell and Waxman (ex  
16 officio).

17 Staff present: Allison Busbee, Legislative Clerk; Todd  
18 Harrison, Chief Counsel, Oversight/Investigations; Ruth

19 Saunders, Detailee, ICE; Alan Slobodin, Deputy Chief Counsel,  
20 Oversight; Sam Spector, Counsel, Oversight; John Stone,  
21 Associate Counsel; Ali Neubauer, Democratic Investigator;  
22 Brian Cohen, Democratic Investigations Staff Director and  
23 Senior Policy Advisor; Stacia Cardille, Democratic Counsel;  
24 Rachel Sher, Democratic Counsel; Eric Flamm, Democratic FDA  
25 Detailee; and Karen Lightfoot, Democratic Senior Policy  
26 Advisor and Communications Director.

|  
27           Mr. {Stearns.} Good morning, everybody, and welcome to  
28 the Subcommittee on Oversight and Investigation on Import  
29 Safety and the Status of FDA Screening Efforts at the border.

30           My colleagues, today the Subcommittee on Oversight and  
31 Investigations will examine the status of the Food and Drug  
32 Administration's efforts to ensure that Americans have access  
33 to the safest and highest quality imported food, drugs and  
34 medical products. This subcommittee has a bipartisan  
35 tradition of periodically meeting with and demanding  
36 accountability from the federal officials tasked with  
37 screening imported food and medicines that the American  
38 people increasingly rely on for their health and quality of  
39 life. As Commissioner Hamburg herself noted in February  
40 2010, FDA-regulated products are currently imported from more  
41 than 150 countries, with more than 130,000 importers of  
42 record, and more than 300,000 foreign facilities.

43           This hearing marks Commissioner Hamburg's first  
44 appearance before our subcommittee since her confirmation.  
45 Since assuming her current position, the commissioner has  
46 touted a vision for FDA to serve as ``a truly global public  
47 health agency.'' In her own words, ``The FDA faces a daunting  
48 set of tasks. Globalization has multiplied the scale of our  
49 responsibility and the challenges that we all face.'' I

50 applaud the commissioner's expressed support for a number of  
51 important FDA initiatives.

52         Our concern this morning, however, is less with what has  
53 been promised, and more about what has been achieved the  
54 interest of the public health. For example, in a February  
55 2010 speech, the commissioner unveiled a new program  
56 developed over the previous decade enabling FDA, for the  
57 first time, to comprehensively and intelligently screen all  
58 food, drugs and medical products that are entering the United  
59 States. This system, known as PREDICT, which is short for  
60 Predictive Risk-Based Evaluation for Dynamic Import  
61 Compliance Targeting, is a cutting-edge, risk-based tool that  
62 could help reduce our vulnerability to poor-quality imported  
63 food, and counterfeit or otherwise prohibited  
64 pharmaceuticals.

65         However, despite promises to begin deploying it  
66 nationwide by late 2009 and have it fully up and running by  
67 the spring of 2010, PREDICT has only been deployed in three  
68 districts over the last 14 months. At this rate, it would  
69 take FDA over 5 years to deploy PREDICT in the remaining 16  
70 FDA districts. FDA has informed committee staff that the  
71 technical glitches holding up PREDICT's nationwide deployment  
72 have been resolved, and that FDA anticipates deploying the  
73 system to Florida and Puerto Rico by the end of this month.

74           If the technical issues have been resolved, why does FDA  
75 continue to deploy PREDICT in such a piecemeal manner? I  
76 don't see any reason not to push more aggressively for its  
77 immediate deployment nationwide. I also expect to have the  
78 commissioner back here before the committee at a future time  
79 to comment on the progress of PREDICT's deployment.

80           Serious vulnerabilities in our import screening systems  
81 do remain. For example, millions of parcels arrive by  
82 international mail and express couriers' facilities every  
83 year. PREDICT is not deployed at any of these facilities  
84 presently, nor am I aware of any plans for PREDICT to be used  
85 in these settings. FDA must treat each and every one of  
86 these parcels just as it does imported cargo shipments, as  
87 potential carriers of dangerous, tainted foods and  
88 adulterated or counterfeit drugs. FDA cannot claim to be  
89 doing all it can to protect the American people from these  
90 threats so long as a major entry point for goods into the  
91 country remains largely unmonitored.

92           FDA also should not overlook the threats posed by rogue  
93 Internet pharmacies that falsely market their products as  
94 Canadian in origin. A recent 60 Minutes CBS report on  
95 counterfeit drug imports featured a senior FDA official  
96 admitting that his agency lacked the authority to destroy  
97 dangerous shipments and was forced to simply return them to

98 the sender. This report highlighted a serious and  
99 frustrating problem with our current screening process.

100 We need to better protect the health and safety of all  
101 Americans. In March 2007, FDA learned that melamine-  
102 contaminated vegetable proteins imported from China and found  
103 in certain pet foods were sickening and killing cats and  
104 dogs. Also, the commissioner noted on 60 Minutes that over  
105 80 Americans died in 2008 as a result of contaminated  
106 heparin, a blood thinner, which had also been imported from  
107 China. The commissioner suggested earlier this year that  
108 ``regrettably, another public health crisis like heparin or  
109 melamine seems inevitable'' unless certain changes are made  
110 in our import screening process. We cannot and must not  
111 accept this inevitability.

112 PREDICT is the most promising tool we have to enhance  
113 our defenses against such a threat. Let us deploy it  
114 nationwide and without further delay.

115 So Commissioner, I look forward to discussing with you  
116 the possibilities of legislation or perhaps legislative  
117 report language to help provide more focus and support to the  
118 deployment of PREDICT and other improvements to FDA's import  
119 screening. Let me welcome our witness, Commissioner Hamburg.

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

121 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
122           Mr. {Stearns.} I will now yield to the ranking member,  
123 Ms. DeGette from Colorado, for the purposes of an opening  
124 statement.

125           Ms. {DeGette.} Thank you very much, Mr. Chairman. I am  
126 very pleased that we are having a hearing today about the  
127 safety of imports regulated by the FDA.

128           I think that the FDA plays a vital role in protecting  
129 the health and security of Americans, and I know we will have  
130 probably many oversight hearings about this role over the  
131 next couple of years.

132           Although I am really happy to see Commissioner Hamburg  
133 here before us today, though, Mr. Chairman, I am dismayed  
134 that out of three of the last four hearings, the majority has  
135 denied the minority a witness, and this approach is  
136 inconsistent with the practice of all the other subcommittees  
137 on this committee and this Congress and frankly I think  
138 inconsistent with the practices of this committee in previous  
139 Congresses.

140           In the case of today's hearing, we requested testimony  
141 from Allan Coukell, Director of the Pew Prescription Project.  
142 Mr. Coukell is an expert on issues raised by the influx of  
143 imported drugs and other medical products, and his testimony  
144 would have enhanced the--our understanding of this matter.

145 So I ask unanimous consent to put his testimony in the  
146 record, Mr. Chairman.

147 Mr. {Stearns.} By unanimous consent, so ordered.

148 [The information follows:]

149 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
150 Ms. {DeGette.} Thank you so much.

151 Over the past decade, imports of FDA-regulated products  
152 have grown at an astronomical pace. In 2004, the FDA oversaw  
153 the entry of 12 million shipments of products like food,  
154 pharmaceuticals and medical devices. In just 6 years, the  
155 number of imports nearly doubled, reaching 21 million  
156 shipments by 2010, and the number of imports is expected to  
157 grow.

158 Unfortunately, the FDA faces resource constraints that  
159 pose significant challenges to the agency's ability to keep  
160 the food and drug supply safe. For example, the FDA is able  
161 to physically inspect less than 2 percent of imported  
162 shipments.

163 In the face of such challenges, FDA has worked hard to  
164 become more efficient. One example of this is the creation  
165 of the PREDICT database system. This system enables the FDA  
166 to target higher-risk shipments for inspection, enhancing  
167 FDA's ability to ensure the safety of imported food and drugs  
168 at ports of entry into the United States. The system is  
169 currently in use in New York, Los Angeles, Seattle and San  
170 Francisco, and it will soon be implemented nationwide.

171 So given the increasing number of imports and the  
172 resource constraints facing the FDA, it is difficult to

173 understand why we would be cutting FDA funding.

174         In H.R. 1, for example, which was the majority's opening  
175 salvo in the budget debate, the Republicans proposed cutting  
176 FDA's budget by \$241 million. The Republicans' fiscal year  
177 2012 budget, recently introduced by Representative Paul Ryan,  
178 calls for massive reductions, rolling back the agency funding  
179 to 2008 levels. In FDA's case, this would mean a budget cut  
180 of over \$600 million, a nearly 20 percent reduction in the  
181 agency's total budget.

182         So make no mistake about it: a cut of this size would  
183 have a significant impact on the FDA's ability to keep the  
184 food and drug supply safe. We are going to be voting on this  
185 budget this week, and I am hoping that we can reconsider  
186 these devastating FDA budget cuts. Even once PREDICT is  
187 implemented nationwide, it is not going to substitute for the  
188 budget that the FDA needs to have to undertake its oversight  
189 responsibilities.

190         Mr. Chairman, as you so accurately noted, in the last  
191 Congress we took an important step forward regarding food  
192 safety, passing the bipartisan Food Safety Modernization Act,  
193 which gave the FDA new tools to protect the safety of the  
194 Nation's food supply. Now we have an opportunity to provide  
195 the FDA with the additional resources and authorities it so  
196 desperately needs for pharmaceuticals. Nearly 40 percent of

197 the pharmaceuticals in this country are imported, and up to  
198 80 percent of the active ingredients in drugs come from  
199 foreign sources.

200 The Drug Safety Enhancement Act, introduced yesterday by  
201 Mr. Dingell, will hold manufacturers responsible for the  
202 safety of the entire pharmaceutical supply chain, including  
203 components produced in foreign countries, and it will give  
204 FDA tools it needs to enforce these requirements. This is  
205 good legislation that deserves bipartisan support.

206 Mr. Chairman, there is a lot of ground to cover in  
207 today's hearing, and again, I appreciate Commissioner Hamburg  
208 coming today. I am looking forward to hearing about FDA's  
209 efforts on imports, about the PREDICT database system, about  
210 its work implementing the new food safety law, and its views  
211 on the Drug Safety Enhancement Act. And I hope that we can  
212 work together to explain why budget cuts to the FDA right now  
213 are not the way to go in order to protect our Nation's  
214 citizens when it comes to drugs and food. Thank you.

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

216 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
217           Mr. {Stearns.} I thank the gentlelady. I am just a  
218 little puzzled because I thought the National Journal just  
219 reported the FDA got \$107 million increase, so maybe our  
220 figures are different, and I would also say to the  
221 gentlelady, the Hon. Hamburg is really the Administration's  
222 witness. Probably the Republicans could argue that--

223           Ms. {DeGette.} You know, if the gentleman would yield?

224           Mr. {Stearns.} I would be glad to yield. I mean, we  
225 could almost request our witness because she is really more  
226 or less your witness, and as you and I talked earlier that we  
227 want to concentrate on this PREDICT model, and she is the  
228 only one that can do it, and we just wanted one panel, and  
229 she is the top person. I yield to you. Go ahead.

230           Ms. {DeGette.} You know, this was the same thing, Mr.  
231 Chairman, that you told me the last time you denied the  
232 minority a witness when you called the Administration in to  
233 testify, so I talked to our chairman emeritus, Mr. Dingell,  
234 about this, and I said, you know, when we were in the  
235 majority and we called an Administration in when the  
236 Administration was of the other party, did we allow the  
237 minority a witness, and he said yes. If someone calls a  
238 witness, it doesn't matter if they are a Democrat or  
239 Republican. The fact is, the minority retains the ability to

240 call witnesses. In the case of the hearing today, the  
241 witness we would have wanted to call would have actually  
242 helped us understand this PREDICT system.

243 Mr. {Stearns.} Okay. I think the Hon. Ms. Hamburg  
244 seems very competent and capable of handling this all by  
245 herself.

246 With that, I will recognize Chairman Emeritus Mr. Barton  
247 from Texas for 2 minutes.

248 Mr. {Barton.} Thank you. Well, I want to congratulate  
249 you and Ms. DeGette. You at least got an Administration  
250 person to come. We have a hearing upstairs where apparently  
251 everybody at EPA is on vacation. So I want to give you two  
252 credit. You have our distinguished commissioner, and I am  
253 absolutely certain that she is going to be able to handle any  
254 questions either group of us posed to her.

255 We do welcome you, Madam Commissioner. You have a very  
256 difficult job, and we are always glad to hear your input.

257 This is an important issue. It is not on the front  
258 pages right now, which is a good thing. In the last 3 to 4  
259 years, we have had several food poisoning situations that  
260 have made the front pages, so it is good to hold a hearing in  
261 a non-crisis situation.

262 We all know how much of our food is being imported, how  
263 much of our medical devices, how many of our pharmaceutical

264 finished products and precursor ingredients, so how the FDA  
265 regulates and inspects these products is extremely important.  
266 This is an area where there has been bipartisan support in  
267 the past. Chairman Dingell, Chairman Waxman, myself,  
268 Chairman Upton have all in the past 6 years worked together  
269 to improve our food system and improve the screening process.

270 I am going to be very interested in your comments on the  
271 PREDICT model. I know that is being used now in four  
272 locations or four regions. I would like to know why perhaps  
273 we can't go ahead and implement it nationwide.

274 So Mr. Chairman and Madam Ranking Member, this is a good  
275 hearing. Hopefully it will be bipartisan in nature, and we  
276 will put the facts before the American people. With that, I  
277 yield back.

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

279 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
280           Mr. {Stearns.} I thank the gentleman and recognize the  
281 gentleman from Texas, Dr. Burgess, for 2 minutes.

282           Dr. {Burgess.} I thank the chairman for the  
283 recognition, and I will just mention to the gentlelady from  
284 Colorado, the ranking member of the committee, that I will  
285 support her efforts to have a full and open hearing on the  
286 heparin issue. I tried to do that when I was ranking member  
287 of the minority and then-Chairman Waxman refused those  
288 entreaties. I was fortunate enough to get a briefing by Dr.  
289 Hamburg in my office but nothing substitutes for a full and  
290 open hearing so the American people can actually hear what is  
291 going on.

292           Now, the Food and Drug Administration is truly at a  
293 crossroads of the issues that really impact our country today  
294 and will shape tomorrow from the food on our tables today to  
295 the cures, the drugs and devices that our Nation's doctors  
296 will offer the patients of America. The ability of  
297 tomorrow's doctors to alleviate human suffering is going to  
298 be something on a scale that none us have ever seen before if  
299 they can get through the FDA, and your agency, Commissioner,  
300 is obviously at the forefront of those battles.

301           This committee with its oversight of Food and Drug is  
302 responsible for maintaining an active dialog with you on the

303 full breadth of your jurisdiction to ensure that you have the  
304 tools that you need but you are using them in a way that is  
305 beneficial for the country at large. Primarily this hearing  
306 today will focus on food safety, and I have been concerned  
307 about that for years. In 2007, I introduced legislation that  
308 would give the Secretary of Health and Human Services the  
309 power to refuse admission to a food that was strongly  
310 associated with a suspected foodborne illness. We all  
311 remember the Lou Dobbs' reports from a couple of years ago  
312 when contaminated tomatoes were quarantined in Texas, Georgia  
313 and Florida and it turned out these were peppers coming  
314 across the border. It was found on a Friday afternoon and  
315 nothing could be done until Monday because, after all, it was  
316 a weekend. We have to be able to stop that stuff when we  
317 find it. When there is a known source of contaminated food,  
318 you should be able to act without wasting time.

319 Now, we all knew this hearing that coming into this year  
320 that another salmonella outbreak was going to happen. We  
321 passed a food safety law last year. We have increased the  
322 FDA budget. So I am interested in, do you have the tools you  
323 need with the new legislation that you have, the budgetary  
324 allowance that you have had. Now, Dr. Sharfstein came in and  
325 said you needed no more money for drugs and devices, so I am  
326 assuming you have put a lot into food safety, and we do want

327 to know what is going to be different this April, this May,  
328 this June than previous years when this inevitable salmonella  
329 outbreak occurs.

330 I thank the chairman for the recognition. I will yield  
331 back my time.

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

333 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
334           Mr. {Stearns.} The gentleman yields back. The  
335 gentleman from California, Mr. Bilbray, is recognized for 1  
336 minute.

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

338           Mr. Chairman, I come from a State where you can't talk  
339 about health without talking about holistic issues too and  
340 the interrelationship between components, that nothing in  
341 health is isolated. One of the things that is quite obvious  
342 that we are not going to specifically address today but I  
343 think that we all have to be aware of, that the reality of  
344 what is happening with the development of drugs and the  
345 production of drugs in this country, this issue of  
346 importation is going to grow dynamically. Literally right  
347 now, you have companies that are leaving this country in  
348 droves and going overseas to not only produce the drugs but  
349 also the research and development, and I just think this  
350 committee needs to be aware that this issue may be  
351 increasingly substantially basically because we are seeing  
352 the next generation of innovation and drug development  
353 literally leaving the country, and sadly, the fact is, is  
354 that things like drug manufacturing and research doesn't take  
355 a lot of time to leave the country and evaporate as much as,  
356 let us say, auto manufacturing. We are seeing that going.

357 So this issue is going to grow.

358           The one place where it is going to probably be reduced  
359 by this crisis is the reimportation, and that is something we  
360 need to talk very openly and frankly about, the assumption  
361 that something claims to being reimported so it is not  
362 reviewed, there is no oversight. As somebody who was born  
363 and raised along the border and seeing what happens across  
364 the largest port of entry in the world, the Tijuana-San Diego  
365 port of entry, this is obviously something that is very near  
366 and dear not just to my constituents but to my family, and I  
367 think that we need to address those issues and really talk  
368 about them extensively.

369           But I just think that as we look at this, we have got to  
370 be aware of the crisis coming down the pike and address that  
371 with this. Thank you very much, Mr. Chairman.

372           [The prepared statement of Mr. Bilbray follows:]

373 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

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374           Mr. {Stearns.} I thank the gentleman. The gentleman  
375 from California, Mr. Waxman, the ranking member, is  
376 recognized for 3 minutes.

377           Mr. {Waxman.} Mr. Chairman, this is the fourth  
378 oversight hearing, and three out of the four, we have been  
379 denied minority witnesses. I want to join Ms. DeGette in  
380 complaining about it. Representatives of this Administration  
381 are not minority witnesses. They represent the other branch  
382 of government, and we are going to have a serious talk about  
383 this. This isn't the way this committee has operated when  
384 the Republicans controlled or when the Democrats controlled  
385 the committee in the past.

386           FDA's ability to protect the American public is an  
387 important topic for oversight, and our witness would have  
388 added to that understanding of this hearing. FDA is  
389 responsible for ensuring the safety of food, drugs and  
390 medical devices, and if FDA does not do its job, lives are at  
391 stake.

392           In the official hearing memo for today's meeting on the  
393 safety of imports, the right questions were posed: What are  
394 FDA's solutions for enhancing the screening of imported food,  
395 drugs and medical devices? What is FDA doing to improve its  
396 IT infrastructure for risk-based screening? How can FDA

397 better ensure the safety of imported products?

398           But there is an enormous disconnect between these  
399 questions and what is happening in Congress this very week.  
400 GAO told us that improving the safety of our food and drugs  
401 requires that we provide FDA with more funding and resources,  
402 yet we are doing the exact opposite.

403           Just last week, Representative Paul Ryan introduced the  
404 Republican budget for fiscal year 2012. The House will soon  
405 be voting on this proposal. There is not a lot of detail but  
406 there is enough to know what it would mean for FDA.

407 Republicans propose to roll back discretionary funding for  
408 all federal agencies to fiscal year 2008 levels.

409           In the case of the FDA, the agency budget would be  
410 reduced by \$600 million, a budget cut of almost 20 percent.  
411 This Republican budget would require a dramatic reduction in  
412 FDA's funding to keep the food and drug supply safe. The  
413 result would be the reverse of what the American people want:  
414 fewer inspections and more adulterated and dangerous food and  
415 drugs.

416           Mr. Chairman, there is a word now, I think part of the  
417 American language, called chutzpah. It means you have got a  
418 lot of nerve, I think the Republicans have a lot of nerve to  
419 haul the FDA commissioner up here and grill her about why FDA  
420 is not doing more to keep the food and drug supply safe while

421 simultaneously passing a budget that takes away the resources  
422 she needs to do her job. It is chutzpah as well for the  
423 Republicans on this subcommittee to complain that FDA is not  
424 doing enough about food safety when the majority of the  
425 members on this committee voted against the Food Safety  
426 Modernization Act, which was the first expansion of FDA's  
427 food safety authorities in 70 years.

428         Commissioner Hamburg, I am pleased you are here. We  
429 appreciate your being here. You are not here at the request  
430 of the minority. It would be ridiculous to have this hearing  
431 without you.

432         Mr. Chairman, I want to yield the rest of my time, 2  
433 minutes, to Mr. Dingell, who has been instrumental in the  
434 food safety and drug and medical device safety questions and  
435 it is important that we hear from him.

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

437 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
438           Mr. {Stearns.} The gentleman is recognized for 2  
439 minutes.

440           Mr. {Waxman.} And I am pleased you are allowing him to  
441 give an opening statement.

442           Mr. {Dingell.} Mr. Chairman, I thank you. I thank my  
443 good friend from California for yielding me this time. I  
444 commend you for having this hearing because it is a great  
445 opportunity for us. I think for us to spend time caviling  
446 over whether a witness is a Democratic or a Republican  
447 witness is a prodigious waste of time. This committee has a  
448 fine history of having worked together to put out good  
449 legislation and includes the food safety legislation in the  
450 last Congress, also the wonderful legislation we put together  
451 over the question of Consumer Product Safety Commission and  
452 giving it the authority.

453           Americans suffer from unsafe pharmaceuticals coming into  
454 this country. They have neither the personnel nor the money  
455 to do the job that we need to do to catch these things coming  
456 in. They function under inadequate law which does not enable  
457 us to seize the products coming into this country and to  
458 destroy them and rather they are turned around and sent out  
459 and come back in through another port. Americans are dying  
460 of this. They are being denied proper prescription

461 pharmaceuticals in order to address the problems that they  
462 confront in terms of dealing with major problems like cancer,  
463 heart disease, hypertension and other things that are killing  
464 Americans.

465         Yesterday I introduced with my colleagues, Ranking  
466 Members Waxman, Pallone and DeGette, H.R. 1483, the Drug  
467 Safety Enhancement Act. This legislation would require  
468 manufacturers to implement improved quality and safety  
469 standards including stronger supply-chain management, a  
470 matter often the concern of my Republican colleagues. It  
471 would require manufacturers to notify FDA of counterfeits or  
472 safety concerns and to list drugs and components by the  
473 country of origin to enable us to track the movement of these  
474 pharmaceuticals as they move through commerce. It would  
475 strengthen importers' and custom brokers' oversight. It  
476 would arm FDA with administrative detention to structure  
477 mandatory recall authorities, subpoena power and clear  
478 extraterritorial jurisdiction. It would strengthen criminal  
479 and civil penalties for crime deterrents, and it would  
480 increase foreign manufacturing inspections to be on a par  
481 with those that are suffered by American manufacturers. It  
482 would also create new funding mechanisms for FDA inspectional  
483 activities so that globalization is not going to burden  
484 American taxpayers.

485 I have an excellent article about the safety problems  
486 that we confront together with an analysis of the  
487 legislation, H.R. 1483. I ask unanimous consent that those  
488 be inserted into the record.

489 Mr. {Stearns.} By unanimous consent, so ordered.

490 [The information follows:]

491 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
492           Mr. {Dingell.} And I commend for this, Mr. Chairman.  
493 You are leading an effort which I believe can bring great  
494 food to our people.

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

496 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
497 Mr. {Stearns.} And I thank the chairman emeritus and  
498 his long serving as the former chairman of this committee,  
499 and I would point out, I asked staff based on what Ms.  
500 DeGette and Mr. Waxman indicated, that last year under  
501 Democratic majority, they had a hearing with only the FDA  
502 commissioner on May 6, 2010. So I think at this point--

503 Mr. {Waxman.} Mr. Chairman, will you yield to me? This  
504 is kid stuff.

505 Mr. {Stearns.} Well, no--

506 Mr. {Waxman.} I don't know if you requested a witness  
507 or not. If we request a witness who we think adds to it, it  
508 is going to be 5 minutes more out of your life to hear from  
509 that witness.

510 Mr. {Stearns.} All right.

511 Mr. {Waxman.} I think it is very narrow and mean-  
512 spirited to try to deny us an opportunity to hear witnesses  
513 that we think could add to the hearing.

514 Mr. {Stearns.} Well, I appreciate your sentiments. I  
515 just don't agree with you.

516 Okay. With that, we are very pleased--

517 Mr. {Waxman.} We will invoke rules that require it if  
518 that is the way the chairman wishes to deal with it.

519 Mr. {Stearns.} We welcome our witness today, the Hon.

520 Margaret A. Hamburg, medical doctor, Commissioner of the Food  
521 and Drug Administration. If you don't mind, just turn your  
522 speaker on and move the speaker a little closer to you and  
523 that will be very helpful. I have to swear you in.

524 [Witness sworn.]

525 Mr. {Stearns.} We welcome your opening statement.

|  
526 ^TESTIMONY OF HON. MARGARET A. HAMBURG, M.D., COMMISSIONER,  
527 FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY DAVID ELDER,  
528 ACTING DEPUTY ASSISTANT COMMISSIONER FOR REGULATORY AFFAIRS  
529 FOR FIELD OPERATIONS

530 } Dr. {Hamburg.} Thank you very much, and good morning,  
531 Chairman Stearns, Ranking Member DeGette, members of the  
532 subcommittee. I am Dr. Margaret Hamburg, Commissioner of the  
533 Food and Drug Administration, and joining me here is David  
534 Elder, Acting Deputy Assistant Commissioner for Regulatory  
535 Affairs for Field Operations. He has been with the agency  
536 for 23 years, 15 of which he spent in the field.

537 I appreciate the opportunity to be here with you to  
538 discuss our approach to import safety and the Predictive  
539 Risk-Based Evaluation for Dynamic Import Compliance Targeting  
540 application, or PREDICT, and its role in our efforts to  
541 protect our Nation's supply of food and medical products in  
542 an increasingly globalized market.

543 When President Franklin Delano Roosevelt established the  
544 modern FDA back in 1938, the percentage of food and medical  
545 products imported into the United States was minimal. Today,  
546 the landscape, as you have already been discussing, is  
547 dramatically changed. FDA-regulated products are currently

548 imported from more than 150 countries. This year, we expect  
549 that nearly 24 million shipments of FDA-regulated products  
550 will arrive at U.S. ports of entry. It is estimated that  
551 between 15 to 20 percent of all food now consumed in the  
552 United States originates outside our borders. Further, up to  
553 40 percent of the drugs Americans take and up to 80 percent  
554 of the active pharmaceutical ingredients in those drugs come  
555 from foreign sources.

556         We face great challenges in ensuring that products are  
557 high quality and travel safely throughout their complex  
558 supply chain. As members of this committee well know, our  
559 concerns are not purely hypothetical. The consequences of  
560 adulterated medical products throughout the world have  
561 already been noted, and they have been tragic. Pet food  
562 adulterated with the industrial chemical melamine in 2007  
563 sickened several thousand pets here in the United States, and  
564 that same contaminant was added to infant formula in China,  
565 fatally poisoning about six babies and making 300,000 others  
566 gravely ill in that country. And members of this committee  
567 are well aware of the 2008 heparin contamination crisis in  
568 which adulterated heparin was associated with several deaths  
569 and cases of serious illness.

570         To address these threats and others, we need a paradigm  
571 shift in our approach to import safety where the border is no

572 longer our primary line of defense. We must partner with  
573 industry and our global counterparts to push responsibility  
574 for safety and quality further up the supply chain and to  
575 monitor the integrity of that supply chain throughout. That  
576 is why FDA is developing a global strategy and action plan,  
577 more fully detailed in my written testimony, which will allow  
578 us to more effectively oversee the safety of all products  
579 that reach U.S. consumers in the future. While we cannot  
580 simply be guardians at the gate, border screening,  
581 surveillance and intervention must remain an important part  
582 of our comprehensive import safety program.

583         The task is enormous. In fiscal year 2010, FDA received  
584 a total of 21.2 million lines of FDA-regulated commodities  
585 imported from over 150 countries. FDA is currently managing  
586 264 active import alerts, which flag potentially high-risk  
587 imports representing 3,100 types of products from over 11,000  
588 manufacturers in 150 different countries or areas.

589         To help make our imports screening more efficient, FDA  
590 has developed the PREDICT application, a sophisticated  
591 information technology system which provides FDA staff on the  
592 front lines with more information regarding the many risks  
593 associated with products entering our borders and allows them  
594 to target for examination those shipments at greatest risk.  
595 PREDICT has been launched in Los Angeles, New York, Seattle

596 and San Francisco, covering about 40 percent of all imports  
597 at the present time. Some technical difficulties, as noted,  
598 delayed our national rollout. However, I am pleased to  
599 report that we have addressed those issues and are back on  
600 track. This month, PREDICT will be implemented in our  
601 Florida and San Juan districts, expanding coverage to almost  
602 50 percent of all imports. If successful, it will then be  
603 rolled out across the country.

604 PREDICT is an exciting and important innovation that  
605 harnesses advances in information science to enable us to do  
606 our job better and to improve our service to the Nation. But  
607 as I mentioned earlier, it is just one step in our efforts to  
608 fully secure the supply chain.

609 Congress has provided the agency with critical tools to  
610 assure the safety of imported food. New regulatory  
611 authorities for drugs similarly may help ensure that we can  
612 hold industry accountable for the security and integrity of  
613 their supply chains and the quality control systems they use  
614 to produce drugs for the American people. Those may include  
615 authorities in the areas of corporate responsibility,  
616 enforcement and information sharing, which are detailed more  
617 fully in my testimony.

618 Thank you for the opportunity to testify this morning,  
619 and I look forward to answering your questions.

620 [The prepared statement of Dr. Hamburg follows:]

621 \*\*\*\*\* INSERT 1 \*\*\*\*\*

|  
622 Mr. {Stearns.} Thank you, Commissioner Hamburg.

623 We have a clip we are going to show on the screen here,  
624 which is from a speech you gave in January discussing the  
625 FDA's new global challenges. If we can, play the clip and  
626 maybe just drop the lights a little bit.

627 [Video shown.]

628 Mr. {Stearns.} That statement indicates that you  
629 believe the current threat is pretty serious and you have  
630 spoken repeatedly about the challenges assuring the safety  
631 and quality of imported products in a global age. You  
632 mentioned that in your opening statement, and I think we can  
633 conclude obviously that import safety is one of your top  
634 priorities, and you have promoted PREDICT as an important  
635 tool to leverage FDA's resources in responding to this global  
636 challenge.

637 As you mentioned in your testimony, you formally  
638 unveiled PREDICT in February 2010 in a speech and you stated  
639 that you hoped to have it up and running nationwide by the  
640 end of the spring of 2010, as we recollect. I guess the  
641 question is, what did you do to try and accelerate the  
642 implementation of the process considering you had indicated  
643 that you thought it would be up and running by the spring  
644 2010.

645 Dr. {Hamburg.} Well, as noted, PREDICT is a very  
646 important tool that will enable greater efficiencies in who  
647 we target resources, and it is very exciting to see it now in  
648 action in four of our districts and covering about 40 percent  
649 of all imports at the present time. As we rolled it out,  
650 from the very beginning it was determined that it should be  
651 done in a systematic stepwise way because very often with  
652 computer system implementations that involve extremely large  
653 databases, there are issues that emerge in the process. So  
654 we began in one location with a limited focus, expanded the  
655 focus and then began to roll it out.

656 In the course of that, unfortunately, some issues did  
657 emerge and we actually at a certain point decided to stop  
658 with the actual use of PREDICT in the field while we brought  
659 in experts and put together a team which examined that.

660 Mr. {Stearns.} So really, in a sense, rather than  
661 trying to accelerate the implementation process, you really  
662 stopped it then.

663 Dr. {Hamburg.} Well, what we did was when the problems  
664 emerged--

665 Mr. {Stearns.} I mean, isn't that true?

666 Dr. {Hamburg.} --in its implementation, we stopped it  
667 in order to identify what those problems were rather than  
668 keeping a system--

669 Mr. {Stearns.} Let me get a little more specific for  
670 you. After PREDICT was deployed in the New York district in  
671 the spring of 2010, there appeared to have been a 5- to 6-  
672 month delay while a government contractor wrote a white paper  
673 on a performance assessment of PREDICT. Given that import  
674 safety is one of your top priorities, I guess our question  
675 is, is this delay of this deployment acceptable considering  
676 how important it is? And you said earlier in your speech and  
677 everything that this has to be enforced.

678 Dr. {Hamburg.} Mr. Chairman, I understand your concern  
679 about an unfortunate delay that occurred in the process.  
680 However, this system is very, very important. It is critical  
681 that it work effectively and efficiently. We had identified  
682 problems with its implementation. We stopped the full  
683 rollout while we brought in outside experts and our internal  
684 experts to identify the source of the problem. The effort  
685 that you mentioned was an effort to identify the--

686 Mr. {Stearns.} Can I say this morning that all the  
687 technical problems have been solved?

688 Dr. {Hamburg.} We believe that we identified the  
689 underlying problem that led to the--

690 Mr. {Stearns.} So the answer is yes?

691 Dr. {Hamburg.} --inefficiencies in the system.

692 Mr. {Stearns.} The answer is yes, that you think all

693 the technical problems have been taken care?

694 Dr. {Hamburg.} It seems to be now functioning very well  
695 in the sites where it is present.

696 Mr. {Stearns.} Can you, based upon that, make a  
697 prediction this morning that PREDICT nationwide will be fully  
698 implemented by the end of the year?

699 Dr. {Hamburg.} That is our absolute goal but if there  
700 are problems in the implementation, we will of course examine  
701 those and correct them, but we are moving forward. We see no  
702 barriers to the further implementation of PREDICT in the two  
703 additional sites at the end of this month and extending it to  
704 100 percent implementation by the end of the year.

705 Mr. {Stearns.} In your opinion, wouldn't PREDICT  
706 benefit from a program focused oversight structure with  
707 executive-level involvement?

708 Dr. {Hamburg.} I am sorry. Would it benefit from an  
709 oversight--

710 Mr. {Stearns.} Yes, a more focused approach with more  
711 executive-level involvement. Instead of having these  
712 technical white papers, can't you just have your staff focus  
713 down on this and bring in the executives to make decisions?

714 Dr. {Hamburg.} You know, I feel that we have been  
715 implementing this in a very responsible way with a clear  
716 program plan with internal and external experts overseeing

717 the project. When problems emerge, we have taken the  
718 appropriate actions to remediate them. We now have the  
719 system up and running in the desired way providing benefits.

720 Mr. {Stearns.} Well, right now in Congress I guess the  
721 question is, do you think you need congressional support?  
722 Should we pass legislation specifically authorizing this  
723 program and working with the Appropriations Committee to  
724 include report language? I mean, would that help you at all,  
725 or do you think that is not necessary?

726 Dr. {Hamburg.} The continuing support of Congress for  
727 our efforts to support import safety is extremely welcome. I  
728 don't think we need targeted legislation or activities for  
729 the PREDICT program. As I said, I believe that it is moving  
730 forward in an appropriate and valuable way and that it was  
731 our responsibility as problems emerged to identify the source  
732 of those underlying problems, fix them and make sure that the  
733 program in place in fact was fully functional and able to do  
734 the tasks that we are asking it to do and it is proving to be  
735 of great value as we screen products today.

736 Mr. {Stearns.} My time is expired. The gentlelady from  
737 Colorado is recognized for 5 minutes.

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

739 So Dr. Hamburg, let me get this straight. It was about  
740 14 months ago, February of last year, that the FDA announced

741 this PREDICT program, right?

742 Dr. {Hamburg.} In the speech that you saw the segment  
743 of we formally announced that this PREDICT was--

744 Ms. {DeGette.} About 14 months ago, correct?

745 Dr. {Hamburg.} --going to start to unfold.

746 Ms. {DeGette.} And then you started implementing it and  
747 you found some problems and so you had to correct those  
748 problems as the implementation went forward, correct?

749 Dr. {Hamburg.} That is correct.

750 Ms. {DeGette.} And if you had just tried to implement  
751 the whole thing within 2 months, it is your view that it may  
752 not have worked because it had some problems, right?

753 Dr. {Hamburg.} It would not have worked.

754 Ms. {DeGette.} Now, as of today, 14 months later, it is  
755 about 40 percent implemented, correct? You need to use  
756 words. It is about 40 percent implemented?

757 Dr. {Hamburg.} It is implemented in four sites that  
758 cover 40 percent of the imports.

759 Ms. {DeGette.} And so is it the FDA's view that the  
760 major problems in the PREDICT problem have now been solved by  
761 these efforts over the last 14 months?

762 Dr. {Hamburg.} It is our belief that through the  
763 systematic scale-up and the examination of problems as they  
764 emerge that we have been able to correct the underlying

765 problem in code, which actually wasn't in PREDICT, it was in  
766 an interface with PREDICT.

767 Ms. {DeGette.} I see. Okay.

768 Dr. {Hamburg.} And that now the system, you know, is  
769 working in the sites that it is in place and we see no  
770 barriers at the present time to the full implementation in a  
771 timely manner.

772 Ms. {DeGette.} And the FDA believes in this program and  
773 wants to implement it as quickly as possible as well as us,  
774 right?

775 Dr. {Hamburg.} Absolutely.

776 Ms. {DeGette.} So, you know, I join with Mr. Stearns in  
777 saying, you know, whatever we can do to help you implement  
778 this, we think that it is important and it should be done as  
779 soon as possible but it should also be done right.

780 But here is my next question. You said in your  
781 testimony, PREDICT isn't the only thing we need to do. Why  
782 is that?

783 Dr. {Hamburg.} Because the volume of imports coming in  
784 at the borders and the number of sites of importation are so  
785 huge that the ability to really do the hands-on inspection,  
786 even with a screening tool like PREDICT, limits us in our  
787 reach. We want to reach back further, closer to where the  
788 products are actually produced and manufactured and try to

789 build in assurances of safety and quality from the very  
790 beginning and throughout the supply chain, so working more  
791 closely with industry in terms of the standards that are  
792 expected, working with sister regulatory authorities in  
793 countries around the world so we have this harmonization of  
794 standards, sharing information with others.

795 Ms. {DeGette.} Okay. And so let me ask you, because we  
796 passed the Food Safety Modernization Act last year. Do you  
797 think that the FDA needs new authorities to begin to do what  
798 you are talking about and to protect the safety of the drug  
799 supply?

800 Dr. {Hamburg.} I think the Food Safety Modernization  
801 Act has clearly given us additional authorities and a new  
802 framework for addressing food safety in this context. I  
803 think we do need to very carefully examine the opportunities  
804 on the drug side as well. We know that there are huge  
805 challenges and as noted, they are growing. We do need  
806 additional authorities to be able to do our job and of course  
807 resources as well.

808 Mr. {DeGette.} Yes. One thing that I worked a lot on  
809 in this food safety bill that is also in the Drug Safety  
810 Enhancement Act is mandatory recall authority for the FDA for  
811 drugs. Do you believe this authority is necessary?

812 Dr. {Hamburg.} I do believe that authority is

813 necessary.

814 Ms. {DeGette.} And why is that?

815 Dr. {Hamburg.} So that we can move swiftly when there  
816 is an imminent threat to the health of the public, to take  
817 action to make sure that a product with risks does not get  
818 out to consumers, is pulled back from shelves when it is out  
819 there. It is very vitally important, and our current  
820 authorities require us to either act through the authorities  
821 of States to embargo or pull back these products or to seek  
822 the support of the courts in taking these actions.

823 Ms. {DeGette.} You know, this is one thing when I  
824 worked on mandatory recall for the food safety, my  
825 constituents were shocked because they thought the FDA  
826 already had that authority, and I bet that is true with drugs  
827 too. I bet people just think the FDA has that authority with  
828 drugs.

829 One last question. One of the controversial areas in  
830 this new bill that we introduced calls for new registration  
831 fees on importers. I am wondering if you can talk about what  
832 the FDA opinion is on these registration fees.

833 Dr. {Hamburg.} Well, I think it is very, very important  
834 that we recognize that the magnitude of the problem is huge  
835 and growing and outstrips available resources. Clearly, we  
836 need to bring appropriate resources to bear. Clearly, this

837 is the responsibility that the American people care about as  
838 well as industry, and I think it is appropriate that these  
839 programs be supported with industry contributions as well,  
840 and the ability to work with industry to achieve common goals  
841 in reducing these threats to health and safety will be, I  
842 think, enhanced in this kind of an approach.

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

845 Mr. {Stearns.} I thank the gentlelady. Dr. Burgess is  
846 recognized for 5 minutes.

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

848 Well, they can be enhanced in that kind of approach only  
849 if we understand the problem that we had and how to deal with  
850 the problem. That of course brings me back to the heparin  
851 question, and you were kind enough to come and brief me last  
852 year in the last Congress. If I could, let me just  
853 recapitulate a couple of the things that we talked about that  
854 day. I would like to have them part of the committee's  
855 record. Can you provide to the committee a list of the  
856 people with whom you met in China, the Chinese officials with  
857 whom you met?

858 Dr. {Hamburg.} A list of officials with whom I met  
859 while I was visiting China?

860 Dr. {Burgess.} Yes.

861 Dr. {Hamburg.} I could.

862 Dr. {Burgess.} Because you met with several.

863 Dr. {Hamburg.} For the record. I mean, I can't produce  
864 that right now.

865 Dr. {Burgess.} Correct, and I understand that. That is  
866 why I was asking you if you could produce it for us. And did  
867 the subject of the adulterated heparin come up when you met  
868 with the Chinese officials?

869 Dr. {Hamburg.} It did. I raised it with them to  
870 express our--

871 Dr. {Burgess.} They didn't bring it up spontaneously?  
872 You had to raise it?

873 Dr. {Hamburg.} I believe that I raised it.

874 Dr. {Burgess.} Okay. And what did they commit to you  
875 as far as action to investigate and uncover what happened?

876 Dr. {Hamburg.} What was indicated to me was that they  
877 felt that there was not anything to be gained at this point  
878 by trying to continue the investigations of the underlying  
879 cause and instigators of the heparin contamination but they  
880 did recommit to working with us to ensure that this specific  
881 problem and similar problems will not occur going forward,  
882 and we do have a memorandum of understanding with the Chinese  
883 government with respect to some of the critical public health  
884 measures that need to be in place and are in place to help

885 protect--

886 Dr. {Burgess.} See, that whole approach is problematic  
887 to me because now we have, with all good intentions, drug  
888 safety legislation being introduced but we don't really  
889 understand what happened and how we are going to control it,  
890 and that then makes for legislative difficulties. But the  
891 heparin question is so fundamentally different from the  
892 melamine. Melamine, it can be argued, was the equivalent of  
893 a dishonest grocery putting his thumb on the scale when he  
894 weighed your produce, but the heparin, this was a molecule  
895 that was developed specifically to defeat the mass spect that  
896 was used by the manufacturer to document that in fact what  
897 they had extracted from the live specimen was the desired  
898 active pharmaceutical ingredient. So hypersulfated and  
899 chondroitin sulfate would exactly reside within the peak that  
900 normal heparin would provide one the mass spect, and only  
901 when it was done with an ultra-sensitive machine could you  
902 separate out and see, oh, there is actually two compounds  
903 here instead of one, and that compound was patented under the  
904 Chinese system. So why was it created and what possible use  
905 could it have had in a commercial application and how in the  
906 world did it find its way in to contaminate the  
907 pharmaceutical supply chain? I mean, these are some pretty  
908 critical questions that need to be answered, and to just say

909 well, going forward we are going to be sure things are done  
910 right, I am sorry, maybe the heparin will be done right but  
911 what was the intent here? Was it simply a dishonest retailer  
912 or was there something more nefarious afoot? And we just  
913 simply don't know.

914         So now you have the chairman emeritus and the ranking  
915 member writing legislation which in all likelihood I could  
916 support in principle but we don't know what we are trying to  
917 fix. We don't know how it happened in the first place. That  
918 is why we need your help. You were in China. You met with  
919 these officials. We need your help to understand how we do  
920 in fact prevent this happening in the future. Would you not  
921 agree with that?

922         Dr. {Hamburg.} I agree that this is a very serious  
923 concern and I agree that the heparin contamination was a very  
924 sophisticated example of a broader phenomenon in fact, which  
925 you note, the economic adulteration of products, and I think  
926 it speaks to the urgency of our really strengthening the  
927 activities to ensure import safety, the importance of  
928 additional resources and authorities, the importance of  
929 stronger authorities to enable us to do investigations when  
930 there are problems outside of our--

931         Dr. {Burgess.} Right. It almost requires that we think  
932 like the criminal because after melamine, you know, melamine,

933 shame on us, but heparin, why didn't we see it coming.

934           Let me just ask you a question though because it is so  
935 important that I get this in too. We have a hearing with  
936 device manufacturers. We hear from drug manufacturers.  
937 There is a lot of complaints that the process that people  
938 have to go through with FDA to get drugs and devices approved  
939 is in fact at this point unknowable and it makes the  
940 investment community nervous and in fact it makes the  
941 investment dollars dry up, or worse yet, go overseas so these  
942 drugs and devices are developed in other markets rather than  
943 the United States so it is an outsourcing, it is an  
944 offshoring problem as well. What are you doing within the  
945 agency to ensure that those pathways can in fact be known  
946 before someone starts--so that you can actually tell people  
947 what they will need to provide and then not change the rules  
948 of the game as they go through it?

949           Dr. {Hamburg.} You raise a really important issue, you  
950 know, for our Nation in terms of supporting innovation,  
951 critical industries, economic and global competitiveness, and  
952 FDA clearly has an important role to play. We are looking  
953 very carefully at our regulatory pathways and how we can be  
954 more transparent and predictable, also looking at how we can  
955 bring the best possible science to bear so that we have  
956 better knowledge and tools and approaches to make the

957 regulatory pathways more effective and efficient. We are  
958 working in partnership with academic scientists and industry  
959 scientists and government scientists to really try to  
960 strengthen the underlying science because some of the problem  
961 with the regulatory pathway is in fact scientific uncertainty  
962 about how do you take a good idea and make it into a real-  
963 world product, and of course, a bit outside of the FDA's  
964 bailiwick is the important question of what are the economic  
965 incentives to help ensure investments in important candidate  
966 products that hold real promise.

967 Dr. {Burgess.} I think we both have to agree that the  
968 timeline is a strong economic disincentive. I heard from a  
969 physician who developed a product as he watched his son being  
970 circumcised and decided there had to be a better way to do  
971 some of these things. His son is going to college and it is  
972 still tied up in the FDA.

973 Thank you. I yield back.

974 Mr. {Stearns.} The gentleman's time is expired. The  
975 gentleman from Michigan, Mr. Dingell, is recognized for 5  
976 minutes.

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

978 Commissioner, I want to focus on the adulterated drugs  
979 that are crossing our borders. Some have said it is as much  
980 as \$75 million a year. I think it is rather more. And

981 recent scares like heparin and other matters show how much  
982 needs to be done to monitor imported drugs and  
983 pharmaceuticals. Now, having said that, in recent reports by  
984 CBS News, more than 36 million Americans have unknowingly  
985 purchased drugs on counterfeit-drug websites. Often these  
986 purchases are being dropped in the mail where they may not be  
987 tested either by Customs or Border Patrol. It is my  
988 understanding that under current law, if FDA recognizes  
989 counterfeit or adulterated drugs, FDA cannot detain or  
990 destroy products on site without going through a lengthy  
991 process providing notice and an opportunity for hearing so  
992 that FDA often ships these drugs back to the sender. Is that  
993 correct?

994 Dr. {Hamburg.} That is correct.

995 Mr. {Dingell.} So under current law, it is possible for  
996 a drug operation that is counterfeiting or adulterating drugs  
997 to put it in a package that was rejected by the FDA at one  
998 mail facility and to simply resend it through a different  
999 mail facility or again through the same fiscal year? Yes or  
1000 no.

1001 Dr. {Hamburg.} Unfortunately, yes.

1002 Mr. {Dingell.} I believe I am correct in believing that  
1003 if FDA had the authority to destroy drugs believed to be  
1004 adulterated, misbranded or counterfeit that this would help

1005 to keep counterfeit drugs from reentering our country through  
1006 alternative mail facilities or other facilities. Yes or no.

1007 Dr. {Hamburg.} That is correct.

1008 Mr. {Dingell.} Now, section 201 of the Drug Safety  
1009 Enhancement Act, which I introduced yesterday with my  
1010 colleagues, Mr. Waxman, Mr. Pallone and Ms. DeGette, would  
1011 give FDA's officers or employees the authority to order  
1012 destruction. Section 202 of the bill would authorize the  
1013 destruction of any drug valued at \$2,000 or less or that the  
1014 Secretary deems to be a significant adverse health risk.  
1015 Anything valued at more than \$2,000 could not be destroyed  
1016 until notice and opportunity for hearing occurred. Do you  
1017 believe having this authority would discourage counterfeit  
1018 drug operations from shipping their products into the United  
1019 States? Yes or no.

1020 Dr. {Hamburg.} Yes.

1021 Mr. {Dingell.} Now, we know that these counterfeit and  
1022 adulterated drug operations are a lucrative business. These  
1023 operations make money out of the pockets of consumers who may  
1024 not know that their prescriptions are either unsafe or  
1025 ineffective. I believe that we must impose severe penalties  
1026 at least equivalent to similar violations relating to  
1027 different kinds of products so as to discourage their  
1028 continued operation. The legislation introduced yesterday

1029 proposes strengthening civil and criminal penalties for any  
1030 person who knowingly distributes unsafe pharmaceuticals. Do  
1031 you believe that criminal and civil penalties discourage the  
1032 counterfeit and adulterated drug operations? Yes or no.

1033 Dr. {Hamburg.} Yes, I believe they would.

1034 Mr. {Dingell.} Now, Commissioner, the Drug Safety  
1035 Enhancement Act would also require FDA to inspect every  
1036 establish, foreign and domestic, at least once every 2 years  
1037 following registration. You at FDA have been continuously  
1038 and chronically underfunded. Personnel from FDA have said  
1039 publicly that FDA's resources do not keep pace with the  
1040 volume of products coming into the United States. The  
1041 majority proposed the 2012 budget cut \$600 million from FDA  
1042 in spite of the fact there are new safety authorities for  
1043 food safety that you are required to implement. Would you  
1044 agree that a fee system could help provide a stable funding  
1045 source for drug safety activities? Yes or no.

1046 Dr. {Hamburg.} I believe we need additional resources  
1047 to do the task before us.

1048 Mr. {Dingell.} Would you support such a fee system,  
1049 Commissioner?

1050 Dr. {Hamburg.} Pardon me?

1051 Mr. {Dingell.} Would you support a fee system?

1052 Dr. {Hamburg.} Yes, I would.

1053 Mr. {Dingell.} Now, can you give us an appreciation of  
1054 how many people you have in charge of dealing with imports of  
1055 pharmaceuticals? You don't have to tell us this morning.  
1056 Submit that for the record. Would you also submit to us how  
1057 much that costs and would you submit to us how many people  
1058 you need to do this work and how much that would cost,  
1059 please?

1060 Dr. {Hamburg.} I would be delighted to put that  
1061 together and submit it for the record.

1062 Mr. {Dingell.} I believe we need to know that. Now,  
1063 this committee going back as far as when I was chairman of  
1064 Oversight used to have people in to discuss these matters and  
1065 we never got around to doing anything about it. Last year,  
1066 we passed by overwhelming vote, it came unanimously out of  
1067 this committee, if my memory serves me correctly, the food  
1068 safety bill. Is that working well?

1069 Dr. {Hamburg.} We are still very early in the  
1070 implementation but it is a huge contribution and historic  
1071 shift really in how we are able to address food safety issues  
1072 giving us a new--

1073 Mr. {Dingell.} It gives you lots of new and added  
1074 authorities?

1075 Dr. {Hamburg.} It does.

1076 Mr. {Dingell.} And you recognize many of those

1077 authorities in the pharmaceutical safety bill introduced  
1078 yesterday, do you not?

1079 Dr. {Hamburg.} I think we would like to see parallel  
1080 authorities in the drug area in many key arenas.

1081 Mr. {Dingell.} Mr. Chairman, I thank you for your  
1082 courtesy to me. I hope that we will be able to use this  
1083 hearing as a mechanism to move forward towards safety of our  
1084 people from bad pharmaceuticals as we have done with regard  
1085 to bad food safety, and I would hope my colleagues would work  
1086 with me in a bipartisan fashion towards this end. Thank you,  
1087 Mr. Chairman.

1088 Mr. {Stearns.} I thank the gentleman. Dr. Gingrey is  
1089 recognized for 5 minutes.

1090 Dr. {Gingrey.} Mr. Chairman, thank you.

1091 Dr. Hamburg, thank you for being here today and for your  
1092 leadership at the helm of the FDA. I greatly appreciate your  
1093 efforts and focus on efforts to encourage the FDA to adapt  
1094 and improve its functions including the use of the PREDICT  
1095 software at our borders and ports of entry, and we appreciate  
1096 that. Going to the PREDICT model, one that is flexible and  
1097 able to meet new and emerging threats to our borders and  
1098 ports, in many respects I see the FDA reform in much the same  
1099 light and I think from your previous statements here, I know  
1100 you do as well.

1101 Federal initiatives to develop new drugs and  
1102 diagnostics, whether in the antibiotic space or elsewhere,  
1103 can be greatly supported by an FDA that is flexible,  
1104 adaptable to new technologies, and understanding of the human  
1105 body and genome is critical. How important of a role do you  
1106 think that the regulatory science--you referenced that  
1107 earlier--how important of a role do you think regulatory  
1108 science can be to support the FDA in its work in the coming  
1109 years and decades?

1110 Dr. {Hamburg.} You know, I think it is enormously  
1111 important, and I truly appreciate your question. It is an  
1112 area of science. It is the knowledge and the tools that are  
1113 needed to really effectively and efficiently evaluate a  
1114 product for safety, efficacy, quality and performance, and  
1115 there have been huge advances in science and technology that  
1116 can be brought to bear on the regulatory process as well as  
1117 on the drug development and medical product development  
1118 process to make it more streamlined and more modern, and will  
1119 give us tools so that we can really shorten the timeframe for  
1120 the regulatory process in key ways using innovative clinical  
1121 trial models, using biomarkers to help us identify early  
1122 concerns like toxicity--

1123 Dr. {Gingrey.} Dr. Hamburg, thank you, and I think you  
1124 know I am currently working on some proposals in support of

1125 regulatory science and I am hoping that I can get your  
1126 commitment that you will sit down and work with me and my  
1127 staff in support of this worthy goal.

1128 Dr. {Hamburg.} I am extremely eager to work with you on  
1129 that.

1130 Dr. {Gingrey.} I really appreciate that. Thank you,  
1131 Dr. Hamburg.

1132 You expressed support for developing a track and trace  
1133 and authentication system to help combat the counterfeit  
1134 drugs. Can you update us on FDA's efforts in this area and  
1135 give me your thoughts on the scope of drug counterfeiting and  
1136 diversion in the United States? What else can we as a  
1137 Congress do?

1138 Dr. {Hamburg.} Well, with respect to the big picture,  
1139 we know that counterfeit drugs represent a very large and  
1140 growing problem. It is most--the burden is most pronounced  
1141 in the developing world where in some countries 30 to 50  
1142 percent of drugs for serious diseases being used in fact are  
1143 not what they purport to be. It is a smaller problem in this  
1144 country in large part because we have a very strong  
1145 regulatory framework and we work very closely with  
1146 counterpart agencies to minimize the problem but with the  
1147 growing complexity of supply chains and globalization and the  
1148 fact that we know that especially in the absence of strong

1149 civil and criminal penalties that counterfeiting is an  
1150 increasingly attractive area for some bad guys, I am sad to  
1151 say. We cannot be complacent and we need to make sure that  
1152 we have the programs and policies that--

1153 Dr. {Gingrey.} Well, before the hearing started, I had  
1154 spoke with you briefly about the 60 Minutes clip that I am  
1155 sure a lot of folks on both sides of the aisle saw recently,  
1156 and the magnitude of the problem is downright scary, and  
1157 certainly this is a timely hearing.

1158 Real quickly in the last minute that I have, the events  
1159 and controversy related to the approval and subsequent price  
1160 increase of a drug manufactured by KV Pharmaceuticals for the  
1161 prevention of premature birth--premature labor and possibly  
1162 premature birth. While not directly tied to import  
1163 screening, it does involve FDA's mission to ensure the safety  
1164 and efficacy of our Nation's drug supply, and it was  
1165 initially thought that pharmacies would be precluded from  
1166 compounding versions of this product which they had been  
1167 doing for some time and selling for much less than the  
1168 product marketed by KV, and because of the controversy that  
1169 ensued, KV ultimately significantly lowered the price and FDA  
1170 announced that it would not initiate enforcement against the  
1171 compounding pharmacies. I have a couple of questions in  
1172 regard to that issue. Are you aware of any safety concerns

1173 with patients taking a compounded version of this drug versus  
1174 the Makena product?

1175 Dr. {Hamburg.} As far as I know, we have not had  
1176 reports of adverse events associated with compounding of this  
1177 particular product.

1178 Dr. {Gingrey.} And then the last thing, and I realize I  
1179 am a little bit over time, are any ingredients for the  
1180 compounded version imported as far as you know?

1181 Dr. {Hamburg.} You know, I would have to get back to  
1182 you. I honestly don't know the answer to that question.

1183 Dr. {Gingrey.} And then real quickly, Mr. Chairman, I  
1184 just wanted to ask you, Dr. Hamburg, in regard to Dr.  
1185 Burgess's line of questioning about the heparin. Have we  
1186 then abandoned the heparin investigation? Is that pretty  
1187 much over and done with?

1188 Dr. {Hamburg.} In terms of the investigation of who  
1189 actually instigated this economic adulteration of the heparin  
1190 product, the investigations have come up dry and there are  
1191 not active new leads. I think the other side of it that is  
1192 important for you all to understand the American people to  
1193 understand is that we do have a very large number of steps in  
1194 place and safeguards to protect against the importation of  
1195 contaminated heparin if there were those who chose to try to  
1196 begin again with this contamination of this important

1197 product.

1198 Dr. {Gingrey.} Dr. Hamburg, thank you. Mr. Chairman,  
1199 thank you for your indulgence. I appreciate it.

1200 Mr. {Stearns.} The gentlelady from Illinois, Ms.  
1201 Schakowsky, is recognized for 5 minutes.

1202 Ms. {Schakowsky.} Thank you, Mr. Chairman.

1203 Thank you, Dr. Hamburg. The job that you have taken is  
1204 so expansive from baby food to medical devices in between,  
1205 and I know that imports of FDA-regulated products have  
1206 dramatically increased over the last 7 years. In 2004, FDA  
1207 oversaw 11.8 million shipments of products like food and  
1208 pharmaceuticals and medical devices, but by 2010, the  
1209 importation of FDA-regulated products had nearly doubled,  
1210 totaling in 2010, 21.1 million shipments. That is a lot.  
1211 And so I wanted to ask you about the resources that you  
1212 really have to deal with that.

1213 The President's budget for 2012 asks for a significant  
1214 increase in the FDA's budget, approximately 33 percent, which  
1215 actually includes the new user fees that Mr. Dingell had  
1216 mentioning, bringing it to a total of \$4.3 billion, but the  
1217 Republican budget as presented by Paul Ryan we understand  
1218 would likely roll back FDA funding to the fiscal year 2008  
1219 funding levels, which means the agency would be cut by about  
1220 \$600 million. So what I am concerned about, and my first

1221 question is, what effect would a funding cut on have the  
1222 ability as specifically as possible to be able to do its job?  
1223 How would that affect ordinary consumers and what would you  
1224 have to do?

1225 Dr. {Hamburg.} Well, the magnitude of the cut you  
1226 described, you know, would be enormously difficult for our  
1227 agency to absorb without taking serious cuts in critical  
1228 programs to the health and safety of the American people with  
1229 respect to our ability to inspect and support the safety of  
1230 the food supply, our ability to ensure the safety of the drug  
1231 supply, our ability to approve new and promising medical  
1232 products for the American people, our ability to protect the  
1233 safety of the blood supply and other critical FDA-regulated  
1234 products that people depend on every day, and it would  
1235 certainly make it very, very hard for us to move forward to  
1236 more fully and effectively address the challenges of import  
1237 safety.

1238 Ms. {Schakowsky.} And what then would be your  
1239 priorities were the increases to go through, if the Congress  
1240 were in fact to give you more money? For example, would we  
1241 be able to--as Dr. Burgess mentioned, would there be any  
1242 possibility of speeding up the permits for new  
1243 pharmaceuticals or new products?

1244 Dr. {Hamburg.} We are trying to target additional

1245 resources and additional energy in the area of supporting  
1246 innovation and really modernizing our regulatory pathways.  
1247 Dr. Gingrey mentioned the importance of regulatory science,  
1248 and investments there are making a difference in really  
1249 moving our systems forward. But a lot of what matters in  
1250 moving a product swiftly and surely through the regulatory  
1251 pathway involves having the staff resources to work with the  
1252 sponsor companies to lay out the expectations for what kinds  
1253 of data and evidence they need to put forward to support the  
1254 approval of their product and to work with them as they are  
1255 collecting that data, analyzing that data and presenting it  
1256 to us.

1257         So if we have deep cuts, we will not be able to achieve  
1258 some of what we know makes a difference in terms of the  
1259 review teams and what needs to be done. We won't be able to  
1260 apply advances in science and technology to modernize our  
1261 regulatory pathways, and we won't be able to do the important  
1262 work every day both to ensure the safety and quality of the  
1263 manufacturing and production of drugs and the important work  
1264 to make sure that once those drugs are approved and they are  
1265 being used by people in the real world, we continue to  
1266 monitor for the safety and the efficacy of those drugs so  
1267 that the American people can actually trust and depend on  
1268 these important products.

1269 Ms. {Schakowsky.} Thank you very much.

1270 Mr. {Stearns.} I thank the gentlelady. Ms. Myrick is  
1271 recognized for 5 minutes.

1272 Mrs. {Myrick.} Thank you, Mr. Chairman, and thank you  
1273 both for being here, and we do appreciate the work. I know  
1274 you have got a very difficult job.

1275 As was previously mentioned, Dr. Hamburg, you and Mr.  
1276 Elder were interviewed on that 60 Minutes special regarding  
1277 the threat of counterfeit imported drugs to the U.S.  
1278 pharmaceutical supply. Would you mind if we just play the  
1279 clip so everybody could see?

1280 Dr. {Hamburg.} Okay.

1281 [Video shown.]

1282 Mrs. {Myrick.} It is really frightening, I think, to  
1283 all of us because we share your concern, and I know you have  
1284 already answered the questions that you don't have the  
1285 authority, etc., but in 2009 and 2010, the U.S. Customs and  
1286 Border Protection seized approximately 2,000 parcels of  
1287 pharmaceuticals coming through the mail. Do you have any way  
1288 of knowing how many of those were screened by the FDA that  
1289 were destroyed or returned to the sender? Do you have way to  
1290 track any of that?

1291 Dr. {Hamburg.} The way the system works is that the  
1292 products come in to the mail facility. Customs and Border

1293 Patrol screens. Those that look like they contain drugs or  
1294 medical products get then targeted to the FDA. We work  
1295 closely with CBP, of course. And then we undertake the  
1296 examination of a subset of those products that have been  
1297 targeted to us through Customs and Border Patrol, and  
1298 unfortunately, we cannot screen all of those products because  
1299 of limited resources, and we do lack the authority when we  
1300 find violative products to actually detain and destroy them.

1301 Mrs. {Myrick.} And when they are returned to the  
1302 sender, I mean, that is kind of the majority of the work that  
1303 you do. In other words, you can't destroy them so you have  
1304 to return them to the sender. Is that correct?

1305 Dr. {Hamburg.} We have a couple of options. We can  
1306 hold the product and seek support from the courts to destroy  
1307 them.

1308 Mrs. {Myrick.} I know it would be helpful to you if you  
1309 had some authority from us to be able to--

1310 Dr. {Hamburg.} Absolutely. It would make much more  
1311 sense in terms of addressing important public health problems  
1312 and efficient use of resources.

1313 Mrs. {Myrick.} This is a separate question. I hear a  
1314 lot from patients and doctors in my area. They have really  
1315 big concerns about the FDA's risk-benefit analysis. FDA  
1316 threatens to remove certain drugs and devices from the market

1317 that have relatively low risk compared to a patient's risk of  
1318 death without access to the drugs or devices, and in some  
1319 cases we are talking about terminal illnesses, and patients  
1320 are often willing in that case to take a little extra risk  
1321 because it means they can live longer. So how does the FDA  
1322 take these patients into account when it comes to approval  
1323 and sometimes withdrawing the approval, and can the approach  
1324 that you use be improved in any way, in your opinion?

1325 Dr. {Hamburg.} Well, it is such an important part of  
1326 how we think about and use drugs in this country. We  
1327 obviously do look at the risks and benefits in the context of  
1328 a given disease and what other treatments are available, and  
1329 people are willing to accept many more risks if they have a  
1330 fatal disease and they have no other option.

1331 Mrs. {Myrick.} So you do take that into account?

1332 Dr. {Hamburg.} Yes. We are in the middle of a process  
1333 of really trying to make this all more transparent and really  
1334 systematic and lay out the criteria for weighing risks and  
1335 benefits in different contexts both in terms of the  
1336 understanding that our own staff have about how to think  
1337 about it and the training but also so that medical product  
1338 sponsors and the public including patients can understand  
1339 this as well, and we are doing this in an open way, getting  
1340 input as we try to shape this model.

1341 Mrs. {Myrick.} I really appreciate it, because it is  
1342 heartbreaking when you sit with somebody who is using a drug  
1343 and it has successfully prolonged their life and they are  
1344 living a normal life and then the drug is pulled or it can't  
1345 be used for that particular disease. So it presents a big  
1346 challenge, and it just breaks your heart. So I appreciate  
1347 your looking at it. Thank you.

1348 Mr. Chairman, I yield back.

1349 Mr. {Stearns.} The gentlelady yields back. The  
1350 gentlelady from the Virgin Islands is recognized for 5  
1351 minutes.

1352 Dr. {Christensen.} Thank you, Mr. Chairman, and  
1353 welcome, Dr. Hamburg. I regret that I have been in and out,  
1354 and I may be repeating some of the questions, but I think it  
1355 is important for us to understand the implementation of  
1356 PREDICT, so I have some questions about the PREDICT database  
1357 and realizing that it is a new tool that was created to  
1358 enhance FDA's risk-based screening efforts at ports of entry  
1359 and recognizing, of course, that FDA can't inspect every  
1360 import shipment. The system enables the agency to target  
1361 shipments that are more likely to violate FDA regulations.

1362 So as I understand it, now PREDICT is fully operational  
1363 for all FDA-regulated products in Los Angeles, New York,  
1364 Seattle and San Francisco. Did you say San Juan as well?

1365 Dr. {Hamburg.} Not yet in San Juan. It is being  
1366 implemented in a staged way and so components even aren't as  
1367 fully fleshed out as they will be over time but the major  
1368 components are fully operational and covering 40 percent of  
1369 imports out of those four districts.

1370 Dr. {Christensen.} Thank you. And I know that the  
1371 chairman asked several questions about the delay, and you  
1372 said that there were problems, and if you have already  
1373 specifically stated what those problems are, I apologize, but  
1374 why specifically, what were the problems that caused the  
1375 delay in the full deployment of PREDICT?

1376 Dr. {Hamburg.} Well, as we started to implement the  
1377 system, it was operating much more slowly than people  
1378 expected. It was much more cumbersome. And so questions  
1379 were asked about why that would be. It was initially thought  
1380 that it was an infrastructure problem that we were overlying  
1381 a very large data management set of tasks onto our existing  
1382 infrastructure. That was systematically looked at. It  
1383 actually turned out that the problem was really most focused  
1384 on a piece of software that interfaced with the PREDICT  
1385 system that was slowing it down because it was doing a series  
1386 of initializations underlying the entry process and that was  
1387 corrected and it is now working in a very efficient way and  
1388 we are seeing measurable improvements in our ability to

1389 quickly move low-risk products through and target high-risk  
1390 products.

1391 Dr. {Christensen.} And then you convened a high-level  
1392 group of FDA officials to identify and fix the problem. Just  
1393 to clarify, did the problems that you identified with PREDICT  
1394 cause any risk to the public health or food or drug safety at  
1395 any time?

1396 Dr. {Hamburg.} I really appreciate that question  
1397 because I should emphasize that even when we were having  
1398 problems with PREDICT, we still had underlying systems that  
1399 were supporting our screening, and while not as robust and  
1400 rich as PREDICT, they were still able to provide the core set  
1401 of public health responsibilities that go with our import  
1402 screening activities.

1403 Dr. {Christensen.} Thank you. You know, I think it is  
1404 important not to make a mountain out of a molehill here. The  
1405 FDA is implementing a brand-new IT system to help keep the  
1406 food and drug supply safe, and it seems to me the agency is  
1407 doing exactly the right thing in the right way. No IT system  
1408 is implemented without problems. But the key is that when  
1409 you found the problems, you acted rapidly to identify and fix  
1410 them and to make sure that the public health was not harmed.  
1411 So we are looking forward to the full implementation.

1412 Let us see if I can get another question. I would like

1413 to ask you about courier fees because millions of shipments  
1414 of FDA-regulated products enter the U.S. through express  
1415 courier facilities like FedEx and UPS every year, and the  
1416 President in his budget for 2012 proposes a new international  
1417 courier fee that would be assessed. The President's budget  
1418 requests a new international courier fee not to exceed \$5.3  
1419 million. What activities would that fee support?

1420 Dr. {Hamburg.} It would enable us to do the kind of  
1421 review and when necessary examination of products coming in  
1422 through that mechanism. It is a growing component of  
1423 imported products. It is one that operates on a 24/7 time  
1424 frame. Because of our limited resources, we haven't been  
1425 able to target the courier services in the way that would  
1426 most benefit them and so actually this is something that I  
1427 think they are very eager to work with us on in order to  
1428 support greater deployment of FDA personnel.

1429 Dr. {Christensen.} So you don't expect that this fee  
1430 would cause hardships for the couriers and importers, do you?

1431 Dr. {Hamburg.} I think it will benefit them because  
1432 they very much are committed to very rapid transit of the  
1433 materials that they are importing and this will enable FDA to  
1434 be able to support their business model in terms of transit  
1435 of products that are safe and low risk.

1436 Dr. {Christensen.} Thank you.

1437 Thank you, Mr. Chairman.

1438 Mr. {Stearns.} I thank the gentlelady. The gentleman  
1439 from California, Mr. Bilbray, is recognized for 5 minutes.

1440 Mr. {Bilbray.} Thank you.

1441 Dr. Hamburg, I appreciate your being here. In the last  
1442 2 years prior to the new majority being here, how has your  
1443 budget been impacted by the new Administration proportionally  
1444 from the previous Administration? Has the budget been  
1445 severely reduced or has it been enhanced to some degree, or  
1446 what is the deal?

1447 Dr. {Hamburg.} Well, actually, beginning in the last  
1448 Administration we began to see some significant increases in  
1449 our budget though over the last few years we had had  
1450 increases in our budget that have been very, very welcome.  
1451 We do have--

1452 Mr. {Bilbray.} Do you have any idea what kind of  
1453 percentages you have seen in the last 24 months?

1454 Dr. {Hamburg.} In the last 24 months?

1455 Mr. {Bilbray.} Since you have been there.

1456 Dr. {Hamburg.} Well, we have had--in the last year, it  
1457 was--you know, it is a little hard to--

1458 Mr. {Bilbray.} But it has been a healthy increase?

1459 Dr. {Hamburg.} We have had significant increases in the  
1460 last couple of years.

1461 Mr. {Bilbray.} Okay. I appreciate that. I want to get  
1462 back to this issue that we have got China demanding that  
1463 research be done in China for drug development for anything  
1464 sold there, so we are going to see a shift there. We will  
1465 see a shift in the emphasis why manufacturing should go to  
1466 China with this basic extortion game going there. You have  
1467 got Europe that is really reducing their review of drugs and  
1468 devices to a point way below basically it looks like much  
1469 more efficient. They are getting more efficient going out.  
1470 So we have got this potential of this big increase of imports  
1471 coming in as we are watching our manufacturing capabilities  
1472 be exported. Are you reflecting that? Are you planning on  
1473 that increase in your inspection at the borders that looks  
1474 which everybody in the industry is saying is basically an  
1475 indication we are seeing across the board?

1476 Dr. {Hamburg.} Let me first address some  
1477 misperceptions. There is a sense that we are much slower  
1478 than Europe, our counterparts there, in reviewing drugs and  
1479 devices. In the drug area, in fact, we went back and looked  
1480 over the last couple of years and the majority of new  
1481 molecular entities, new drugs that both of us approved were  
1482 approved first in the United States. In fact, if you look at  
1483 priority drugs, the number is actually higher.

1484 Mr. {Bilbray.} I would like to see that because the

1485 applications were made here first many times and they were  
1486 basically moved on others because of the perception but the  
1487 fact is that from the data we have, from the data I have  
1488 received basically reflects the fact that even though you had  
1489 major increases--and I think this is an issue about what do  
1490 we do with the money, you know, we are looking at a 28  
1491 percent slowdown of the review of drug processing by FDA at a  
1492 time your budget was expanding. So there are a lot of these  
1493 institutional changes that we have to address, and just  
1494 sending money across over doesn't necessarily guarantee the  
1495 job is going to be done efficiently or--you know, not  
1496 efficiently but basically the mindset of the bureaucracy does  
1497 affect timeline and performance, does it not?

1498       Dr. {Hamburg.} Let me just assure you, we take very  
1499 seriously the timeliness of our reviews, and through the  
1500 user-fee program we actually negotiate with industry about  
1501 timelines for performance.

1502       Mr. {Bilbray.} Doctor, let me just say, we have got  
1503 industry people that we are going to have to testify about  
1504 your operation behind closed screens because they are that  
1505 scared of the process. But in all fairness, at a time when  
1506 you had major expansion of resources to get the job done, the  
1507 numbers that we have got before our committee is that 28  
1508 percent longer period for drugs, a 43 percent extension of

1509 time for devices. That means that just by giving you more  
1510 money doesn't mean the system is going to run more  
1511 efficiently.

1512 Dr. {Hamburg.} I don't know those numbers, and we would  
1513 be delighted to sit down with you and go over the numbers,  
1514 but I think the bottom line is that we need to do better, we  
1515 can do better. We are working with industry--

1516 Mr. {Bilbray.} Related to this issue, that means we  
1517 have a vested interest in safety to try to make the system  
1518 more efficient here as it relates to not just safety and  
1519 efficiency but also the timeline because that timeline  
1520 affects the decision of do you produce it in the United  
1521 States or do you go overseas and then we buy our own  
1522 inefficiency here, our lack of reform here in processing, we  
1523 create a crisis for ourselves to have to review that much  
1524 more coming in to address this issue. And I hope we have  
1525 that kind of commitment by your agency showing that slowing  
1526 down the process is not just an issue that makes it safe for  
1527 the bureaucracy, it something that makes it more risky for  
1528 everybody because it may have unintended consequences such as  
1529 causing us to have to now import more drugs and have to be  
1530 reviewing those.

1531 Dr. {Hamburg.} Well, I understand your concerns and we  
1532 are very committed. We do take the performance timelines

1533 very seriously and we are meeting the majority of our goals.  
1534 I am also systematically reaching out, listening to industry  
1535 and their concerns. I just met yesterday most of the day  
1536 with a group representing both device and pharmaceutical  
1537 industry representatives or former representatives to hear  
1538 more about some of these specific concerns and how we can  
1539 identify areas to work on together to streamline the process,  
1540 to help support the need to move critical products into the  
1541 marketplace.

1542 Mr. {Bilbray.} Okay. I would just like to ask one last  
1543 question. Were you consulted about the potential of the  
1544 device tax that was placed in the bill last year, the  
1545 potential that device tax being an incentive to bootleg  
1546 devices into this country?

1547 Dr. {Hamburg.} I was not.

1548 Mr. {Bilbray.} Okay. Do you have a position on that  
1549 device tax and its impact?

1550 Dr. {Hamburg.} You know, it is a complex issue and it  
1551 is not within our jurisdiction.

1552 Mr. {Bilbray.} I appreciate that.

1553 Mr. Chairman, I think before we do things like device  
1554 taxes, we should be asking regulators about how it is going  
1555 to impact their job. These things are all related, like I  
1556 said. It is holistic. You can't do one without impacting

1557 the other. And I yield back.

1558           Mr. {Stearns.} The gentleman's time is expired. I  
1559 think we will go a second round here. As the chairman, I  
1560 have the prerogative to start but I am going to let Dr.  
1561 Burgess, who has to leave, if he will take and start on our  
1562 side. So Dr. Burgess, you are recognized for 5 minutes.

1563           Dr. {Burgess.} Thank you, Mr. Chairman. And just on  
1564 Mr. Bilbray's point about the devices, I can hardly go  
1565 anywhere and speak to any group without someone pulling me  
1566 aside so I am heartened by the fact that you are hearing some  
1567 of these same things but also his point that people are  
1568 afraid to come forward. When I have someone come and tell me  
1569 their particular tale of woe about what they have developed  
1570 and where they are in the process, and I say would you be  
1571 willing to come to the committee and talk about this, and  
1572 they say no, you know, I don't want to jeopardize whatever  
1573 chance I might have now with the FDA, I wouldn't want to put  
1574 myself out there and jeopardize it. That is an unfortunate  
1575 place for us to be.

1576           And Mr. Bilbray is also correct, the device tax  
1577 essentially zapped the research and development budget for  
1578 many of these small startup companies. Also, in addition to  
1579 your agency's regulations, we also have the comparative  
1580 effectiveness, PCORI, the Patient-Centered Outcomes and

1581 Research Institute, that was funded in the Patient Protection  
1582 and Affordable Care Act. All of these things now interplay  
1583 with the bringing of new drugs and devices to market.  
1584 Witness the controversy that has existed over Provenge and  
1585 Avastin since the first of the year. We have certainly heard  
1586 a lot about Provenge for prostate cancer and the period of  
1587 time that it provides for survival, it is not cost-effective  
1588 to provide it to prostate-cancer patients but I think there  
1589 was recently a relaxation of that ruling, breast cancer with  
1590 Avastin, some of the same considerations.

1591 I also hear people ask me why can we not talk about  
1592 surrogate endpoints. It was very effective in developing the  
1593 drugs that are now useful for treating HIV/AIDS, if  
1594 survivability is the only endpoint that can be used and we  
1595 are not certain how reduction of viral load will affect that  
1596 survivability. In the early days of that, having a surrogate  
1597 endpoint actually allowed those products to move forward with  
1598 a great deal more facility and provide relief to a segment of  
1599 the population that previously had been denied relief.

1600 So these are not just abstract issues that we are  
1601 talking about. They are very real issues. And again, I know  
1602 that because I can't go anywhere in the country without  
1603 someone telling me that, you know, I was delayed 4 years with  
1604 this anti-cancer drug, I am saving 2,500 people a year now so

1605 I have to assume 10,000 died while I was put on hold by a  
1606 regulatory agency. I mean, that is pretty severe when we put  
1607 it in those types of numbers. So I am encouraged that you  
1608 are considering this, but please also understand that we  
1609 don't even have the freedom to bring these folks to  
1610 committee and ask them questions because they are fearful of  
1611 retaliation from the FDA. Surely you have heard that before.

1612 Dr. {Hamburg.} You know, I can assure you that we make  
1613 our decisions based on the best available data, not on, you  
1614 know, other information. They do not need to worry about  
1615 retaliation. I think what we need to focus on together,  
1616 though, is to make sure that our regulatory pathways are as  
1617 well defined and as predictable as possible for sponsors who  
1618 are bringing new candidate products before us. We need to  
1619 make sure that we are able to work with them closely so that  
1620 there is clear understanding of what is expected of them and  
1621 why we need to make sure that we are bringing the best  
1622 possible science to bear in terms of making sure that the  
1623 data that is being collected in support of a product is the  
1624 right data and that, you know, things you just mentioned  
1625 about surrogate endpoints, we do use surrogate endpoints, but  
1626 we need to be undertaking a massive effort working with  
1627 scientists and industry and government to really develop more  
1628 much more innovative clinical trial models that will enable o

1629 us to get the robust scientific answers we need but with  
1630 shorter times, lower costs and fewer patients and other areas  
1631 where we can apply better science to both the drug and  
1632 medical product development and the review.

1633 Dr. {Burgess.} And we can't move the goalpost, which  
1634 again, is a frequent criticism that I am hearing.

1635 Let me just ask you question. I was talking about  
1636 heparin in the first round of questioning and the molecule,  
1637 hypersulfated chondroitin sulfate. Am I correct that that  
1638 was actually patented under a Chinese patent?

1639 Dr. {Hamburg.} I don't know the answer to that.

1640 Dr. {Burgess.} What is the purpose in developing a  
1641 molecule like that? Does it have a use in industry?

1642 Dr. {Hamburg.} I don't know the answer to that. I  
1643 would be happy to get our experts at the agency to provide  
1644 you with additional information.

1645 Dr. {Burgess.} Well, it might be something that is  
1646 useful to know. Again, we are talking about the committee  
1647 developing legislation to prevent these products from coming  
1648 into the country. We kind of need to know what was involved  
1649 and why even develop such a product if it wasn't to cheat  
1650 somebody who is buying heparin.

1651 Thank you. I will yield back, Mr. Chairman.

1652 Mr. {Stearns.} The gentlelady from Colorado is

1653 recognized in the second round for 5 minutes.

1654 Ms. {DeGette.} Thank you very much, Mr. Chairman.

1655 Dr. Hamburg, how many drug approval applications do you  
1656 know offhand does the FDA get in a year? Do you know  
1657 offhand?

1658 Dr. {Hamburg.} Let me see if one of my other experts  
1659 knows. I don't know offhand but that is easy information for  
1660 us to actually get.

1661 Ms. {DeGette.} Well, the reason I am asking the  
1662 question is because I know that the FDA is working on trying  
1663 to streamline the approval process but at the same time  
1664 making sure that the process for each new drug is thorough,  
1665 correct?

1666 Dr. {Hamburg.} Right.

1667 Ms. {DeGette.} If we have a large budget cut to the FDA  
1668 in next year's budget, is that going to help or hurt our  
1669 ability to expedite the drug approval process?

1670 Dr. {Hamburg.} Well, unfortunately, it will clearly  
1671 hinder our ability, and we are talking very large numbers,  
1672 especially if you look at the drug and the device side, and  
1673 as we have been talking about already, the ability to really  
1674 support sponsors in their efforts to bring products before us  
1675 does require--is a resource-intensive, staff-intensive  
1676 activity to be able to provide the best possible and the most

1677 timely review.

1678 Ms. {DeGette.} You know, you can streamline processes,  
1679 and I assume you are doing that, but at some point it does  
1680 take the resources to pay for the staff to review the  
1681 applications and to do what needs to be done. Is that right?

1682 Dr. {Hamburg.} That is correct.

1683 Ms. {DeGette.} A second question I have is, this  
1684 discussion that a lot of folks have been having in this  
1685 hearing about the approval process resulting in a slow and  
1686 more cumbersome process than in the EU, and I hear this a lot  
1687 and I have read it a lot in the media. I am wondering, I  
1688 don't think you got to fully explain what the FDA found when  
1689 they looked at this claim that the EU is much more fast and  
1690 efficient and does a better job. I am wondering if you can  
1691 just finish your answer to that question.

1692 Dr. {Hamburg.} Okay. You know, we did take a very  
1693 serious look at the exact numbers because we were hearing  
1694 more and more questions raised in this area, and what we  
1695 found was very striking. I may get the numbers slightly  
1696 wrong because I didn't review them before coming to this  
1697 hearing. I was more focused on the import safety issues.  
1698 But I believe that between 2006 and 2010, there were about 53  
1699 or 54 new molecular entities that were approved by both the  
1700 EU and the U.S. and that we were in fact significantly more

1701 rapid in approving those drugs in well over 50 percent, I  
1702 think it was 43 or so of those products. If you actually  
1703 look at cancer drugs, and the time frame that we looked at  
1704 that was a little different, I think it was 2003 to 2010, but  
1705 there were 23 new cancer drugs that were approved by both  
1706 entities and that we were first in approving those.

1707         So there clearly is a misperception that we are slower  
1708 than our counterparts in the European Union, and for the  
1709 priority drugs we were almost twice as fast in approving  
1710 these drugs.

1711         Ms. {DeGette.} Was this a study that you did?

1712         Dr. {Hamburg.} It was a systematic review. I mean, I  
1713 fear I probably should not have even tried to give numbers--

1714         Ms. {DeGette.} If you could supplement your testimony  
1715 with that today, that would be great.

1716         Dr. {Hamburg.} Okay.

1717         Ms. {DeGette.} And I just have a couple more questions.  
1718 One is, we have been talking about this terrible adulterated  
1719 heparin so I guess my view would be, under this Drug Safety  
1720 Enhancement Act which Mr. Dingell and some of us introduced  
1721 yesterday, would that give the FDA new authorities to address  
1722 issues like intentional economic adulteration like in the  
1723 heparin situation?

1724         Dr. {Hamburg.} I think it could very well give us

1725 important authorities that would make a difference,  
1726 additional authorities to really pursue investigations in  
1727 places outside of our borders when there are public health  
1728 concerns, our ability to share information with counterpart  
1729 regulatory authorities so that we can get a richer  
1730 understanding of potential or emerging threats. Those would  
1731 certainly make a difference, and I think that enhanced civil  
1732 and criminal penalties could reduce the attractiveness of  
1733 pursuing some of these kinds of nefarious activities as well.

1734 Ms. {DeGette.} Thank you, Mr. Chairman.

1735 Dr. {Hamburg.} Thank you.

1736 Dr. Hamburg, I am just sort of curious about these 150  
1737 countries that import food and drugs to us. If you don't  
1738 mind, if you could send us a list of those countries, that  
1739 would be helpful.

1740 Dr. {Hamburg.} Okay.

1741 Ms. {Stearns.} Just going to your website and pulling  
1742 up the website, I noticed that just for this year it lists  
1743 countries that there have been alerts on. For example,  
1744 Bangladesh had 10 alerts, Cambodia had one. Indonesia, there  
1745 are 27 alerts. The Ivory Coast, considering what is going on  
1746 there, had three, Nicaragua had nine, Thailand had 47 and  
1747 Zimbabwe had one. Do you have the authority to stop all when  
1748 there is, shall we say, huge turmoil, war, a revolution,

1749 civil war that is going on over there? Do you stop imports  
1750 from those countries considering the danger coming?

1751 Dr. {Hamburg.} Well, our import alerts are based on  
1752 public health risks but certainly they are targeted to events  
1753 in the world.

1754 Mr. {Stearns.} Do you have the authority to stop, for  
1755 example, from Thailand where there is unrest and they had 47  
1756 alerts? Isn't that enough to say you are going to stop  
1757 altogether?

1758 Dr. {Hamburg.} Well, I think an important and timely  
1759 example is--

1760 Mr. {Stearns.} Do you have the authority to do that?

1761 Dr. {Hamburg.} We do an import alert based on--

1762 Mr. {Stearns.} Just yes or no.

1763 Dr. {Hamburg.} --a public health threat.

1764 Mr. {Stearns.} I would just like to know, yes or no, do  
1765 you have the authority to stop--for example, the Ivory Coast  
1766 had three alerts this year. Do you have the authority to  
1767 stop all imports from them?

1768 Dr. {Hamburg.} No, we would have to be able to show  
1769 that there was reason to believe that a product or set of  
1770 products was violative.

1771 Mr. {Stearns.} But if you had an alert in Ivory Coast  
1772 of three and Indonesia of 27, isn't that enough to suddenly--

1773 especially if there is a civil war?

1774 Dr. {Hamburg.} I know that for particular products  
1775 where there are concerns--

1776 Mr. {Stearns.} So you don't have the authority? You  
1777 have to identify the risk in detail before you do that.  
1778 Otherwise you don't have the authority.

1779 Dr. {Hamburg.} Right. We don't do blanket restrictions  
1780 based on circumstances within a country.

1781 Mr. {Stearns.} Okay. Mr. Bilbray had talked a little  
1782 bit about the budget, and I mentioned it earlier, that your  
1783 budget went up by \$107 million. Did you know that?

1784 Dr. {Hamburg.} We have, as I said, had, you know, very  
1785 significant increases in our budget in the last couple of  
1786 years. It has made a difference. I think it is important to  
1787 recognize, though, that we have been underresourced for  
1788 literally decades.

1789 Mr. {Stearns.} But you understand the budget has gone  
1790 up for this fiscal year?

1791 Dr. {Hamburg.} I do, and I have been appreciative of  
1792 that.

1793 Mr. {Stearns.} But as I understand, when you were  
1794 talking to Mr. Bilbray, you weren't sure clearly what the  
1795 percent the budget has gone up and you weren't really clear  
1796 what your budget number is. Is that correct, that you

1797 weren't quite clear on that?

1798 Dr. {Hamburg.} You know, this has been an unusual  
1799 budget period. He was asking me what the budget increase was  
1800 in the last, did he say 24 months?

1801 Mr. {Stearns.} Yes.

1802 Dr. {Hamburg.} But, you know, we certainly do have that  
1803 information.

1804 Mr. {Stearns.} So you don't really know your budget  
1805 numbers at this point. You don't know what they have gone  
1806 up. Is that correct?

1807 Dr. {Hamburg.} Well, we are still looking forward to  
1808 learning our budget numbers for this year.

1809 Mr. {Stearns.} Okay. We have a chart here that has  
1810 come from you folks, fiscal year 2010 ORA fieldwork plan. I  
1811 just want to show you this, and staff has given it to you.  
1812 If you go down to the fifth line, I know President Obama has  
1813 talked about food safety being one of his top priorities, and  
1814 he has indicated that it is very important for the  
1815 Administration, yet when you look at import foods in general  
1816 on this line and the work plan for FTEs, which I understand  
1817 FTEs are basically the federal time equivalents, which are  
1818 not people but are just block outs. It appears to me that in  
1819 2009 to 2010, 2009 was the Bush Administration and 2010 was  
1820 the Obama Administration, it actually has gone down in terms

1821 of the work power that has actually been extended and  
1822 enforced on import foods. Is that correct? It is a little  
1823 surprising considering the priorities in particular which you  
1824 have talked about, to think that the man-hours actually in  
1825 this area have gone down, and I just want you to explain, why  
1826 has it gone down?

1827 Dr. {Hamburg.} I am going to let my colleague, Mr.  
1828 Elder, respond. This is a very specific question of a line.  
1829 It is less than one full-time equivalent person.

1830 Mr. {Stearns.} But at the same time--

1831 Dr. {Hamburg.} But I will let him--

1832 Mr. {Stearns.} You know, the imports have increased so  
1833 the figure it not to say that--but the point is, with the  
1834 increase of the imports and yet your manpower has gone down  
1835 on this is just a little puzzling.

1836 Yes, Mr. Elder, you are welcome to take the mic. Is it  
1837 turned on?

1838 Mr. {Elder.} I believe it is, Mr. Chairman. Thank you.  
1839 The highlighted decrease involves one particular program  
1840 within our overall foods program. It is what we call program  
1841 assignment code 03819 A and B. It is import foods in  
1842 general. It does reflect a 0.7 FTE decrease from the  
1843 previous year. It is not the only program, however, in which  
1844 we cover imported foods. You can see that imported seafood

1845 products were raised by 7 FTEs in the fiscal year. There was  
1846 an overall increase of 61 FTEs--

1847 Mr. {Stearns.} But Mr. Elder, you would agree that that  
1848 is the biggest program you have. When you look at all the  
1849 other figures, it is multiples of all the other programs. So  
1850 I think you are sort of discounting a program in which it is  
1851 the top program, and to see the top program actually in man-  
1852 hours go down in terms of the FDA's work plan is quite  
1853 startling.

1854 Dr. {Hamburg.} I think that Mr. Elder was indicating,  
1855 though, that this is just one component of our overall import  
1856 safety program for foods and that that program has actually  
1857 expanded.

1858 Mr. {Stearns.} But wouldn't you agree, Dr. Hamburg,  
1859 that all these things should have a positive, they should not  
1860 have a negative?

1861 Dr. {Hamburg.} Well, I think we want to make sure that  
1862 we are deploying our resources in the most responsible and  
1863 efficient way possible. I don't--

1864 Mr. {Stearns.} But I would think import foods is one of  
1865 your most highest priorities.

1866 Dr. {Hamburg.} But I think we also need to look at the  
1867 overall program and how individuals are being deployed, and  
1868 this does not mean that the overall food import program has

1869 decreased. In fact, it has increased in terms of--

1870 Mr. {Stearns.} Well, I would say that your workplace  
1871 changes that you showed does not show an increase, rather, it  
1872 shows a decrease.

1873 So my time is expired. The gentleman from Michigan is  
1874 recognized for 5 minutes.

1875 Mr. {Dingell.} Mr. Chairman, I thank you for your  
1876 courtesy.

1877 Dr. Hamburg, you have in response to a question from Ms.  
1878 DeGette said that review times in United States and Europe  
1879 vary and that FDA is faster in reviewing drugs. We have also  
1880 been hearing that Europe is 2 years faster in clearing  
1881 devices than our FDA. Is that statement true, and if so,  
1882 why?

1883 Dr. {Hamburg.} You know, first of all, it is not a  
1884 competition and we obviously have different regulatory  
1885 frameworks, but when you look at the numbers in both drugs  
1886 and devices, the lag times are not what have been put  
1887 forward. In fact, in the drug area, as I said, in key areas  
1888 we clearly have approved critical products more swiftly. The  
1889 device system in Europe is quite different than that here but  
1890 we are not--

1891 Mr. {Dingell.} It is a difference in what is done over  
1892 there as opposed to--

1893 Dr. {Hamburg.} They have a very different approach to  
1894 device review, and it is also--

1895 Mr. {Dingell.} Would you submit to us a statement as to  
1896 why that is so, please, for the record?

1897 Dr. {Hamburg.} We would be happy to, the numbers that  
1898 are available about comparative times.

1899 Mr. {Dingell.} Thank you, Doctor. I want to get now to  
1900 some other things. I would like to come back to the new  
1901 authorities given FDA in the Food Safety Modernization Act  
1902 and how they are going to make the food supply and imported  
1903 food safer. Is that statute working and do you have the  
1904 authorities now you need? Do you need new authorities or do  
1905 you need more money?

1906 Dr. {Hamburg.} We are obviously very early in the  
1907 implementation of this historic piece of legislation but we  
1908 are making good progress and we can see that it will very  
1909 significantly strengthen our ability to protect the safety of  
1910 the food supply to be able to really shift to a preventive  
1911 approach and to work in greater partnership with our State  
1912 and local partners, with foreign governments and with  
1913 industry. Clearly, in terms of being able to implement all  
1914 of the requirements, and there are many in that Food Safety  
1915 Modernization Act, you know, we again face the resource  
1916 limitation issue and we are hoping to be able to work

1917 Congress on--

1918           Mr. {Dingell.} Let me interrupt you. I remember,  
1919 Doctor, that when one of your predecessors, Frank Young, for  
1920 whom I had great respect and still do, used to call me up and  
1921 say John, we are going to move this situation forward, we are  
1922 doing a real fine job and we have a great new plan and we are  
1923 going to do this without new money. And I said Frank, that  
1924 is a lot of hooley. And a couple days later he would call me  
1925 up and say well, John, we just can't do it because we don't  
1926 have the money for this, and this brings us back to the  
1927 question of registration fees.

1928           The House bill as it came out of this committee had  
1929 registration fees in it with the support of the industry,  
1930 which still supports that idea. It was taken out in the  
1931 Senate. So user fees in that regard both with regard to food  
1932 and with regard to pharmaceuticals would ease your financial  
1933 stresses and strains, would it not?

1934           Dr. {Hamburg.} We clearly cannot fully implement this  
1935 bill without additional resources.

1936           Mr. {Dingell.} The other thing I remember that is very  
1937 troublesome to me is, we had a movie before this subcommittee  
1938 one time when I was the chairman and it showed a bunch of  
1939 stuff coming into this country, mostly pharmaceuticals and  
1940 things of that kind, and most of these pharmaceuticals were

1941 unsafe, misbranded, counterfeit, and some of them, believe it  
1942 or not, were controlled substances, and they were just coming  
1943 in through the mails. Everybody was sort of waving them as  
1944 they went by. And I see you confronting the same problem,  
1945 and I would be willing to bet if somebody were to put movies  
1946 down there at some of the points where these things are  
1947 imported, we would find the same situation is going on. Now,  
1948 this situation happened to relate to the center at Miami  
1949 where they would come in, and so I think that something here  
1950 has to be done.

1951           Mr. Chairman, I just want you to know that I appreciate  
1952 your holding this hearing. It my hope that we can work in a  
1953 bipartisan fashion with us all working together as we have  
1954 done in the past. It makes great good sense. It is  
1955 something that the public needs. Americans are being killed  
1956 either by bad stuff coming into this country that poisons  
1957 them or makes them sick or they are being killed by being  
1958 denied workable and worthwhile treatments and pharmaceuticals  
1959 because people are sending in things like chalk and sugar as  
1960 part of the medicines that we are receiving.

1961           So I want to commend you and thank you for the hearing  
1962 and hope that as we go forward that we will be able to use  
1963 this hearing as the beginning of an honest effort to work  
1964 together to do something that we can do by working together,

1965 and I think it is a lot better than quibbling about whether  
1966 we have got Democratic or Republican witnesses because that  
1967 is not really important. I will be happy to take credit for  
1968 the presence of Dr. Hamburg, and I am sure you would too, and  
1969 not to quibble about whether she is a Republican or a  
1970 Democratic witness.

1971 So I commend you, Mr. Chairman, for your leadership in  
1972 this matter and I thank you for your recognizing me, and I  
1973 again appreciate the opportunity to start moving on something  
1974 that is in the public interest.

1975 Mr. {Stearns.} I thank the distinguished chairman  
1976 emeritus of the Energy and Commerce Committee and I  
1977 appreciate his past leadership and his spirit of  
1978 bipartisanship, that he continues to reach out, and I think  
1979 it is a good example for all of us to remember in this  
1980 process.

1981 Dr. Hamburg, I want to thank you very much for your  
1982 forbearance and patience for this hearing.

1983 All members have 10 days in which to submit any  
1984 extraneous material they would like to, and with that, the  
1985 subcommittee is adjourned.

1986 [Whereupon, at 12:26 p.m., the Subcommittee was  
1987 adjourned.]