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4 COUNTERFEIT DRUGS: FIGHTING ILLEGAL SUPPLY CHAINS

5 THURSDAY, FEBRUARY 27, 2014

6 House of Representatives,

7 Subcommittee on Oversight and Investigations

8 Committee on Energy and Commerce

9 Washington, D.C.

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

13 Members present: Representatives Murphy, Burgess,
14 Blackburn, Griffith, Johnson, Long, Elmers, DeGette, Braley,
15 Tonko, Dingell, and Waxman (ex officio).

16 Staff present: Karen Christian, Chief Counsel,

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17 Oversight; Noelle Clemente, Press Secretary; Brad Grantz,
18 Policy Coordinator, Oversight and Investigations; Brittany
19 Havens, Legislative Clerk; Sean Hayes, Counsel, Oversight and
20 Investigations; Alan Slobodin, Deputy Chief Counsel,
21 Oversight; Tom Wilbur, Digital Media Advisor; Jessica
22 Wilkerson, Legislative Clerk; Brian Cohen, Democratic Staff
23 Director, Oversight and Investigations, and Senior Policy
24 Advisor; Eric Flamm, Democratic FDA Detailee; Kiren Gopal,
25 Democratic Counsel; Hannah Green, Democratic Staff Assistant;
26 and Stephen Salsbury, Democratic Investigator.

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|
27 Mr. {Murphy.} Good morning, and welcome to the
28 Oversight and Investigations Subcommittee hearing of Energy
29 and Commerce titled ``Counterfeit Drugs: Fighting Illegal
30 Supply Chains.''

31 The hearing could also be titled ``Poison Pills in Your
32 Medicine Cabinet, or Counterfeiters Deliver Deadly Drugs,''
33 and it is to the fact that we need to examine the growing
34 problem of counterfeit drugs in our country.

35 Last year Congress took an important first step against
36 this threat by enacting the new track-and-trace law known as
37 the Drug Quality and Security Act of 2013. This new law will
38 secure the legitimate distribution channels, and when
39 implemented will solve the legal supply chain part of the
40 counterfeit drug problem.

41 However, many Americans purchase medicines through
42 illegal supply chains, such as rogue Internet pharmacies and
43 other black markets. It is that part of the counterfeit drug
44 threat that we address today. This hearing focuses on the
45 illegal supply chains of counterfeit drugs, and on efforts to
46 deter and disrupt these illegal supply chains.

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47 The legitimate U.S. drug supply is safe. But
48 counterfeit drugs from illegal sources are a significant and
49 growing global public health threat, potentially causing
50 treatment failure or death and contributing to increased
51 antimicrobial resistance. The policy of the U.S. government
52 is not to wait for a full-blown crisis before taking
53 appropriate action.

54 Drug counterfeiters do not just steal intellectual
55 property. They recklessly and intentionally endanger human
56 lives. They sell counterfeits that do not contain active
57 ingredients and provide no treatment benefit to the patient.
58 Thus, a child suffering from malaria who takes a fake
59 anti-malaria drug might die within 48 hours because the
60 malaria remains untreated. The counterfeiters sell fakes
61 that may contain incorrect ingredients, improper dosages,
62 hazardous or poisonous ingredients. For example, an
63 emergency room doctor from Texas in 2011 took a counterfeit
64 weight loss drug he bought from an online pharmacy. The drug
65 was contaminated with a controlled substance and he suffered
66 a stroke.

67 The counterfeiters sell drugs with risks for harmful

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68 side effects or allergic reactions. For example, in 2007 and
69 2008, dozens of heart surgery and kidney dialysis patients in
70 the United States suffered unexpected allergic-like reactions
71 and several lost their lives due to intentionally
72 contaminated heparin imported from China that had entered the
73 Chinese heparin supply purporting to be pure heparin.

74 The counterfeiters do not care about the patients who
75 are hurt. One counterfeiter, Richard Taylor, was notified in
76 May 2011 that two patients who had been on a counterfeit
77 cancer drug he had distributed had started to shake in the
78 middle of being transfused and had to be disconnected from
79 treatment.

80 However, the penalties for drug counterfeiters under the
81 Federal Food Drug and Cosmetic Act have not been updated
82 since 1938. As the FDA Commissioner has said, there is a
83 steeper penalty for counterfeiting a designer purse under the
84 Federal Criminal Code than a drug product under current FDA
85 law.

86 Drug counterfeiting is highly profitable, and the
87 criminals only face the maximum penalties under the FDA law
88 of \$10,000 or 3 years in prison. In contrast, penalties for

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89 trafficking narcotics can have prison sentences up to life
90 and fines in the millions of dollars. There is one estimate
91 that the return on counterfeit drugs may be 10 times greater
92 than that of the sale of illegal narcotics.

93 Now, experts tell us the counterfeit drug problem has
94 worsened over the last decade, and the reasons for this
95 disturbing trend include increasing opportunities created
96 by larger, more complex supply chains; more customers
97 reachable through the Internet; more cases where the
98 counterfeiting crimes occur in several countries making
99 enforcement more difficult; and the expansion of
100 counterfeiting from so-called lifestyle drugs into
101 therapeutic medicines used to treat cancer, heart disease
102 or other illnesses.

103 The illegal supply chains are numerous and global.
104 Rogue Internet pharmacies are now proliferating. There
105 are believed to be about 35,000 to 50,000 active online
106 sellers, 97 percent of which do not comply with U.S. laws,
107 according to one review of over 10,000 Internet sites.
108 One report estimated that one in six Americans--36
109 million people--have bought medicines online without a

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110 valid prescription. These illegal pharmacy operations
111 are big business, with the largest ones reportedly making
112 \$1 to 2.5 million of sales each month.

113 The sheer volume of imported drugs into the United
114 States is overwhelming and opportunities have never been
115 greater for foreign, unapproved drugs to get into the
116 United States. Nearly 40 percent of drugs taken by
117 Americans are made overseas, and 80 percent of the active
118 ingredients are imported from about 3,800 foreign
119 manufacturers, in more than 150 countries. According to
120 a 2011 FDA report, the number of foreign drug suppliers
121 has doubled in the last 7 years. The Government
122 Accountability Office has found FDA is only able to
123 inspect foreign drug plants every 9 years while FDA
124 inspects domestic drug manufacturers every 2 years.

125 The subcommittee will also examine other illegal
126 supply chains such as medical clinics and doctors who
127 purchase drugs from illegal sources, business-to-business
128 networks, and smugglers bringing unapproved or
129 counterfeit drugs from Mexico into the United States.

130 I welcome all of today's outstanding witnesses and I

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131 look forward to your testimony.

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

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

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|

134 Mr. {Murphy.} And now I turn to recognize my friend
135 Ranking Member, Ms. DeGette, of Colorado.

136 Ms. {DeGette.} Thank you very much, Mr. Chairman. I
137 really appreciate you having this hearing.

138 We had a number of hearings some years ago in this
139 committee on drug counterfeiting, and it was shocking and
140 appalling to see how serious this problem is. While we did
141 pass that great bill last year, still I think that drug
142 counterfeiting is a terrible problem that we need to address
143 in a bipartisan fashion.

144 As you said, counterfeit drugs can contain dangerous
145 impurities, incorrect ingredients, improper doses, and also
146 have improper handling, and legitimate drugs have been
147 diverted or stolen from the supply chain and they have been
148 handled improperly or stored at the wrong temperature, and
149 then of course, these fraudsters spend a lot of time
150 recreating labels and packaging for the dangerous drug so
151 that they look exactly like the real thing.

152 I got some samples today. These are Lipitor samples,
153 and they look exactly the same. The blister packs are the

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154 same, the pills are exactly the same, the alleged doses are
155 exactly the same, and if you ordered these online, you would
156 think that you were getting Lipitor. However, which one is
157 the real and which one is the fake? You couldn't possibly
158 tell except where there is a label on the package. Here is
159 the fake and here is the real. And this is what these
160 counterfeiters do. They spend more time worrying about what
161 the packaging is going to like look so it will fool the
162 consumer and a lot less time worrying about whether there's
163 actual medication inside that's going to help people.

164 We have seen a number of troubling cases recently.
165 Criminals have tampered with pharmaceuticals used to treat
166 illnesses like cancer and HIV/AIDS. Drugs used to treat
167 schizophrenia were replaced with aspirin. Counterfeit cancer
168 drugs were tainted with non-sterile tap water, and
169 counterfeit AIDS drugs have been found to lack any
170 ingredients, and as you said, the Internet is really
171 especially problematic for these unsafe drugs, and according
172 to a recent FDA survey, approximately one in four Americans
173 has purchased prescription drugs online. Most consumers
174 purchase drugs from reputable businesses but there are

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175 thousands of rogue Internet pharmacies, some of which you
176 couldn't tell from just looking onsite that sell drugs of
177 dubious quality without a prescription. I couldn't believe
178 it that you said that there was a doctor who bought these
179 drugs online. I mean, surely if anybody should know, it
180 should be a doctor.

181 Now, Congress passed the Ryan Haight Act in 2008 and
182 then last year, as you said, the Drug Quality and Security
183 Act, which provide additional enforcement tools, and so I am
184 eager to hear from the GAO whether these laws have had an
185 impact in combating this problem and what more can be done.
186 I am also interested to learn from the stakeholders and
187 agencies how we can increase awareness and education in the
188 medical community and the public more broadly about the
189 prevalence of and risks associated with counterfeit drugs.

190 I must say, I talked to my constituents, and people
191 assume if they are buying drugs from a pharmacy online that
192 it would be safe, and that is an incorrect assumption to
193 make. I think we need to have partnerships between the
194 pharmaceutical companies, between government agencies,
195 between nonprofit agencies and a variety of sources to let

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196 people know how dangerous it can be to buy drugs from an
197 Internet source.

198 And I want to commend the FDA, ICE and the other federal
199 agencies for their work in protecting consumers from unsafe
200 drugs, but I also want to learn more about what we can do
201 about counterfeiting drug activity and whether we need more
202 authorities or stricter penalties to effectively carry out
203 this work.

204 Globally, the FDA works with World Health Organization
205 and Interpol to build global capacity to monitor counterfeit
206 drugs and to coordinate international law enforcement action,
207 and so I know that our witness from the University of
208 Michigan, Dr. Yadav, will talk about the global health
209 implications of counterfeit drug activity and how existing
210 international efforts can be strengthened. Prosecuting these
211 wrongdoers is difficult because they are shady and they are
212 international, but I think if we have domestic and
213 international partnerships, we can do it.

214 Consumers should never have to fear the prescription
215 drug they need may actually make them sick or endanger the
216 lives of their loved ones, and so that is why these

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217 partnerships are critical. I look forward to hearing from
218 our witnesses and continuing to work together to make sure
219 that when a consumer buys a drug, they know that it is going
220 to be safe.

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

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

223 ***** COMMITTEE INSERT *****

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|
224 Mr. {Murphy.} The gentlelady yields back and I now
225 recognize the vice chairman of the committee, Dr. Burgess,
226 for 5 minutes.

227 Dr. {Burgess.} I thank the chairman for the
228 recognition. I thank our witnesses for being here, a
229 terribly important hearing that we are having this morning.

230 Let me begin my statement with a quote: ``The market
231 for prescription drugs has been the catalyst for a continuing
232 series of frauds against American manufacturers and has
233 provided cover for counterfeit drugs. The effect of these
234 practices and conditions is to create an unacceptable risk
235 that counterfeit, adulterated, misbranded, subpotent or
236 expired drugs will be sold to American consumers.''

237 Now, you might think I am reading from today's hearing
238 memo but in fact they were from the findings of the
239 Prescription Drug Marketing Act of 1987. That bipartisan law
240 was the result of a series of hearings conducted with
241 Chairman Dingell in this very subcommittee. In the report
242 accompanying the bill from 1987, this subcommittee found,
243 again quoting, ``American consumers cannot purchase

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244 prescription drugs with the certainty that the products are
245 safe and effective. This is not to say that the shelves of
246 the Nation's pharmacies are lined with substandard products
247 or that there are inadequate controls in the manufacturing
248 process. Rather, the integrity of the distribution system is
249 insufficient to prevent the introduction and the eventual
250 retail sale of substandard, ineffective or even counterfeit
251 pharmaceuticals," again, quoting from the findings in 1987.

252 The United States has the best drug supply chain in the
253 world, and this committee's work has been long and notable
254 and medications have become more advanced. Our supply chain
255 has become more global in its reach. The equally consistent
256 and sophisticated attacks each and every day by
257 counterfeiters, rogue distributors and those willing to
258 adulterate products and put patients at risk are no less
259 today than they were in 1987.

260 According to the World Health Organization, in 2010
261 worldwide counterfeit medicine sales topped \$75 billion.
262 That was almost doubling in 5 years, and some speculate the
263 number will continue to grow by 20 percent each year.

264 At its most extreme, these criminals are willing to

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265 literally risk patients' lives to sell counterfeits. As a
266 doctor, such immorality of knowingly sentencing a patient to
267 death by either denying them treatment or selling them an
268 adulterated product, that is an absolutely chilling
269 proposition. In my opinion, punishment for counterfeiting
270 prescription medications is so far from adequate as to be
271 laughable.

272 From fake flu vaccines to oncology drugs, counterfeit
273 medications have been able to enter the supply chain and in
274 fact administered to patients. Detecting counterfeit drugs
275 is difficult, if not impossible. There is no field test that
276 we can send people out to perform to indicate whether a drug
277 is fake or real, and even the trained experts are often
278 unable to detect whether a drug is what it purports to be.
279 Counterfeit and other adulterated drugs present an
280 unreasonable risk to Americans.

281 Thankfully, this committee, this subcommittee has
282 remained vigilant, and I believe the passage of the Drug
283 Quality and Security Act last year will provide a valuable
284 tool. Some will argue it took too long but nevertheless, it
285 does tighten our distribution system. While our system may

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286 be the best in the world, our health care workforce does not
287 have the confidence that they should have that the drugs they
288 are dispensing or administering are the ones that came from
289 the manufacturer.

290 I will also note that a December 2005 report found that
291 nearly half of the imported drugs the Food and Drug
292 Administration intercepted from four selected countries to
293 fill orders placed with firms that consumers thought were
294 Canadian, in fact, 85 percent came from 27 other countries
295 around the globe. A number of these products were also found
296 to be counterfeit.

297 Just as a practical matter, I will never forget the day
298 in my practice back in north Texas when the story broke that
299 fake oral contraceptives had been introduced into the market.
300 Our phones melted down that morning, and many anxious
301 patients spent many anxious hours trying to determine if they
302 had the pill or the lot number from the inappropriate
303 counterfeit pills and whether or not they would have the
304 potency to provide the protection they were purported to
305 provide.

306 Maintaining the integrity of the United States

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307 prescription drug supply is a compelling national priority
308 and requires national solutions involving business, health
309 care providers and governments coming together and being
310 vigilant in the face of threats. The vigilance of this
311 committee, this subcommittee, has been established in the
312 past and continues today.

313 I thank the chairman for the recognition. I will yield
314 back the balance of my time.

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

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

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|
317 Mr. {Murphy.} The gentleman yields back. I now
318 recognize the ranking member of the full committee, Mr.
319 Waxman, for 5 minutes.

320 Mr. {Waxman.} Thank you very much, Mr. Chairman. I am
321 pleased that we are having an important oversight hearing
322 where the 20 minutes so far into the opening statement, no
323 one has blamed the problem on President Obama. This is rare
324 for this committee.

325 But we are doing the job that we should be doing because
326 the entry of counterfeit drugs into our drug supply chain
327 poses a great public health threat. Time and again, we have
328 read stories about patients getting drugs from Internet
329 pharmacies or even their doctors or local pharmacies that
330 were unsafe or ineffective counterfeit, stolen or not stored
331 properly so they no longer worked.

332 We have taken legislative steps on a bipartisan basis to
333 address this problem. In 2012, we passed the bipartisan Food
334 and Drug Administration Drug Safety and Innovation Act. The
335 law requires companies to notify FDA of drug thefts and
336 counterfeit or adulterated drugs that could cause serious

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337 harm. It requires manufacturers and importers to register
338 annually with the FDA and provide unique facility identifiers
339 so that FDA knows who and where they are. It bans imports of
340 drugs from foreign facilities that delay, deny or limit FDA
341 inspection, and it enhances criminal penalties for
342 intentionally counterfeiting or adulterating a drug in a way
343 that could cause severe adverse health consequences.

344 Last year, we passed the bipartisan Drug Quality and
345 Security Act. This law gives the FDA an industry of new
346 tools to deter, discover and remedy the entry of illegal
347 drugs into the supply chain. However, the legislation was
348 not designed for sophisticated criminal enterprises intent on
349 evading the law and the most useful of the new tools, an
350 electronic unit-level tracking and tracing system is not
351 required to be in place until 2023. So it is hard to reach a
352 conclusion other than more needs to be done.

353 Today the government has to prove an intent to violate
354 the law before it can even win a criminal case, and even
355 then, the maximum penalty for some violations with
356 potentially life-threatening consequences is only 3 years.
357 We need a stronger deterrent.

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358 We also need to consider what to do about the fact that
359 so many of our drugs are sourced from abroad. This can
360 create serious drug safety and security issues. In India,
361 where FDA inspections have tripled since FDASIA, FDA is
362 finding serious lapses in quality. And as the New York Times
363 reported recently, even India's top drug regulator concedes
364 that most of the drug facilities supplying the domestic
365 Indian market do not meet FDA standards. This is a serious
366 problem because India is the second largest exporter of drugs
367 to the U.S., supplying 40 percent of our generic and over-
368 the-counter drugs.

369 In China, the U.S. government had to negotiate for
370 almost a full year just to get visas for the additional
371 inspectors that FDA needs to conduct more frequent and timely
372 inspections. It could put much of our drug supply at risk
373 because the crucial ingredients for nearly all antibiotics,
374 steroids and many other lifesaving drugs are now made
375 exclusively in China.

376 Well, Mr. Chairman, I look forward to hearing from our
377 witnesses today, and I thank you for holding this important
378 hearing. It is appropriate, it is legitimate, it is what

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379 oversight committees should be doing, and I hope it is the
380 first step towards passing legislation that will effectively
381 deter and punish those who put Americans' health at risk with
382 counterfeit pharmaceuticals.

383 And I want to say in my closing minute, Mr. Chairman,
384 unfortunately, there is another subcommittee meeting at the
385 same time so I will be in and out of this hearing. I will
386 review the testimony of the witnesses that will be making a
387 presentation. Thank you.

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

389 ***** COMMITTEE INSERT *****

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|
390 Mr. {Murphy.} Thank you. Mr. Waxman yields back.

391 I would now like to introduce our witnesses on the first
392 panel for today's hearing. We do have two panels of
393 distinguished people. First, Mr. Howard Sklamberg is the
394 Deputy Commissioner for Global Regulatory Operations and
395 Policy for the Food and Drug Administration. I would like to
396 note that due to the amount of exhibits the FDA would like to
397 show in support of the testimony, both sides agree to allow
398 Mr. Sklamberg 10 minutes for his oral testimony instead of
399 the usual 5.

400 And Mr. Lev Kubiak, welcome, the Director of the
401 National Intellectual Property Rights Coordination Center for
402 the Department of Homeland Security's Immigration and Customs
403 Enforcement.

404 I will now swear in the witnesses. You are aware that
405 the committee is holding an investigative hearing, and when
406 doing so has had the practice of taking testimony under oath.
407 Do either of you object to testifying under oath? The Chair
408 then advises you that under the rules of the House and the
409 rules of the committee, you are entitled to be advised by

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410 counsel. Do either of you desire to be advised by counsel
411 during the testimony today? In that case, would you please
412 rise and raise your right hand, and I will swear you in.

413 [Witnesses sworn.]

414 Mr. {Murphy.} You are now under oath and subject to the
415 penalties set forth in Title XVIII, section 1001 of the
416 United States Code.

417 Mr. Sklamberg, you may now give your opening statement
418 and video.

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419 ^TESTIMONY OF HOWARD SKLAMBERG, J.D., DEPUTY COMMISSIONER FOR
420 GLOBAL REGULATORY OPERATIONS AND POLICY, FOOD AND DRUG
421 ADMINISTRATION (FDA); AND LEV KUBIAK, DIRECTOR, NATIONAL
422 INTELLECTUAL PROPERTY RIGHTS COORDINATION CENTER, DEPARTMENT
423 OF HOMELAND SECURITY, IMMIGRATION AND CUSTOMS ENFORCEMENT
424 (ICE)

|
425 ^TESTIMONY OF HOWARD SKLAMBERG

426 } Mr. {Sklamberg.} Thank you very much, Mr. Chairman,
427 Ranking Member DeGette and members of the subcommittee. I am
428 Howard Sklamberg, Deputy Commissioner for Global Regulatory
429 Operations and Policy at the Food and Drug Administration,
430 and thank you for this opportunity to be here today to
431 discuss the important issue of counterfeit drugs.
432 Counterfeit drugs raise significant public health
433 concerns. A counterfeit drug could be made using ingredients
434 that are toxic to patients and processed under poorly
435 controlled and unsanitary conditions. In the United States,
436 a relatively comprehensive system of laws, regulations and

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437 enforcement by federal and State authorities has kept drug
438 counterfeiting incidents in the United States relatively
439 rare. FDA continues to believe and works to ensure that
440 Americans can have a high degree of confidence in the drugs
441 they obtain through legal channels. Nonetheless, with the
442 dramatic increase in the complexity of the global supply
443 chain, we face enormous challenges regarding supply chain
444 security.

445 FDA is not alone in its effort to address the problem of
446 counterfeit drugs, and I want to note the efforts of my
447 colleagues on this panel and on the other panels in their
448 work on this problem as well.

449 Growth in counterfeiting may be spurred by several
450 things including the increasing volume of drugs, longer
451 supply chains, the development of technologies that make it
452 easier to counterfeit drugs, and the involvement of
453 international organized crime. This growth also is
454 exacerbated by the relatively low criminal penalties for
455 distribution of adulterated, unapproved or misbranded drugs
456 under the Federal Food, Drug and Cosmetic Act compared to
457 other types of crime.

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458 In addition, the Internet presents another layer of
459 complexity by introducing more players and more opportunities
460 for criminals to reach consumers. The global anonymity of
461 the Internet can provide a safe haven for illicit
462 prescription drug sales. Many Web sites leave unsuspecting
463 customers in the United States to believe the dispensing
464 pharmacy is in the United States or Canada.

465 FDA has made it a priority to investigate reports of
466 counterfeit products. As part of these efforts, FDA's Office
467 of Criminal Investigations, or OCI, aggressively investigates
468 reports of counterfeit products in order to protect U.S.
469 citizens. OCI's investigations have led to some notable
470 successes. I would like to provide some examples from our
471 investigations.

472 The first is from an investigation into counterfeit
473 Alli, and would the clerk please pull up the Alli video?

474 [Video.]

475 Thank you. And would the clerk please load picture one?

476 [Slide.]

477 And as it is being loaded, the picture shows a
478 refrigerator used to store illegally imported, adulterated

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479 and misbranded prescription drugs that were smuggled into the
480 United States. These drugs were discovered in the home of a
481 repacker who had subsequently shipped the drugs to doctors
482 throughout the United States.

483 Would the clerk please load picture two?

484 [Slide.]

485 One of the ways some traffickers obtain prescription
486 drugs is to buy them from customers at various pharmacies
487 whose medications were paid for by Medicaid. In order to be
488 able to reuse the bottle with the original label, they would
489 have to clean the pharmacy label and the Medicaid sticker off
490 of the label using things such as lighter fluid. Where we
491 have observed bottle washing with a solvent, we generally
492 observe chemicals in the solvent that have migrated through
493 the bottle onto the drug.

494 Would the clerk please load picture three?

495 [Slide.]

496 Well, through the particular bottle, I am not sure in
497 the instances what type of bottle it is but we can get back
498 to you on that, but it is common or things to migrate through
499 plastic.

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500 Would the clerk please load picture three?

501 [Slide.]

502 The following photos were taken from a Belize-based
503 manufacturing facility involved in selling unapproved
504 prescription drugs and controlled substances. The pills from
505 the trashcans in this picture were transferred into plastic
506 bags to be counted and bagged by using a scoop. The same
507 scoop was used for many different drugs including controlled
508 drugs. This led to cross-contamination.

509 Would the clerk please load picture four?

510 [Slide.]

511 This picture shows some of the conditions at the
512 manufacturing facility.

513 Would the clerk please load picture five?

514 [Slide.]

515 This picture shows the condition of a tablet room at the
516 facility. I want to show a comparison of what a legitimate
517 tablet press should look like. Would the clerk please load
518 picture six?

519 [Slide.]

520 So you can see the difference.

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521 FDA has been working with industry and international
522 partners to develop new methods to address the problem of
523 counterfeit drugs. FDA scientists have developed and have
524 been testing a counterfeit detection device, CD-3, at U.S.
525 ports of entry and elsewhere for use by FDA investigators to
526 check for suspect counterfeit products. CD-3, which I am now
527 holding, is a battery-operated, handheld and inexpensive tool
528 that costs a fraction of the price of existing laboratory-
529 based and field-deployed technologies. Would the clerk
530 please play the CD-3 video?

531 [Video.]

532 It won't solve the problem, particularly given the
533 volume of products that come through ports of entry.

534 FDA also participates in Operation Pangaea, which is a
535 global cooperative effort in partnership with international
536 regulatory and law enforcement agencies to combat the online
537 sale and distribution of potentially dangerous counterfeit
538 and illegal medical products. As part of the 2013 annual
539 effort, the partnership took action against more than 13,700
540 Web sites illegally selling potentially dangerous unapproved
541 prescription medicines to customers. These actions included

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542 the issuance of regulatory warnings and the seizure of
543 offending Web sites and over \$36 million worth of illegal
544 medicines worldwide. FDA in coordination with the U.S.
545 Attorney's Office for the District of Colorado seized and
546 shut down 1,677 illegal pharmacy Web sites.

547 The case of Manuel Calvelo illustrates the inherently
548 international and thus difficult-to-prosecute nature of the
549 Internet pharmacy investigations. Calvelo is a Belgian
550 citizen operating a global Internet pharmacy with a call
551 center in the Philippines and a credit processor in the
552 Netherlands. Calvelo's Web sites offered for sale more than
553 40 prescription drugs such as Viagra, Glucophage, Zoloft,
554 Lipitor, Cialis, Xanax, Ativan and Klonopin. Note that
555 Xanax, Ativan and Klonopin are controlled substances. OCI
556 was able to arrest Calvelo in Costa Rico and extradite him to
557 the United States after an extended undercover operation in
558 which OCI agents posed as pharmaceutical wholesalers seeking
559 to do business with them.

560 Public education is very important as a first line of
561 defense against counterfeit drugs. The agency is conducting
562 proactive educational outreach to the medical community and

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563 other stakeholders. In September 2012, FDA launched a
564 national campaign called Be Safe RX: Know Your Online
565 Pharmacy. Be Safe RX provides resources for patients and
566 caregivers who might purchase prescription drugs online to
567 enable them to better understand who they are buying from and
568 to help ensure the drugs they buy match the product the
569 doctor prescribed.

570 The Food and Drug Administration Safety and Innovation
571 Act, or FDASIA, enacted in July 2012, provided the agency
572 with new authorities that with help to secure the safety and
573 integrity of drugs imported and sold in the United States.
574 For example, the law provides the FDA with the authority to
575 administratively detain drugs believed to be adulterated or
576 misbranded and the authority to destroy certain adulterated,
577 misbranded or counterfeit drugs offered for import. The law
578 also requires foreign and domestic companies to provide
579 complete information on threats to the security of the drug
580 supply chain and to improve current registration and listing
581 information. The recently enacted Drug Quality and Security
582 Act outlines critical steps to build an electronic and
583 operable system to identify and trace certain prescription

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584 drugs. Within 10 years after enactment, the system will
585 facilitate the exchange of information at the individual
586 package level about where a drug has been in the supply
587 chain.

588 While the new authorities under FDASIA and the DQSA help
589 address some of the risks posted by counterfeit drugs, they
590 will not prevent all types of illegal diversion or
591 distribution schemes. These laws would not prevent the
592 numerous instances FDA has uncovered of medical practitioners
593 deliberately obtaining unapproved drugs, some of which has
594 been counterfeits directly from foreign sources for
595 administering to patients. The reality is that the criminal
596 penalty under the Food, Drug and Cosmetic Act for the risky
597 and inherently dangerous practice of importing unapproved
598 foreign drugs is simply not sufficient to deter the criminal
599 element. The penalty for such conduct, which generally falls
600 under the misbranding and unapproved new drugs provisions of
601 the FD&C Act is 3 years imprisonment and then only if the
602 government can show there is a specific intent to defraud or
603 mislead. Otherwise it is a misdemeanor punishable only by a
604 maximum of one year of imprisonment.

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605 The Ryan Haight Act also sets forth for the first time
606 under federal law the definition of a valid prescription with
607 regard to controlled substances. Many online pharmacies,
608 however, sell prescription drugs that are not controlled
609 substances. These drug sales are regulated under the FD&C
610 Act and require a valid prescription, but the FD&C Act does
611 not define what constitutes a valid prescription. In the
612 online pharmacy context where numerous doctors and their
613 respectively customers are often located in different States,
614 this can complicate criminal prosecution under the FD&C Act.

615 Given the challenges and threats posed by an
616 increasingly globalized marketplace, it is important that FDA
617 regulatory and law enforcement partners and industry continue
618 to work together to address the problem and threat of
619 counterfeit drugs and that we continue to ensure authorities
620 keep pace with the complex system that counterfeiters and
621 traffickers take advantage of. We look forward to continuing
622 to work together to achieve our shared goal of protecting
623 American consumers.

624 I would be happy to answer any questions. Thank you.

625 [The prepared statement of Mr. Sklamberg follows:]

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626 ***** INSERT 1 *****

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|

627 Mr. {Murphy.} Thank you, Mr. Sklamberg.

628 Mr. Kubiak, you are now recognized for 5 minutes.

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|

629 ^TESTIMONY OF LEV KUBIAK

630 } Mr. {Kubiak.} Good morning, Chairman Murphy, Ranking
631 Member DeGette and distinguished subcommittee members, thank
632 you very much for this opportunity to speak today about the
633 efforts of ICE--Immigration and Customs Enforcement--and the
634 Center that I run, the National Intellectual Property Rights
635 Center.

636 I currently serve as the Director of that Center. It is
637 led by ICE, and the Center operates as a task force model
638 comprised of 21 federal and international partners including
639 FDA, which I am pleased to join today here on this panel. It
640 is this collection of agencies partnered together pooling
641 resources, expertise and authorities that makes the IPR
642 Center truly unique and effectively. No subset of agencies
643 has the individual capacity or capability to address the
644 significant and growing threat of IP crime alone. The Center
645 optimizes the effectiveness of each agency and provides a
646 single location for industry collaboration and reporting.

647 Can you put the second slide up, please?

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648 [Slide.]

649 As the picture that you are about to see illustrates,
650 our biggest challenge right now is that criminals now
651 counterfeit and effectively market virtually any product with
652 no regard to public health and safety, be it exploding
653 airbags, as it represented in the right hand of that same, to
654 counterfeit industrial bearings used in mineshafts and mining
655 equipment, to drugs without active ingredient, the callous
656 nature of counterfeiting results in dangerous, even deadly
657 outcomes.

658 Another significant challenge we face is while ocean-
659 crossing shipping containers are necessary for the bulk
660 movement of quantities of counterfeit items like handbags,
661 batteries or razor blades, other high-value items including
662 counterfeit pharmaceuticals and semiconductors used by our
663 United States military are being smuggled in thousands of
664 smaller packages through mail and express courier packages.
665 Next slide, please.

666 [Slide.]

667 As this slide shows, the Internet poses yet another
668 significant challenge. Criminals operating unregulated Web

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669 site, providing counterfeit pharmaceuticals continue to be a
670 growing global phenomenon. In April 2013, Legit Script, an
671 online pharmaceutical verification service, stated there were
672 over 34,000 active rogue Internet pharmacies selling
673 substandard, counterfeit or harmful prescription drugs. The
674 screenshot you see here is from an actual criminal Web site
675 that we seized as one of the 686 Web sites seized as a result
676 of Operation Better Pill, a worldwide operation run by ICE
677 through the IPR Center targeting the online of counterfeit
678 illegal medicine. This Web site was run by a criminal
679 organization based overseas and purported, as you can see, to
680 be a legitimate Canadian health care facility.

681 With this type of ambiguity, consumer fraud can run
682 rampant. Next slide, please.

683 [Slide.]

684 In early 2010, law enforcement authorities from the
685 United Kingdom provided FDA information on an intercepted
686 shipment of unapproved oncology drugs. The package, derived
687 from Pakistan, was destined for California. Together, ICE,
688 FDA, FBI, the U.S. Postal Service, and Customs and Border
689 Protection collaborated on the investigation discovering that

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690 Martin Paul Bean of Florida ordered the unapproved drugs from
691 foreign sources in Turkey, India and Pakistan and then sold
692 those drugs to doctors in the United States at substantially
693 reduced prices. In September, Bean was sentenced to 2 years'
694 incarceration for distributing more than \$7 million worth of
695 unapproved and misbranded oncology drugs through his illicit
696 pharmaceutical scheme, significant harm caused by just one
697 criminal.

698 And this case example on the slide on the screen
699 illustrates our strategy, which is to attack the criminal
700 network throughout the entire global supply chain from the
701 point of manufacturer through shippers of illegal commodities
702 to those that distribute the illegal drugs to unsuspecting
703 people in need of effective medicine. This strategy requires
704 a robust collaboration through our attaché network with
705 foreign counterparts where the majority of counterfeit items
706 are made and through which they are shipped en route to the
707 United States and our trading partners worldwide.

708 I know we are not going to be able to arrest and seize
709 our way out of this growing problem, and that is why the IPR
710 Center has committed significant effort to close

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711 collaboration with industry and education to the public. I
712 do believe that we can reduce demand through education and I
713 also believe that this is the most critical component of any
714 long-term viable solution. Next slide, please.

715 [Slide.]

716 As part of our robust public education efforts, we have
717 developed the IPR Center Web site, which includes information
718 on efforts of all of our partner agencies and where they can
719 report IP crime through our ``report IP theft'' button.
720 Industry and other U.S. government agencies have joined the
721 fight by placing the ``report IP theft'' button on their Web
722 sites as well, now totaling more than 100 industry and
723 embassy Web sites worldwide, including this one from the
724 Pharmaceutical Security Institute pictured in the screen.
725 New leads to the Center have increased nearly 500 percent
726 since fiscal year 2012 as a result of this. I encourage the
727 members of this committee to visit our Web site, and I invite
728 you to place our ``report IP theft'' button on your page as
729 well. Recently we had Congressman Green visit the Center
730 himself and we are working with his staff to do just that for
731 his constituents. And I also welcome other members of this

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732 committee to visit the Center. It is one thing to hear about
733 it; it is another to see it, and we are just across the river
734 in Crystal City.

735 Once again, thank you very much for the opportunity to
736 appear before you today, and I am pleased to answer any
737 questions you may have at this time.

738 [The prepared statement of Mr. Kubiak follows:]

739 ***** INSERT 2 *****

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|
740 Mr. {Murphy.} I thank you both our witnesses today for
741 giving us some honest, solid and somewhat chilling testimony
742 of this huge public health risk.

743 Mr. Sklamberg, in your video you showed Alli, that drug
744 there. I had referenced something in my opening statement
745 about an emergency room doctor in Texas ordering this drug
746 from a rogue Internet pharmacy. Was that the same pharmacy,
747 do you know?

748 Mr. {Sklamberg.} I don't believe it was the same one.

749 Mr. {Murphy.} But he suffered a stroke. Is that
750 correct?

751 Mr. {Sklamberg.} Yes, the one you are referring to, Mr.
752 Chairman.

753 Mr. {Murphy.} And unfortunately, he wasn't alone. I
754 mean, many, many Americans, there are dozens of cases of
755 death or serious injury suffered from these counterfeit,
756 unapproved drugs from these rogue Internet pharmacy sites.
757 Is that correct?

758 Mr. {Sklamberg.} That is correct, and in fact, the
759 illnesses that we know about would severely understate what

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760 is actually happening because, as you pointed out, Mr.
761 Chairman, and some of your colleagues have, a lot of times
762 the patients who are receiving these drugs are already quite
763 sick, so if you are taking Avastin and you have cancer, the
764 Avastin, let's say it is counterfeit and let's say completely
765 doesn't work, it has no active ingredients, you may well end
766 up dying from your cancer. The doctor who is giving you the
767 Avastin might not know that in fact the Avastin was
768 counterfeit and might think that you had died from your
769 cancer despite getting real Avastin, and so it is very hard
770 to establish the cause and effect. So what instances we have
771 we think severely absolutely understand the effect and the
772 problem.

773 Mr. {Murphy.} Thank you. Are you aware that the
774 National Association of Boards of Pharmacy and Legit Script
775 indicate that 97 percent of online pharmacies are actually
776 rogue Web sites that operate in violation of federal law?

777 Mr. {Sklamberg.} Yes, I have seen that statistic. The
778 number of them is astonishing. I believe the GAP report as
779 well has a rather astonishing number.

780 Mr. {Murphy.} And my understanding is, when they don't

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781 recover any prescription, that number may go closer to 100
782 percent.

783 Mr. {Sklamberg.} It would go up.

784 Mr. {Murphy.} Are you aware that according to a report
785 from the PartnershipforDrug-Free.org, one in six Americans,
786 or 36 million people, have bought medication online without a
787 valid prescription?

788 Mr. {Sklamberg.} Yes.

789 Mr. {Murphy.} And given all this, would it be fair to
790 conclude there are probably millions and millions of
791 Americans right now who in their purse and their medicine
792 cabinet and their pocket have some significant safety risk of
793 some medication that they may be taking today?

794 Mr. {Sklamberg.} There are millions of Americans now
795 who may very well have a medication that what they think is
796 medication but that in reality could make them very sick.

797 Mr. {Murphy.} While I am asking these questions, I went
798 into an online pharmacy, and there's cancer drugs here and
799 hypertension and psychiatric drugs, et cetera. I could just
800 tap a button here, buy these. No one is asking me any
801 questions, and I would assume that none of that is helpful.

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802 So this is really a major public health nightmare.

803 Mr. {Sklamberg.} It is a major and growing problem.

804 Mr. {Murphy.} Could the CD-3 device that the FDA is
805 developing be made available to pharmacies or clinical
806 settings or others to help spot counterfeit drugs?

807 Mr. {Sklamberg.} Right now it is still in the early
808 stages. We developed it a short time ago. We have something
809 like about 25 of them now. There are, to put the number in
810 perspective, 1.2 million international mail entries in the
811 United States every day, so we have about 25 of these. We
812 are testing them. We are working on agreements with private
813 industry to scale it up.

814 Mr. {Murphy.} Just make sure that those aren't
815 counterfeit?

816 Mr. {Sklamberg.} Yes. No, this one is real. But they
817 are an important tool because they can do kind of a quick
818 test, but they are not a panacea for two reasons. First of
819 all, in terms of building a criminal law enforcement case, it
820 catches what you think is counterfeit. If you are actually
821 going to build a criminal case, then you have to test it and
822 send it to a lab and do that right because the criminal law

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823 has standards for evidence that are, you know, awful
824 stringent.

825 Mr. {Murphy.} There are also spectrometers that test
826 the chemical content, and we will probably hear about that
827 from the second panel.

828 Mr. {Sklamberg.} Yes.

829 Mr. {Murphy.} Let me ask this. Heather Bresch, who is
830 the CEO of Mylan Laboratories, which is headquartered in my
831 district, has plants in the United States and India, and the
832 New York Times recently stated that the increased regulatory
833 scrutiny in India was long overdue. Do you agree that we
834 need to have greater scrutiny in places like India and China,
835 and what are the concerns about counterfeit drugs
836 specifically related to India?

837 Mr. {Sklamberg.} I would say that as the supply chain
838 both legitimate and counterfeit grows and becomes more
839 international, FDA has to step up its international presence,
840 which is what we have been doing, so for the legitimate
841 supply chain, we have been using the tools that you gave us
842 in FDASIA, for example, so ways of defining risk more
843 clearly, ways of keeping drugs out, to keep drugs that are

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844 suspected of being adulterated out. We have increased
845 foreign presence, increased number of foreign inspections,
846 and that is part of legitimate supply chain.

847 We have to act aggressively in the legitimate supply
848 chain when we encounter fraud that calls into question the
849 integrity of the products, the integrity of the applications,
850 and of course, as legitimate industry grows, there is also
851 the illegitimate industry around the world that is growing,
852 and what is happening that makes it, you know, particularly
853 challenging for us from a law enforcement perspective is, it
854 is no accident that in the counterfeit industry, it is
855 developing in places where we do not have mutual legal
856 assistance treaties, in places where we don't have
857 extradition agreements, and it makes it harder for us to
858 investigate those folks if they are in a country where we
859 don't have the normal--we don't have the avenues of federal
860 criminal law enforcement cooperation that we do in some other
861 countries. So they are smart, they are careful, and what
862 they are doing is evil, and so we have to, when we do catch
863 them, be very aggressive and try to get penalties that will
864 not only put the person in prison but send a very, very

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865 strong message.

866 Mr. {Murphy.} Thank you. I hope some other members
867 will follow up and get some more details and recommendations
868 for Congress.

869 I am out of time now, and turn to Ms. DeGette for 5
870 minutes.

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

872 Mr. Sklamberg, I just want to ask you quickly, it sounds
873 like the penalties are too low for these counterfeiters, but
874 on the other hand, if we increase the penalties, I want to
875 make sure that that is going to have a deterrent effect. And
876 I have a background before I came to Congress in criminal
877 law, and one thing is that penalties don't deter people
878 unless they think there is a likelihood that they might get
879 caught. So I want to ask you, under the current system, if
880 Congress just increased penalties and did nothing else, would
881 that solve the problem?

882 Mr. {Sklamberg.} I think obviously penalties are an
883 important step in the process, and let me agree with you,
884 Ranking Member DeGette, and particularly single out one
885 penalty that is particularly low. Foreign unapproved drugs

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886 which pose the same public health risk as a counterfeit drug,
887 they could be--

888 Ms. {DeGette.} I understand. I am sorry, I don't have
889 very much time. So if we increase those penalties, do you
890 think that would defer people from counterfeiting those
891 drugs?

892 Mr. {Sklamberg.} I think it would increase the
893 frequency at which those cases are investigated. I think it
894 would increase the frequency which--

895 Ms. {DeGette.} Because prosecutors would take it more
896 seriously?

897 Mr. {Sklamberg.} Yes, and it would increase the
898 penalties.

899 Ms. {DeGette.} Thanks. Now, do you think the problem
900 of counterfeit drugs has gotten worse in recent years?

901 Mr. {Sklamberg.} Yes, and more sophisticated?

902 Ms. {DeGette.} And what new methods are the
903 counterfeiters using to evade detection?

904 Mr. {Sklamberg.} They are more effectively hiding their
905 money around the world and they are more effectively using
906 Web sites around the world, hundreds and hundreds of rogue

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907 Web sites linked together. They resemble international
908 organized crime and they are using the tools of it.

909 Ms. {DeGette.} Okay. And that is why you think we need
910 more serious investigation and prosecution?

911 Mr. {Sklamberg.} Yes. It is hard to prosecute
912 international organized crime.

913 Ms. {DeGette.} They are going to be more sophisticated
914 on that end, and we have got to be more sophisticated.

915 Can you talk to us for a minute about the Office of Drug
916 Security, Integrity and Recalls, about when the office was
917 created, what its mission is, and has it been successful in
918 addressing the supply chain threat?

919 Mr. {Sklamberg.} Yes, the Office of Drug Supply,
920 Integrity and Recalls is part of the Center for Drugs' Office
921 of Compliance, which I used to be director of. That office,
922 ODSIR, as it is called, was created in 2011, I believe, and
923 the part it plays in this is one, it is the office charged
924 with implemented the track-and-trace aspect of the DQSA, and
925 number two, when we have a counterfeit incident, part of it
926 is law enforcement, part of it is public health notification.

927 Ms. {DeGette.} Right.

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928 Mr. {Sklamberg.} So when we have an incident like with
929 Avastin a couple of years ago, ODSIR sent out 1,500 letters
930 to the medical community that note, here is a drug that you
931 have that you think is Avastin that is a counterfeit to
932 protect patients, and also works to educate the medical
933 community.

934 Ms. {DeGette.} So do you think it is working, or could
935 it be working better?

936 Mr. {Sklamberg.} I think it is working quite well, and
937 of course, we also want it to work better.

938 Ms. {DeGette.} And what could you do to make it work
939 better?

940 Mr. {Sklamberg.} We would, and are, putting more
941 resources into the problem, and we think working on
942 implementing track and trace and further educating the
943 medical community--

944 Ms. {DeGette.} Will help? Okay.

945 Mr. {Dingell.} Would the gentlewoman yield?

946 Ms. {DeGette.} I would love to yield to my friend, Mr.
947 Dingell.

948 Mr. {Murphy.} Just so people could hear, his microphone

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949 wasn't on, he is asking if you could submit to the committee
950 what changes you would suggest that we make.

951 Mr. {Sklamberg.} We would be glad to.

952 Ms. {DeGette.} Thank you.

953 Now, I want to talk about resources for a minute because
954 this FDA report that the chairman referenced in his opening
955 statement says that the FDA is inspecting the foreign sites
956 once every 9 years compared with the domestic sites every 2
957 years. Is that because of a lack of resources, Mr.
958 Sklamberg?

959 Mr. {Sklamberg.} That was a relic of the way the drug
960 industry looked years ago. FDASIA has--

961 Ms. {DeGette.} No, no, I mean why only once every 9
962 years? Is that because of a lack of resources to do it?

963 Mr. {Sklamberg.} That was the difficulty and expense of
964 foreign inspections and the logistics.

965 Ms. {DeGette.} So your answer is yes?

966 Mr. {Sklamberg.} It is more challenging to do foreign
967 inspections than domestic ones.

968 Ms. {DeGette.} Okay. So what would the FDA need to do
969 more frequent inspections? Would you need more resources to

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970 do that?

971 Mr. {Sklamberg.} As we have gotten more resources, we
972 are able to increase the foreign inspections.

973 Ms. {DeGette.} So do you have enough resources to do
974 these foreign inspections at the regularity you think you
975 need to do them?

976 Mr. {Sklamberg.} We found that as the resources have
977 increased with user fees, we have been able to increase it,
978 so there is a direct relationship.

979 Ms. {DeGette.} So answer my question, please. Do you
980 have enough resources to be able to do these inspections with
981 the regularity you think you need to do them?

982 Mr. {Sklamberg.} We have the resources to do now. The
983 thing is, the situation is going to grow and grow and grow in
984 the future as the percentage--

985 Ms. {DeGette.} You may not have the resources in the
986 future?

987 Mr. {Sklamberg.} We would have to evaluate that in the
988 future, but the situation is growing.

989 Ms. {DeGette.} Okay. Thank you.

990 I yield back.

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991 Mr. {Murphy.} The gentlelady yields back. I now
992 recognize the vice chair of the full committee.

993 Mrs. {Blackburn.} Thank you, Mr. Chairman. I want to
994 thank you all for being with us today, and as you can see, it
995 is an issue that we are all quite concerned about.

996 Mr. Sklamberg, CSIP, are you familiar with Center for
997 Safe Internet Pharmacies?

998 Mr. {Sklamberg.} I am.

999 Mrs. {Blackburn.} Okay. Talk a little bit about who
1000 they are and how you are working with them, and just for the
1001 audience so that they will know, this is a group that is
1002 working Google, Go Daddy, IPEC and trying to root out and
1003 keep some of these rogue Web sites out, and I would love to
1004 hear how you are interfacing with them because it seems as if
1005 they as an industry voluntarily are seeing some results.

1006 Mr. {Sklamberg.} Yes. What we do with CSIP and with
1007 other folks in industry, be they credit card companies and
1008 others, is when we obtain information about a counterfeit or
1009 when industry does, they report it. Now, it is important
1010 that, for example, if it a Web site that the Web site be
1011 taken down; if it is a credit card company, that the credit

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1012 account be disabled.

1013 Mrs. {Blackburn.} Right.

1014 Mr. {Sklamberg.} That is challenging.

1015 Ms. {Blackburn.} Right, and payment processors.

1016 Mr. {Sklamberg.} And payment processors as well.

1017 Mrs. {Blackburn.} Has Google using the Adware program
1018 to permit only U.S.-based online pharmacies, has that been
1019 helpful?

1020 Mr. {Sklamberg.} Well, Google, as you know, entered
1021 into an agreement a couple of years ago where they forfeited
1022 \$500 million because of the Adware program had let in
1023 Canadian, unapproved drugs. As a result of that, Google has
1024 been cooperating with us in our efforts.

1025 Mrs. {Blackburn.} I think all of us have a tremendous
1026 amount of concern about the rogue Web sites and the rogue
1027 pharmacies and the damage that it does, and also the phishing
1028 and the data security issues, you know, it is just a really
1029 sticky ball of wax. So I am pleased to know that you are
1030 working with them and that you all are information sharing.
1031 Do you have the right authority to share information back and
1032 forth, or is there some changes that we should make to allow

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1033 that?

1034 Mr. {Sklamberg.} We have authority but one of the
1035 things that is difficult is, just as an example, Internet
1036 service providers who want to be cooperative with us, so we
1037 have all these Web sites. Right now we have to get grand
1038 jury subpoenas to obtain information that they want to give
1039 to us about Internet service providers. We don't have an
1040 administrative subpoena authority targeted even to just
1041 Internet service providers. That is incredibly time-
1042 consuming and cumbersome for the Assistant United States
1043 Attorney who would get the case and then for us, and it slows
1044 us down. We have to get court orders for subpoenas from
1045 others, and there would be a series of tools that we could
1046 get that would make these investigations move more quickly,
1047 and since we are dealing basically with organized crime, and
1048 that is what it is, organized crime using medicine, fake
1049 medicine, we have to have tools that are as fast as the
1050 criminals are.

1051 Mrs. {Blackburn.} So as we look at data security and
1052 privacy issues, we need to review the elements that would
1053 allow you greater access and speed, a little bit of clarity?

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1054 Mr. {Sklamberg.} I think that would help.

1055 Mrs. {Blackburn.} Okay. Just as I have a little bit of
1056 time left, the botulinum issues, and I know everybody thinks
1057 in terms of just Botox but of course some of my researchers
1058 at our facilities in Tennessee, migraines, Parkinson's,
1059 cerebral palsy for children and they are using the drug
1060 there, and I know you all have had some processes in place
1061 dealing with the unlicensed suppliers of the botulinum and
1062 also your security supply chain pilot project. I am hopeful
1063 that you are seeing companies that are applying for this
1064 pilot. How many--

1065 Mr. {Sklamberg.} Twelve so far, and the program
1066 basically just started, so--

1067 Mrs. {Blackburn.} And you can take up to 100?

1068 Mr. {Sklamberg.} That is correct.

1069 Mrs. {Blackburn.} Okay. And in what countries are the
1070 companies located?

1071 Mr. {Sklamberg.} A variety of countries. I don't have
1072 the information. I can get that to you.

1073 Mrs. {Blackburn.} I would like you to submit for the
1074 record just for our understanding as we go through and

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1075 monitor it.

1076 Mr. {Sklamberg.} We would be glad to.

1077 Mrs. {Blackburn.} And I think also we are going to want
1078 to look at the successes that you have in analyzing the
1079 project, how you are equating the variables, and then what
1080 you see as your deliverables from that project as we move
1081 forward. But thank you for the update.

1082 Mr. {Sklamberg.} Thank you.

1083 Mrs. {Blackburn.} And I will yield back, Mr. Chairman.

1084 Mr. {Sklamberg.} We would be glad to get that to you.

1085 Mr. {Murphy.} The gentleman yields back, and I now
1086 recognize Mr. Waxman.

1087 Mr. {Dingell.} Will the gentlewoman yield?

1088 Ms. {Blackburn.} I yield.

1089 Mr. {Dingell.} Will you submit for the record the
1090 suggestions that you essentially were about to make to my
1091 colleague about what it is you need in the way of authority
1092 to address the questions that you were just describing?

1093 Mr. {Sklamberg.} We would be glad to, sir.

1094 Mr. {Dingell.} I thank the gentlewoman for yielding.

1095 Mr. {Murphy.} Thank you. Now Mr. Waxman is recognized

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1096 for 5 minutes.

1097 Mr. {Waxman.} Thank you very much, Mr. Chairman.

1098 Mr. Sklamberg, has made a number of changes to FDA law
1099 in the last year and a half that should help fight
1100 counterfeit drugs. For example, the FDA Safety and
1101 Innovation Act increased the maximum prison time to 20 years
1102 for knowingly and intentionally selling a counterfeit drug or
1103 knowingly and intentionally adulterating a drug such that it
1104 has a reasonable probability of causing serious harm or
1105 death, and the Drug Quality and Security Act sets up a track-
1106 and-trace system that over the next 10 years should make it
1107 increasingly difficult for criminals to introduce counterfeit
1108 drugs into the drug supply. Can you tell us how useful these
1109 new laws have been?

1110 Mr. {Sklamberg.} They have been quite useful, but of
1111 course, they don't solve the entire problem. I will take
1112 track-and-trace as an example, which I want to thank the
1113 committee for its work on. Track-and-trace works when you
1114 have folks in the supply chain who want it to work, you know,
1115 who want to look and see, is this legitimate product that I'm
1116 dispensing or that I'm getting. What it doesn't do is stop a

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1117 couple of unscrupulous people or criminals who want to have a
1118 transaction together where they are selling a crooked
1119 product. So if you have a person outside the legitimate
1120 supply chain selling to another person outside the legitimate
1121 supply chain administering it to somebody, that is not what
1122 track-and-trace is intended for, and track-and-trace, you
1123 know, wouldn't stop that. The increased penalties in FDASIA,
1124 Congressman Waxman, that you mentioned, are useful but there
1125 is still a major gap, and this is the foreign, unapproved
1126 drugs, and they are as dangerous as counterfeits but you can
1127 sell--in a criminal case--and I used to be a prosecutor, and
1128 one of the hard parts of it is, you have to prove what the
1129 person did and the mental state. So to get the counterfeit
1130 penalties, you have to prove that the person knew it was a
1131 counterfeit that they were selling and you have a conspiracy
1132 involving it could be dozens of people, hundreds of people,
1133 conceivably. We are not going to be able to arrest all of
1134 them.

1135 So you need to be able to show that, for example, it is
1136 a foreign, unapproved drug and not a counterfeit. If you
1137 sell a foreign, unapproved drug and the government can't

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1138 prove fraud, which would often be the case because it is not
1139 purporting to be the U.S. drug, it is a foreign, unapproved
1140 drug, and a person gets sick and dies, that is a misdemeanor,
1141 even with the changes that were made over the last couple of
1142 years. If you are selling a dangerous product that causes a
1143 death, then the criminal penalty under federal law in that
1144 situation would be a misdemeanor.

1145 Now, if there is fraud, the penalties go up under the
1146 Food, Drug, and Cosmetic Act. There is also mail fraud, wire
1147 fraud, other statutes, but we have that gap.

1148 Mr. {Waxman.} I also mentioned in my opening statement
1149 that if you prove an intent to violate the law, which is
1150 necessary before you can win a criminal case for drug
1151 counterfeiting, then even if we win, the maximum penalty for
1152 some violations with potentially life-threatening
1153 consequences is only 3 years. Isn't that correct?

1154 Mr. {Sklamberg.} Under the Food, Drug, and Cosmetic
1155 Act, for fraud, it would be 3. Specifically for counterfeit,
1156 it is higher. But again, counterfeit versus foreign
1157 unapproved from a public health consequence, there is really
1158 often not much of a difference.

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1159 Mr. {Waxman.} So what impact do these weak penalties
1160 have on our ability to deter drug counterfeiting?

1161 Mr. {Sklamberg.} They do significantly. I mean, even
1162 at the front end--so when a case is presented to a federal
1163 prosecutor who has 200 other investigations and they have
1164 narcotics conspiracies, public corruption, fraud, they are
1165 looking at this. It is not an area of law they have seen
1166 before, and if an agent comes to them and says here is a case
1167 and they are looking and they will say, like, well the
1168 penalty is 1 year or 3 years, so I can do an investigation,
1169 take 2 years, put the other cases in the back of my file
1170 cabinet, and as I look at the federal code, and the federal
1171 is, you know, Congress's priority for the crime, it is 3
1172 years, the penalty that was in place since 1938. Rationally,
1173 that prosecutor is going to look at this and say should I
1174 prioritize this, and I am not faulting that prosecutor. That
1175 would have been my calculus. And it affects the whole system
1176 and kind of what drives the priorities in the whole system.

1177 Mr. {Waxman.} Well, as my colleagues have mentioned, we
1178 need your recommendations for what additional tools you need
1179 to help prevent these kinds of actions and to discover such

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1180 actions and to punish these actions, so we will look forward
1181 to getting further recommendations from you.

1182 Thank you, Mr. Chairman.

1183 Mr. {Murphy.} In anticipating Mr. Dingell's question,
1184 details of that to this committee would be most welcome of
1185 all those processes Mr. Waxman asked for.

1186 Mr. {Sklamberg.} And my answer is the same: we would
1187 be glad to.

1188 Mr. {Murphy.} Thank you. I am learning from the
1189 master. We only have a few months left of him, so we are all
1190 trying to learn from him.

1191 I now recognize the vice chair of the committee, Dr.
1192 Burgess, for 5 minutes.

1193 Dr. {Burgess.} Thank you, Mr. Chairman.

1194 Mr. Sklamberg, I just really want to underline the point
1195 you just made, because on the penalty aspect, there is the
1196 deterrent, and then from a prosecutor's perspective, there is
1197 the priority, and we are damaging ourselves on both sides.
1198 We are not really providing a deterrent to the criminal, and
1199 then on the other side, we are not really prioritizing it or
1200 getting that impetus to the prosecutor. Did I understand you

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1201 correctly?

1202 Mr. {Sklamberg.} That is correct, Dr. Burgess.

1203 Dr. {Burgess.} And you think that changing that
1204 certainly would alter the priority from a priority standpoint
1205 at the prosecutorial level?

1206 Mr. {Sklamberg.} It would make it easier for FDA to
1207 present those cases to prosecutors, yes.

1208 Dr. {Burgess.} Now, I do want to also go back to
1209 something that Ms. DeGette was saying on whether or not you
1210 have the funding that you need to inspect foreign sites. My
1211 understanding with the user fee agreement that was
1212 reauthorized in 2012 that we gave you, the FDA, the
1213 authority, you go where you need to go, you stay as long as
1214 you need to stay. Is my understanding correct?

1215 Mr. {Sklamberg.} That is correct. I mean, one thing
1216 that we did in the last round of the user fee negotiations is
1217 went to a goal of parity of foreign and domestic inspections.
1218 So our foreign inspection numbers go up every year, and they
1219 are going to, you know, move up to get into line with what
1220 the reality is. And of course, in the next round of user fee
1221 negotiations, I am sure we will look at what funding would be

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1222 appropriate at that point.

1223 Dr. {Burgess.} And I also presume that during that time
1224 you will provide the committee with feedback as to the
1225 utility of that flexibility which the law, the committee
1226 enabled you to have the last time this was reauthorized.

1227 Mr. {Sklamberg.} Yes, we would do that.

1228 Dr. {Burgess.} I will also point out, it was probably
1229 prior to your time with the agency, but Mr. Sharfstein came
1230 to this committee in 2007 or 2008, and in response to that
1231 same question, perhaps asked by another member, his answer
1232 was, we have everything we need.

1233 So look, I have been on this committee for 10 years. I
1234 understand how this threat has changed, how the globalization
1235 of our economy has in fact affected your ability to do your
1236 work within our shores. So I appreciate the fact that it is
1237 an evolving process, but as Mr. Dingell has pointed out, we
1238 need your feedback so that we can help you keep up with the
1239 threat as it emerges. No one knew back in 1998 when some of
1240 these stories were first being written the degree to which it
1241 would evolve today.

1242 Mr. {Sklamberg.} Yes, and that is why, you know, when

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1243 we have the reauthorization of the user fees, I am sure, you
1244 know, FDA and the committee will be engaged.

1245 Dr. {Burgess.} But don't wait. Let us know along the
1246 way.

1247 Now, Ms. Blackburn was talking, and I didn't realize
1248 this, you have an agreement with Google about online
1249 pharmacies?

1250 Mr. {Sklamberg.} There was, I believe it was in 2011,
1251 Google entered into a non-prosecution agreement where they
1252 forfeited \$500 million, and as part of that, they established
1253 a compliance program.

1254 Dr. {Burgess.} Well, I don't want to speak out of
1255 school, but I just typed in ``cheap Viagra'' to Google, and
1256 you get a lot of sites. Now, the House server won't let me
1257 go to any of them, but just so you know, I am not sure that
1258 is working all that well. You might want to check it out
1259 when you get to a non-House server location.

1260 I do need to ask you this. In 2008, this subcommittee
1261 had a big investigation on, it was an active pharmaceutical
1262 ingredient in the drug thinner heparin imported from China,
1263 and it had been contaminated with a product called

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1264 hypersulfated chondroitin sulfate, if I recall correctly, and
1265 this product that was adulterating the heparin not only
1266 didn't thin the blood, it killed the patients. So it was a
1267 real troublesome aspect of that contamination. I don't feel
1268 like we have ever received the resolution of that that we
1269 should have, so can I just ask you today from the FDA's
1270 perspective, is this still an open and ongoing investigation
1271 or have we just simply said we are never going to get to the
1272 bottom of this?

1273 Mr. {Sklamberg.} I would have to get back to you, Dr.
1274 Burgess, if I may, on that.

1275 Dr. {Burgess.} I wish you would.

1276 Mr. {Sklamberg.} I mean, there is an aspect of it that
1277 is open but I want to make sure about that. I know committee
1278 counsel has been engaged with FDA on this issue.

1279 Dr. {Burgess.} And I would just make the point again
1280 that this molecule, hypersulfated chondroitin sulfate, was
1281 actually patented in China. I mean, I believe this was
1282 criminal attempt before the act occurred, and as a
1283 consequence, American patients were killed, and you think of
1284 somebody in a dialysis center flushing a line with heparin in

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1285 a dialysis patient and they died right after that, I mean,
1286 that is something they are going to have to live with for the
1287 rest of their lives, so this is not a small and
1288 inconsequential thing. We make jokes about Viagra. But this
1289 was a terribly significant event in the lives of patients and
1290 physicians and nurses across this country. I really don't
1291 want to see us not resolve this problem.

1292 So Mr. Chairman, I thank you for the time and I will
1293 yield back.

1294 Mr. {Murphy.} The gentleman yields back. I now
1295 recognize Mr. Dingell for 5 minutes.

1296 Mr. {Dingell.} Mr. Chairman, I thank you for your
1297 courtesy, and I commend you for this hearing. This is a very
1298 important hearing, and I think you have conducted it with
1299 extraordinary skill. I want to welcome a little later Dr.
1300 Prashant Yadav, which is a constituent of mine from the
1301 University of Michigan, who will be testifying on another
1302 panel. I am sorry I may not be able to be here to hear him.

1303 Now, the Congress has taken some remarkable steps under
1304 the leadership of this subcommittee and this committee,
1305 giving FDA the authority they need by passing the FDA Safety

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1306 and Innovation Act, which contained a number of provisions
1307 from my Drug Safety Enhancement Act, and most recently the
1308 Drug Quality and Security Act, and I think that we can all be
1309 proud of what we have done, but as indicated this morning,
1310 you pointed out that more can be done.

1311 So answer if you please yes or no. One of the oldest
1312 challenges facing his Nation is the globalized nature of our
1313 drug supply chain. Commissioner, is it correct that 40
1314 percent of the pharmaceuticals and 80 percent of the active
1315 pharmaceutical ingredients are made in foreign countries, yes
1316 or no?

1317 Mr. {Sklamberg.} Yes.

1318 Mr. {Dingell.} You also have a big problem with some of
1319 the raw materials that later go in to some of these
1320 pharmaceuticals in finished form, do you not?

1321 Mr. {Sklamberg.} Yes, that is correct.

1322 Mr. {Dingell.} You won't have time to answer this, but
1323 would you submit to us a brief comment as to whether you have
1324 authority to get at those people who manufacture and ship
1325 these into the United States and what additional authorities
1326 you need. The FDA Safety and Innovation Act gave your agency

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1327 new authorities such as registration of foreign drug
1328 facilities and mandatory detention to help the agency deal
1329 with globalized drug supply chain. Is your authority there
1330 sufficient and what more is required, if you please, and
1331 answer that for the record.

1332 Now, Commissioner, does FDA need additional authorities
1333 to keep Americans safe from counterfeit and substandard drugs
1334 that are coming in from abroad? Yes or no.

1335 Mr. {Sklamberg.} Additional authorities would help us
1336 do the job.

1337 Mr. {Dingell.} Would you please define in a written
1338 response for inclusion in the record what is required there?

1339 Now, Commissioner, does FDA have the resources it needs
1340 to carry out the new authorities granted to the agency in the
1341 FDA Safety and Innovation Act? Yes or no.

1342 Mr. {Sklamberg.} We found that additional funding has
1343 helped us implement statutes like FDASIA.

1344 Mr. {Dingell.} Would you please submit to us what is
1345 needed there?

1346 I happen to believe one key reason that counterfeit and
1347 substandard drugs are still a public health problem in the

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1348 United States is the penalties are not sufficient to deter
1349 criminals from engaging in this activity. We seem to have an
1350 agreement on this. I am wondering if we should make the
1351 penalties which we collect be turned over to Food and Drug
1352 for additional enforcement. We do that on narcotics. Would
1353 this be helpful, and would you submit additional comments on
1354 how that would work to assist you with your business?

1355 Mr. {Sklamberg.} We would be glad to.

1356 Mr. {Dingell.} Now, Commissioner, the maximum penalty
1357 you mentioned for these activities is only \$10,000 or 3 years
1358 in prison. What should it be, and please define that by
1359 relating it to other questions involving narcotics and other
1360 events which are essentially similar? Would you submit that
1361 for the record?

1362 Mr. {Sklamberg.} We would be glad to.

1363 Mr. {Dingell.} Now, Commissioner, is it correct that a
1364 Utah man was recently convicted of shipping over \$5 million
1365 in unapproved drugs but received only a 1-year prison
1366 sentence?

1367 Mr. {Sklamberg.} That is correct.

1368 Mr. {Dingell.} It seems rather contemptible.

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1369 Now, Commissioner, does FDA support strong civil
1370 monetary penalties against those charged with misbranding or
1371 counterfeiting drugs? Yes or no.

1372 Mr. {Sklamberg.} We have in the past, I believe, but we
1373 can get back to you on that.

1374 Mr. {Dingell.} I would like to have something on the
1375 record. This reminds me of some great lines from Gilbert and
1376 Sullivan where the emperor indicated that it was his purpose
1377 so sublime to make the punishment fit the crime, and it would
1378 seem that this committee might want to do something of that
1379 sort today, and with your guidance, I think we can do it.

1380 Mr. Chairman and my colleagues, I thank you. You have
1381 been very gracious to me this morning.

1382 Mr. {Murphy.} Thank you for also not singing those
1383 lines. We appreciate that.

1384 I now recognize Mr. Griffith from Virginia for 5
1385 minutes.

1386 Mr. {Griffith.} Thank you, Mr. Chairman, and I
1387 appreciate a lot of the questions that have been asked today.
1388 Let me ask some questions. I agree that we ought to figure
1389 out how we need to do this.

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1390 In regard to the situation that Mr. Dingell just
1391 mentioned in Utah, was the gentleman charged with any other
1392 crimes as a part of his scheme?

1393 Mr. {Sklamberg.} I don't recall right now. Maybe I can
1394 get back to you if we can go ahead with another question.

1395 Mr. {Griffith.} That will be fine, because previously
1396 you correctly stated that a lot of times there are other
1397 charges that can be brought and that those may carry
1398 additional time, and so I guess what I would ask you is, is
1399 that since law enforcement can bring other wire fraud, mail
1400 fraud, whatever other charges, are you seeing that
1401 prosecutors are looking at that and raising up the priority
1402 on these crimes, and do we need to look at raising the
1403 penalties or do we just need to encourage prosecutors to go
1404 forward on all fronts as opposed to just one?

1405 Mr. {Sklamberg.} I think what is happening, Congressman
1406 Griffith, is that when the case is initially presented to the
1407 prosecutor, they are not going to know whether they are going
1408 to be able to prove the fraud. So if they prove fraud, mail
1409 fraud's maximum penalty is 20 years, wire fraud is 20 years.
1410 You know, if I sell you a fake Rolex and mail it to you, I am

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1411 getting hammered. But they don't know if they're going to be
1412 able to prove that, and that is going to require a lengthy,
1413 years' long grand jury investigation.

1414 Mr. {Griffith.} So that is what discourages the
1415 prosecutions?

1416 Mr. {Sklamberg.} Up front. Now, they are going to
1417 stack the charges the best they can if they prove it.

1418 Mr. {Griffith.} Sure. Now, obviously you have got a
1419 better shot with somebody in Utah of apprehending the
1420 individual than you do if they are from some foreign nation.
1421 Do you think that there is a better chance of collecting if
1422 we raise the penalties or the civil penalties and criminal
1423 penalties on the financial side more than the prison time,
1424 would that have a greater impact on the foreign imports?

1425 Mr. {Sklamberg.} I think enhancing, for example, asset
1426 forfeiture and seizure would make a big effect because we can
1427 then take the money, which would have a big effect,
1428 deterrence and also just reducing the upside of engaging in
1429 the criminal activity in the first place.

1430 Mr. {Griffith.} And I would agree that a lot of times
1431 that helps law enforcement in other fields and maybe this is

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1432 one of those areas where we need to agree with Mr. Dingell
1433 when he said that perhaps we need to see that the enforcement
1434 agency gets at least a portion of those funds back to help
1435 them go after other bad actors in this area. I do appreciate
1436 that.

1437 Let me ask you this, because you talked earlier about
1438 the prioritization of the various crimes by a prosecutor. If
1439 we raise these penalties up, at what point do we then
1440 deprioritize something else that we may consider important?

1441 Mr. {Sklamberg.} I refer you to the Department of
1442 Justice. No, I mean, obviously that always is a problem, and
1443 to a prosecutor, every case is, you know, like their baby.
1444 But these are ones I think, because they are not common to--
1445 prosecutors or white-collar prosecutors will see mail fraud
1446 cases a lot, typical ones. They will see an odometer
1447 rollback case much more than they would see a counterfeit
1448 drug case, and so they are not--we will present the public
1449 health risk and we will convince them, and we are not saying
1450 Department of Justice is not cooperative; they are. It is
1451 just that the maximum punishments reflect Congress's sense of
1452 the priority, and you go into court, you have a trial. We

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1453 have a case of an unapproved oncology drug. It was a trial,
1454 I believe, late last year. The person was convicted of over
1455 20 misdemeanors, and they were just misdemeanors. And to a
1456 rational prosecutor, do you want to spend a couple of years
1457 investigating what turned out to be a misdemeanor.

1458 Mr. {Griffith.} Sure. Let me switch gears, and I know
1459 it is not your area of jurisdiction but I would ask you to
1460 take the message back. We have been talking about FDA's
1461 authority over the drug supply chain, the Drug Quality and
1462 Security Act. That also had in it an issue of compounded
1463 drugs. Again, I know it is not your jurisdiction but I am
1464 continuing to follow the FDA's regulation activities in that
1465 area, and I would remind the agency that the DQSA was
1466 supposed to preserve the status quo when it comes to
1467 compounding drugs for office use and the repackaging of
1468 sterile drugs. Unfortunately, we are starting to see some
1469 reports that indicate that warning letters are being sent to
1470 prohibit these activities by traditional pharmacies, which
1471 were going on before we passed the bill and there was kind of
1472 an agreement between the House and the Senate that we would
1473 leave that as the status quo. So if you could just take it

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1474 back and just tell them we will keep monitoring this, but I
1475 am concerned about that.

1476 Mr. {Sklamberg.} Okay.

1477 Mr. {Griffith.} I appreciate the work you are doing,
1478 and this hearing has been great. Thank you for your
1479 testimony, and I yield back, Mr. Chairman.

1480 Mr. {Sklamberg.} Thank you, sir.

1481 Mr. {Murphy.} I now recognize Mr. Johnson for 5
1482 minutes.

1483 Mr. {Johnson.} Thank you, Mr. Chairman, and gentlemen,
1484 thank you for your testimony here today.

1485 You know, a large percentage of the people that I
1486 represent in eastern and southeastern Ohio are seniors, and
1487 with often limited and fixed incomes. There are many seniors
1488 who struggle with the cost of prescription drugs, and I have
1489 heard from some individuals who look to purchase drugs from
1490 Canada as a way to achieve drastic savings on their
1491 prescriptions. But I also have concerns about these
1492 practices and how to protect seniors from illegal pharmacies
1493 that may be distributing dangerous drugs and playing on their
1494 need to save.

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1495 So can you clarify the legality of seniors purchasing
1496 drugs either in person or online from Canada in order to
1497 achieve savings? Is this a legal practice?

1498 Mr. {Sklamberg.} It is not a legal practice.

1499 Mr. {Johnson.} It is not a legal practice?

1500 Mr. {Sklamberg.} It is not legal.

1501 Mr. {Johnson.} It is not legal? Okay. Thank you.

1502 Are most Internet pharmacies that purport to be in
1503 Canada actually not in Canada or certainly not providing
1504 drugs that originated in Canada?

1505 Mr. {Sklamberg.} We found many, many online pharmacies
1506 that purport to be Canadian that are not Canadian, and it is
1507 a ruse that is used because a lot of vulnerable Americans and
1508 people who are very sick, seniors, they will think well,
1509 Canada, that is safe, and it turns out it is not Canada, it
1510 is someplace like we saw in the videos.

1511 Mr. {Johnson.} Right. Okay. Didn't FDA's Operation
1512 Bait and Switch survey show that about 85 percent of the
1513 online pharmacies were not from Canada? Is that true?

1514 Mr. {Sklamberg.} I don't remember the exact statistic
1515 but the number is very high.

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1516 Mr. {Johnson.} Can you verify that back to me, please?

1517 Mr. {Sklamberg.} It is correct, 85 percent.

1518 Mr. {Johnson.} Okay. Great. I am not a lawyer, but I
1519 don't typically ask questions I don't already know the answer
1520 to.

1521 Mr. {Sklamberg.} Well, happily I had someone with me
1522 who could answer that.

1523 Mr. {Johnson.} Thank you. Last year, the FDA worked
1524 with international regulatory and law enforcement agencies to
1525 shut down more than 1,600 illegal pharmacy Web sites. Is it
1526 true that most of the Web sites represented themselves as
1527 Canadian pharmacies claiming that the medicines that they
1528 sold were FDA approved or brand-name drugs, which they were
1529 not? Is that also true?

1530 Mr. {Sklamberg.} I believe that many of them were. I
1531 am not sure if it is the majority. Yes.

1532 Mr. {Johnson.} Okay. Thank you.

1533 Mr. {Murphy.} Mr. Johnson?

1534 Mr. {Dingell.} Will the gentleman yield quickly? And I
1535 apologize to him.

1536 This is a very excellent point. Would you submit

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1537 something for the record so that we have something that would
1538 tell us what would assist the gentleman in understanding and
1539 help me to understand what is going on? And I will ask
1540 unanimous consent that the gentleman get the time back that I
1541 have taken from him.

1542 Mr. {Johnson.} My pleasure, Mr. Chairman.

1543 Even in the instance of an online pharmacy actually
1544 being in Canada, haven't some of these Internet pharmacies
1545 come under criminal investigation?

1546 Mr. {Sklamberg.} Correct.

1547 Mr. {Johnson.} All right. Well, shifting gears here
1548 just for a second, let me see if I can get through this next
1549 one.

1550 In 2005, five teenage boys from three different States
1551 died after ingesting raw DXM powder that they bought in bulk
1552 from an online source. All of these tragic deaths were
1553 linked to the same Internet supplier operating out of
1554 Indianapolis where two men bought the drug in bulk from
1555 India, repacked it and sold it over the Internet.
1556 Investigators estimated they made \$70,000 on sales of the
1557 misbranded drug into interspace commerce. This is very

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1558 parent's worst nightmare. These three incidences have been
1559 the subject of scrutiny by this committee in the past when
1560 Chairman Upton introduced legislation on the matter in 2009,
1561 and I am proud to continue his work on the matter along with
1562 my colleague, Mr. Braley, through the introduction of the
1563 PACT Act, which would ensure that only legitimate entities
1564 registered with the FDA or comparable State agencies can
1565 purchase raw, bulk DXM. But there are still questions to be
1566 answered.

1567 How did these young men obtain this drug online? How
1568 easy is it still for teens to purchase bulk drugs online in
1569 order to abuse the substances they get?

1570 Mr. {Sklamberg.} It is very easy to purchase drugs
1571 online, whether it be teens or adults, and teens are better
1572 at using the Internet than adults.

1573 Mr. {Johnson.} That is true. How prevalent are similar
1574 circumstances to the one I just described? How prevalent are
1575 they today in your experience and what you guys are seeing?

1576 Mr. {Sklamberg.} We don't have a number specifically on
1577 teens versus adults but I would say it would stand to reason
1578 that that problem is prevalent.

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1579 Mr. {Johnson.} And it is growing.

1580 Mr. {Sklamberg.} As the whole problem is, I would think
1581 so.

1582 Mr. {Johnson.} What is being done to protect our
1583 Nation's young people and crack down on the illegal online
1584 drug sales targeting those who aim to abuse the substances?

1585 Mr. {Sklamberg.} This would be part of our larger
1586 effort regarding rogue Internet pharmacies and foreign,
1587 unapproved drugs and counterfeit drugs, and obviously we
1588 prioritize more vulnerable victims in how we look at cases.
1589 So it would be part of that effort and obviously a very
1590 important part of it.

1591 Mr. {Johnson.} Okay. Thank you, Mr. Chairman, and I
1592 yield back.

1593 Mr. {Murphy.} Thank you. I now recognize Mr. Long for
1594 5 minutes.

1595 Mr. {Long.} Thank you, Mr. Chairman, and thank you all
1596 for being here today and for your testimony.

1597 Mr. Sklamberg, we asked you for a lot of things here
1598 today, a lot of questions we have of you, but a question I
1599 have for you is, if you were going to say the top three

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1600 things that you need from us, that you need from Congress--
1601 now, you rolled your eyes, so I don't know what that means.
1602 But what can we do to help this dire situation?

1603 Mr. {Sklamberg.} I wasn't rolling my eyes. I was
1604 thinking of--

1605 Mr. {Long.} When I first ran for office, my political
1606 people said that I did that and they told me not to do that.

1607 Mr. {Sklamberg.} Oh, okay.

1608 Mr. {Long.} I still do it.

1609 Mr. {Sklamberg.} I have never won an election nor run
1610 for office.

1611 There is a series of things that I think would help us.
1612 One is, we talked about increased penalties, we talked about
1613 increased authorities.

1614 Mr. {Long.} Let me step you on that one. I had to step
1615 out of the room for a moment, and I don't know if I missed it
1616 or not, but what was the upshot of the video we saw, the
1617 gentleman on there that had this huge operation and
1618 apparently was induced to come to the United States after 7
1619 months of communication? What was the final upshot of that?

1620 Mr. {Sklamberg.} I don't remember what the ultimate

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1621 disposition of the case was. He was arrested and sentenced
1622 but I don't know what the sentence was exactly. Oh, 87
1623 months' imprisonment.

1624 Mr. {Long.} Okay. I interrupted you. Number one is
1625 larger sentences. Number two?

1626 Mr. {Sklamberg.} Yes. Now, that is one where we were
1627 able to prove the crime set at the higher penalties so ones
1628 where--one I had mentioned before where we were unable to
1629 prove counterfeit drugs or fraud, then you end up with
1630 misdemeanor. So I think some of the increased enforcement
1631 tools we talked about, you know, asset forfeiture, we talked
1632 about seizure, we talked about authority for us to obtain
1633 records that would be useful in these cases. I think that
1634 for us, we are working with our foreign regulatory partners
1635 to enhance international cooperation, so that is more
1636 something that FDA is doing, because as this international
1637 organized crime activity grows, that is something we have to
1638 do.

1639 Mr. {Long.} Are we getting more cooperation?

1640 Mr. {Sklamberg.} From certain locations. It is
1641 sporadic, and as I had mentioned, I think, to one of your

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1642 colleagues, international organized crime is clever and so
1643 they are going to situate themselves in places that have
1644 minimal cooperation with the United States, which makes
1645 detection harder and then makes investigation and
1646 apprehension and punishment harder on the back end.

1647 Now, there are lots of countries we have very
1648 cooperative relationships with and their law enforcement.

1649 Mr. {Long.} Let us know what we can do to help you in
1650 those instances, if you will.

1651 Mr. {Sklamberg.} Yes, sir.

1652 Mr. {Long.} And I would like to yield the balance of my
1653 time to my friend, Dr. Burgess, from Texas.

1654 Dr. {Burgess.} I thank the gentleman for the time.

1655 Mr. Sklamberg and Mr. Kubiak, a question to both of you,
1656 but really an observation. What is the main driver here? It
1657 is the ability to make money, and of course, we know people
1658 make money in illicit drug trade all the time, but in this
1659 instance, you can do a counterfeit drug and no one is
1660 shooting at you on the border so in some ways it is a safer
1661 occupation for someone who wants to work on the wrong side of
1662 the law, and then as you pointed out, the penalties are not

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1663 all that great.

1664 Prior to the passage of the Medicare Modernization Act
1665 in 2003, you did see the news stories of large amounts of
1666 seniors getting on buses and going to Canada to shop for
1667 their medications. I don't know if you are aware of it, but
1668 the Affordable Care Act, which began working one way or
1669 another on January 1st, individuals now buying the individual
1670 market, a bronze plan, back in my home State of Texas, it is
1671 \$6,000. So people who have been used to receiving their
1672 medications where something is paid for by the insurance
1673 company now find themselves on the hook for a big part of
1674 that out-of-pocket expense. Some might even argue they are
1675 functionally uninsured when it comes to their prescription
1676 drug benefit. Are you prepared--I mean, what is going to be
1677 the natural tendency of someone who needs whatever, Crestor,
1678 Lipitor, and now they are having to pay the full out-of-
1679 pocket freight or the full freight for the cost of that
1680 medication, are they now likely to seek a lower cost on a
1681 ready device like their iPad or their laptop?

1682 Mr. {Kubiak.} Sir, yes, I think they are likely to seek
1683 that. I think the challenge, though, is they need to

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1684 understand who they are buying it from and--

1685 Dr. {Burgess.} I have no quarrel with that, and I don't
1686 mean to interrupt you but the time is about to expire. Are
1687 you preparing yourself for the fact that there is the
1688 possibility that this type of activity may increase and may
1689 increase significantly for a population where historically it
1690 hasn't been happening?

1691 Mr. {Kubiak.} Congressman, I think across the board we
1692 have been preparing ourselves for an increase in continued
1693 growth unfortunately in this program and this problem over
1694 time, and as we deal with that and deal with these illegal
1695 Internet pharmacy sites, we are trying robustly through
1696 education and also through enforcement to shut down and close
1697 out those opportunities to purchase those that are not secure
1698 sites.

1699 Dr. {Burgess.} I am just not sure you recognize what is
1700 coming your way, and I wanted to warn you what is right over
1701 the horizon because people are going to act in their own
1702 self-interest when they are faced with those questions.

1703 Thank you, Mr. Chairman. I will yield back.

1704 Mr. {Murphy.} The gentleman yields. Yes, Mr. Dingell?

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1705 Mr. {Dingell.} I ask unanimous consent that the
1706 gentleman's time be extended for 1 minute, and I would ask
1707 that the gentleman yield to me.

1708 Dr. {Burgess.} I knew there was a catch.

1709 Mr. {Murphy.} I will tell you what, Mr. Chairman, I
1710 have one follow-up question so I will give you a minute and I
1711 will give myself a minute.

1712 Mr. {Dingell.} I will yield to you, Mr. Chairman. You
1713 are more important than I am in this place.

1714 Mr. {Murphy.} Well, thank you. Let me start with mine
1715 and then I will yield the rest to you.

1716 I want to ask Mr. Kubiak just as a follow-up, are there
1717 any legal barriers that constrain you in sharing information
1718 with foreign government partners and cooperating with efforts
1719 against counterfeit drugs?

1720 Mr. {Kubiak.} Sir, collectively, with all the agencies
1721 that are represented at the Center, we have quite a broad
1722 capability. Individually, each of the agencies has different
1723 capabilities to share. So for instance, within Homeland
1724 Security investigation, ICE, my parent organizations, we have
1725 the broad ability to share information with our customs

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1726 counterparts around the world through customs mutual
1727 assistance agreements, which are outside of the normal mutual
1728 legal assistance treaties that normally are required and that
1729 Mr. Sklamberg talked about earlier in the day. We do have
1730 very broad authority to share, and combined, I think we have
1731 those authorities and those capabilities that we need to do
1732 that.

1733 I would also suggest just if I may that an increase in
1734 the minimum mandatory sentence, an enhancement, if you will,
1735 for pharmaceuticals, for those engaged in the sale of illegal
1736 or unapproved drugs would be a significant improvement as
1737 well. We see kind of across the board that absent that
1738 increase in minimum mandatory sentence, an ability to hold
1739 those people more accountable that are engaged in the life-
1740 threatening activity would greatly enhance our capability to
1741 hold people accountable and also be a major deterrent.

1742 Mr. {Murphy.} Two things we will have to be addressing.
1743 One is the severity of punishment and second is the certainty
1744 of punishment.

1745 I will yield a minute to Mr. Dingell

1746 Mr. {Dingell.} I thank my friend.

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1747 Has there ever been an international conference on this
1748 kind of thing so that we could get everybody together so we
1749 could all pull in the same direction?

1750 Mr. {Sklamberg.} There have been through a variety of
1751 vehicles. The World Health Organization, for example, has
1752 been involved in this.

1753 Mr. {Dingell.} Would something of this kind be useful,
1754 given the way things are changing?

1755 Mr. {Sklamberg.} There is an established mechanism in
1756 the World Health Organization to deal with this issue. FDA
1757 is pursuing that aggressively.

1758 Mr. {Dingell.} All right. My next concern here is the
1759 hard fact, and that is, you have difficulty with the funding
1760 of your agency. If you could get the funding of your agency
1761 to do as it has done by the drug enforcement people where the
1762 proceeds of the stuff that is used in this could be seized
1763 and utilized for either sale so that you could get revenue or
1764 so that you could get other help, would that be of assistance
1765 to you in terms of increasing your levels of funding to deal
1766 with these kinds of questions?

1767 Mr. {Sklamberg.} I think if I could get back to you on

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1768 the record for that?

1769 Mr. {Dingell.} I would rather have you do that after
1770 you have had a chance to think about it.

1771 Mr. Chairman, you have again been most courteous. Thank
1772 you.

1773 Mr. {Murphy.} The gentleman yields back, and with that,
1774 I really want to thank our two distinguished panelists. Mr.
1775 Sklamberg and Mr. Kubiak, you have been most helpful in
1776 giving us information. We will look forward to getting your
1777 follow-up information as soon as you can to this committee so
1778 we can take action from there. Thank you.

1779 With that, those two witnesses are dismissed and I would
1780 like to ask the next set of witnesses on the second panel to
1781 come forward, and while you are coming forward and taking
1782 your seat, I will introduce the panelists. Dr. Marcia Crosse
1783 is the Director of Health Care at the United States
1784 Government Accountability Office. We are also joined by Dr.
1785 Prashant Yadav, who is here on behalf of the Institute of
1786 Medicine. He is the Director of their Health Care Research
1787 Initiative. He is also the director of the William Davidson
1788 Institute at the University of Michigan. We would also like

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1789 to welcome Mr. John Clark, who is the Vice President and the
1790 Chief Security Officer of Global Security in the Compliance
1791 Division at Pfizer Incorporated, and our other panelist is
1792 Mr. Jean-Luc Moreau, the Head of Product Security at Novartis
1793 Corporation. Mr. Bruce Longbottom is the Assistant General
1794 Counsel at Eli Lilly and Company, and Ms. Elizabeth Jungman
1795 is the Director of Drug Safety and Innovation at Pew
1796 Charitable Trusts.

1797 So if the witnesses are ready, I will prepare to swear
1798 all of you in. You are aware that the committee is holding
1799 an investigative hearing, and when doing so has the practice
1800 of taking testimony under oath. Do any of you have any
1801 objections to testifying under oath? All the witnesses say
1802 they do not. The Chair then advises you that under the rules
1803 of the House and the rules of the committee, you are entitled
1804 to be advised by counsel. Do any of the panelists today
1805 desire to be advised by counsel during testimony? And all of
1806 the panelists say no. In that case, if you would all please
1807 rise and raise your right hand, and I will swear you in.

1808 [Witnesses sworn.]

1809 Mr. {Murphy.} So now you are all under oath and subject

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1810 to the penalties set forth in Title XVIII, section 1001 of
1811 the United States Code. You may now each give a 5-minute
1812 summary of your written statement.

1813 We will begin with Dr. Crosse for 5 minutes.

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|
1814 ^TESTIMONY OF MARCIA CROSSE, PH.D., DIRECTOR OF HEALTH CARE,
1815 U.S. GOVERNMENT ACCOUNTABILITY OFFICE; PRASHANT YADAV, PH.D.,
1816 M.B.A., DIRECTOR OF HEALTH CARE RESEARCH INITIATIVE, DIRECTOR
1817 OF THE WILLIAM DAVIDSON INSTITUTE, UNIVERSITY OF MICHIGAN;
1818 JOHN P. CLARK, VICE PRESIDENT AND CHIEF SECURITY OFFICER,
1819 GLOBAL SECURITY, COMPLIANCE DIVISION, PFIZER, INC.; JEAN-LUC
1820 MOREAU, GLOBAL HEAD OF PRODUCT SECURITY, NOVARTIS
1821 CORPORATION; BRUCE LONGBOTTOM, PH.D., ASSISTANT GENERAL
1822 COUNSEL, ELI LILLY AND COMPANY; AND ELIZABETH JUNGMAN, J.D.,
1823 M.P.H., DIRECTOR OF DRUG SAFETY AND INNOVATION, PEW
1824 CHARITABLE TRUSTS

|
1825 ^TESTIMONY OF MARCIA CROSSE

1826 } Ms. {Crosse.} Thank you.
1827 Chairman Murphy, Ranking Member DeGette and members of
1828 the subcommittee, I am pleased to be here today as you
1829 discuss the danger posed by counterfeit drugs.
1830 As we have just heard, one source of counterfeit drugs
1831 is Internet pharmacies. While some Internet pharmacies are

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1832 legitimate businesses that offer consumers a safe, convenient
1833 and cost-effective way to obtain their medications, many are
1834 criminal enterprises that defraud consumers and deny patients
1835 effective treatments. So-called rogue Internet pharmacies
1836 often sell counterfeit prescription drugs, sell drugs that
1837 have not been approved for sale in the United States, sell
1838 drugs that are substandard and have no therapeutic value, and
1839 sell drugs that are harmful to consumers. Drugs sold by
1840 rogue Internet pharmacies have been found to contain too
1841 much, too little or no active pharmaceutical ingredient or
1842 the wrong active pharmaceutical ingredient. Even worse,
1843 these drugs may contain dangerous contaminants such as paint,
1844 heavy metals or poison. Despite the risks, FDA reports that
1845 nearly one in four U.S. adults who shop online have purchased
1846 prescription drugs from Internet pharmacies.

1847 Although the exact number of rogue Internet pharmacies
1848 is unknown and can change daily, one estimate suggests that
1849 there are over 36,000 in operation up from an estimated
1850 34,000 less than a year ago. Most operate from abroad. They
1851 illegally ship prescription drugs into the United States,
1852 sell drugs without a prescription and make efforts to evade

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1853 scrutiny by Customs officials. A recent analysis by NABP,
1854 the professional organization for the State boards of
1855 pharmacy, shows that 97 percent of the Internet pharmacies it
1856 reviewed were out of compliance with laws or industry
1857 standards.

1858 Rogue Internet pharmacies are often complex operations,
1859 and federal agencies face substantial challenges
1860 investigating and prosecuting those involved. Piecing
1861 together these operations can be difficult because they may
1862 be composed of thousands of related Web sites and operators
1863 take steps to disguise their identities.

1864 The ease with which operators can set up and take down
1865 rogue Web sites also makes it difficult for agencies to
1866 identify, track and monitor them because Web sites can be
1867 created, modified or deleted in a matter of minutes.

1868 The global nature of rogue Internet pharmacy operations
1869 complicates federal investigations. These Web sites and
1870 their operators are often located in countries that are
1871 unable or unwilling to aid U.S. agencies with components of
1872 the operations scattered in several countries. If the clerk
1873 would show our first figure?

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1874 [Slide.]

1875 This shows one rogue Internet pharmacy that registered
1876 its domain name in Russia, used Web site servers located in
1877 China and Brazil, processed payments through a bank in
1878 Azerbaijan and shipped its prescription drugs from India.

1879 Rogue Internet pharmacies use sophisticated marketing
1880 methods to appear legitimate. This makes it hard for
1881 consumers to differentiate between legitimate and rogue
1882 sites. Some rogue sites seek to assure consumers of the
1883 safety of their drugs by purporting to be Canadian despite
1884 being located elsewhere or selling drugs sourced from other
1885 countries. They may also fraudulently display an NABP logo
1886 on their Web site despite not having earned the
1887 accreditation.

1888 Our second figure, if the clerk would post it, shows a
1889 Web site that may appear to consumers to be legitimate but
1890 the operators of this site plead guilty to multiple federal
1891 offenses including smuggling counterfeit drugs into the
1892 United States.

1893 Even when such operators are uncovered, the Department
1894 of Justice may not prosecute because of competing priorities

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1895 and the complexity of these operators. Rogue Internet
1896 pharmacy activity clearly violates the Federal Food, Drug and
1897 Cosmetic Act, but as we have heard, proving violations can be
1898 difficult and violations are subject to relatively light
1899 criminal penalties, a maximum of 3 years in jail or a fine of
1900 \$10,000, or both.

1901 When federal prosecutors do pursue such cases, they
1902 often charge operators with violations of other laws such as
1903 smuggling, mail fraud, wire fraud or money laundering since
1904 these violations can be less onerous to prove and carry
1905 stronger penalties, up to 20 to 30 years in jail and fines up
1906 to a million dollars.

1907 In summary, while federal agencies have conducted
1908 investigations that have led to convictions, fines and asset
1909 seizures, rogue Internet pharmacies continue to provide a
1910 convenient mechanism for criminals to sell counterfeit drugs
1911 or substandard prescription drugs to U.S. consumers with a
1912 low probability of being prosecuted.

1913 Mr. Chairman, this completes my prepared statement. I
1914 would be happy to respond to any questions that you or other
1915 members of the subcommittee may have.

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1916 [The prepared statement of Ms. Crosse follows:]

1917 ***** INSERT 3 *****

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|

1918 Mr. {Murphy.} Thank you, Doctor.

1919 I now recognize Dr. Yadav. Am I pronouncing that

1920 correctly, sir?

1921 Mr. {Yadav.} Yes.

1922 Mr. {Murphy.} Thank you. You are recognized for 5

1923 minutes.

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|

1924 ^TESTIMONY OF PRASHANT YADAV

1925 } Mr. {Yadav.} Good morning, Mr. Chairman, Ranking Member
1926 DeGette and members of the committee, my name is Prashant
1927 Yadav. I am the Director of the Health Care Research
1928 Initiative at the William Davidson Institute of the
1929 University of Michigan, and I served as a member of the
1930 Institute of Medicine Committee on understanding the global
1931 public health problem of counterfeit, falsified and
1932 substandard medicines.

1933 The Food and Drug Administration had commissioned this
1934 study in 2011 to advance what at that time was a stymied
1935 public discourse on the topic of pharmaceutical crime. After
1936 deliberating and hearing public testimony for most of 2012,
1937 our committee released our findings and recommendations last
1938 year. I also was a member of another committee of the
1939 Institute of Medicine, which was on regulatory capacity
1940 building in developing countries. This study was also
1941 commissioned by the FDA Office of International Programs, and
1942 it dealt more broadly with questions of food and drug safety

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1943 regulations and globalization. I would like to submit for
1944 your records copies the two mentioned IOM reports as well as
1945 the executive summaries of the two reports and an editorial
1946 on this topic. These documents discuss how improving the
1947 quality of medicines in this country depends to some extent
1948 on better medicine regulation abroad. These reports offer
1949 several suggestions as to how different federal agencies and
1950 international organizations can work together to improve
1951 global drug safety.

1952 In my testimony, I will be using language which is
1953 consistent with the IOM report. The members of our committee
1954 chose to be clear that we saw two rough categories of
1955 dangerous medicines. First, we have the falsified drugs,
1956 those that carry a false representation of identity or source
1957 or both. The other main category is substandard, meaning
1958 medicines that fail to meet our national quality standards.
1959 We recognized that often these two categories overlap. But
1960 we felt that thinking about these two categories separately
1961 helps us characterize the causes of the problem and the
1962 solutions for them in a precise manner. We also agreed not
1963 to describe the drugs as counterfeit, because we felt this

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1964 term tends to hold back discussion. Many speakers who use
1965 the term ``counterfeit'' use it to imply something more broad
1966 than the narrow legal word ``counterfeit.'' The difference
1967 in these two meanings can cause confusion and can alienate
1968 generic drug companies, who sometimes think that this is a
1969 means--who view this as hostility to their products hidden in
1970 a discussion of counterfeit medicines. So our committee
1971 agreed that the problem of trademark infringement was not
1972 within our mandate. We attempted to understand the public
1973 health problem of poor-quality drugs and we limited our
1974 discussions to substandard and falsified, or fake, medicines.

1975 The problem of falsified and fake medicines is
1976 undoubtedly worst in the world's poorest countries, but poses
1977 a risk for American patients as well. We are living in what
1978 the Economist magazine recently described as a golden age for
1979 bad drugs. Different drugs and drug ingredients are made in
1980 different parts of the world. Final drug formulations may be
1981 packaged and repackaged in different countries many times
1982 before reaching a patient, and supervising these supply
1983 chains is a monumental task. The committee recommendations
1984 were for the U.S. FDA to share foreign inspections and work

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1985 towards mutual recognition of inspections done by other
1986 stringent regulatory agencies. We reasoned that it is simply
1987 not good management to have, for example, Japanese and
1988 European and U.S. inspectors repeating each other's work when
1989 so many factories in places like China and India go
1990 uninspected.

1991 The key challenge is to identify gaps before product
1992 safety emergencies occur. Until recently, the inability to
1993 track a package of medicines from the factory to the patient
1994 was one such gap. Our committee had asked the Congress to
1995 authorize the FDA to establish a mandatory track-and-trace
1996 system in the United States. We were concerned that the FDA
1997 had received many unfunded mandates over the years, so we
1998 would also ask the Congress to allocate the appropriate funds
1999 to the agency to ensure the staffing and the technology that
2000 is needed does exist. This is consistent with the
2001 recommendations of the conference and the new Act, the Drug
2002 Quality and Security Act in November is very much in tune
2003 with what the committee had recommended. I would like to
2004 thank the Representatives here today for your work on that
2005 law.

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2006 Track-and-trace legislation is going to help but there
2007 are still many gaps in the supply chain. One of them is the
2008 question of Internet pharmacies. The IOM committee discussed
2009 this problem at great length. We reviewed research that
2010 states people buy drugs online or different reasons. Some
2011 can be described as lifestyle libertarians who believe they
2012 should be allowed to self-prescribe, others are bargain
2013 hunters who are looking on the Internet to get deals, and the
2014 third category are people who are genuinely trying to buy
2015 drugs for making sure they can get them with convenience.
2016 These customers do not understand the risk of their choices
2017 and do not see any better options.

2018 So the committee recommended that the National
2019 Association of the Boards of Pharmacy has a program called
2020 the Verified Internet Pharmacy Practice Sites, or VIPPS.
2021 That program should be strengthened and encouraged. That was
2022 one of the strong recommendations from the committee.

2023 One of the key things the committee recommended was to
2024 strengthen the wholesale market in the United States. We
2025 felt that there are three kinds of wholesalers. There are
2026 primary wholesalers, secondary wholesalers and wholesalers

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2027 who are regional drug wholesalers, and it is easy for
2028 wholesalers to obtain licenses in one State and engage in
2029 commerce without federal or other States knowing about that.

2030 Mr. {Murphy.} I will need you to summarize because you
2031 have gone a minute over.

2032 Mr. {Yadav.} So the committee recommended that FDA
2033 should work with State licensing boards and establish a
2034 public database to share information on wholesale licenses.
2035 This will prevent criminals from licensing in multiple
2036 States. On behalf of my colleagues of the committee, I would
2037 like to once again thank the Representatives for including
2038 this provision in the DQSA law. We also believe that
2039 strengthening the drug wholesale supply chain will set a good
2040 example for other countries in the world.

2041 Thank you, Mr. Chairman.

2042 [The prepared statement of Mr. Yadav follows:]

2043 ***** INSERT 4 *****

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|

2044 Mr. {Murphy.} Thank you.

2045 Mr. Clark, you are recognized for 5 minutes.

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|

2046 ^TESTIMONY OF JOHN P. CLARK

2047 } Mr. {Clark.} Chairman Murphy, Ranking Member DeGette,
2048 members of the subcommittee, it is a pleasure to appear
2049 before you today to discuss an issue of great importance, the
2050 threat that counterfeit medicines pose to the health and
2051 safety of patients in the United States and around the world.

2052 My name is John Clark, and I am the Chief Security
2053 Officer for Pfizer, Inc., and Vice President of its Global
2054 Security Team. Pfizer is a diversified global health care
2055 company and one of the world's largest biopharmaceutical
2056 companies. Our core business is the discovery, development
2057 and marketing of innovative pharmaceuticals for human health,
2058 and we are committing to ensuring the integrity of those
2059 products when they reach the market.

2060 I am responsible for ensuring that programs are in place
2061 to protect Pfizer's personnel, real and intellectual
2062 property, reputation and, most importantly, the integrity of
2063 its medicines. Prior to joining Pfizer in 2008, I served as
2064 Deputy Assistant Secretary at Immigration and Customs

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2065 Enforcement, responsible for the overall management and
2066 coordination of the agency's operations. During my more than
2067 25 years at ICE and its predecessor agency, U.S. Customs, I
2068 held a variety of investigative, management and executive
2069 positions.

2070 A significant aspect of my job at Pfizer is to mitigate
2071 the threat that counterfeit medicines pose to the health and
2072 safety of patients who rely on Pfizer medicines to live
2073 healthier and happier lives. Counterfeit medicines pose that
2074 threat because of the conditions under which they are
2075 manufactured in unlicensed and unregulated sites, frequently
2076 under unsanitary conditions, and the lack of regulation of
2077 their contents. In many instances, they contain none of the
2078 active pharmaceutical ingredient found in the authentic
2079 medicine, or an incorrect dosage, depriving the patient of
2080 the therapeutic benefit of the medicines prescribed by their
2081 physicians. In others, they may contain toxic ingredients
2082 such as heavy metals, arsenic, pesticides, rat poison, brick
2083 dust, floor wax, leaded highway paint and even sheetrock or
2084 wallboard, all of which we found in counterfeits.

2085 Counterfeit medicines are a global problem, one from

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2086 which no region, country, therapeutic area or pharma company
2087 is immune.

2088 While the true scope of the counterfeit problem is hard
2089 to estimate, we can provide some metrics based on the
2090 seizures reported to us by enforcement authorities and
2091 confirmed by our labs. In reviewing those internal metrics
2092 to prepare for today's hearing, I was struck by how
2093 significantly the landscape had changed since November 2011
2094 when I appeared before the House Judiciary Committee.

2095 Since November 2011, authorities have reported to us the
2096 seizure of more than 55 million doses of suspicious Pfizer
2097 medicines. Twenty-eight percent of those seizures--15.5
2098 million doses--were confirmed as counterfeit medicines, and
2099 we differentiate--we are very, very conservative in our
2100 statistics, and if we haven't confirmed, it is just reported,
2101 we don't count it as a statistic. So we are usually
2102 underreporting so we don't get accused of exaggerating.

2103 The number of Pfizer medicines targeted by
2104 counterfeiters has increased by 36 percent, from 50 to 68
2105 different Pfizer medicines now. Counterfeit Pfizer medicines
2106 have been confirmed in six new countries--Armenia, Cameroon,

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2107 Jamaica, Kosovo, Maldives and Saint Lucia--bringing the total
2108 to 107 countries in which counterfeit Pfizer medicines have
2109 been seized by authorities. Counterfeit versions of 26
2110 Pfizer medicines have been confirmed in the legitimate supply
2111 chains of 60 countries, an increase from 22 medicines in 53
2112 countries in November of 2011.

2113 Seizures recorded during 2013 reveal that while Viagra,
2114 a treatment for erectile dysfunction, remains our most
2115 targeted medicine for counterfeiters, other medicines have
2116 attracted significant attention with seizures of each of the
2117 top five exceeding 1 million doses. The seizure of almost
2118 3.6 million counterfeit doses of Viagra represented just 34
2119 percent of the overall confirmed seizures of Pfizer medicines
2120 in 2013, down from 89 percent in 2012.

2121 For the first time, Lipitor, a treatment for high
2122 cholesterol, came a close second, with the seizure of almost
2123 3.1 million tablets, representing 29 percent of all confirmed
2124 doses seized.

2125 Closing out the top 5 most counterfeited Pfizer
2126 medicines last year were Xanax, 1.3 million, Ponstan, 1.1
2127 million, and Centrum, just over 1 million, and again, these

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2128 are relatively low probably compared to what was out there
2129 but just the ones we could confirm.

2130 The increased counterfeiting of Xanax is likely linked
2131 to its popularity, particularly on college campuses, as a
2132 party drug often used to decrease anxiety and insomnia.
2133 Additionally, Xanax appears to be preferred by individuals
2134 taking crystal meth. Counterfeit Xanax seizures in 2013
2135 included those seized from a factory in Texas where 1,000
2136 counterfeit Xanax tablets and tooling were seized by the Drug
2137 Enforcement Administration.

2138 Despite increased breaches in the legitimate supply
2139 chain, the major threat to U.S. patients is the Internet and
2140 the many professional-looking Web sites that promise safe,
2141 FDA-approved branded medicines from countries such as Canada
2142 and the U.K. In 2006, Pfizer Global Security launched a
2143 robust Internet program to identify and disrupt rogue online
2144 pharmacies dispensing Pfizer medicines to unsuspecting
2145 patients. Although that program resulted in a takedown of
2146 several rogue OLPs and arrests, it was in essence a whack-a-
2147 mole approach. Recognizing the limitation of that strategy,
2148 we sought a broader and more permanent remedy.

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2149 Along these lines, in 2013 we partnered with Microsoft
2150 in an innovative OLP disruption program that attacked the
2151 affiliate networks where they were most vulnerable by
2152 simultaneously disabling domains to disrupt traffic to the
2153 sites and eliminating their ability to process credit card
2154 payments for orders placed. This new approach has proven much
2155 more effective, evidenced by the disruption of two affiliate
2156 networks and the removal of more than 3,300 rogue OLPs from
2157 the Internet just last year.

2158 To protect unsuspecting patients from the risk of
2159 obtaining counterfeit medicines online, we have extended our
2160 Internet monitoring program to Craigslist and Facebook along
2161 with other classified-advertising Web sites and social media
2162 outlets. As a result of those efforts, we have identified
2163 several individuals offering Viagra on Craigslist. Our test
2164 purchases confirmed that these individuals are selling
2165 counterfeits. Subsequent referral of these incidents to
2166 local law enforcement resulted in the arrest of several
2167 sellers including a Maryland housewife. The social-network
2168 monitoring also identified several drop shippers of rogue
2169 OLPs who use their access to counterfeit medicines to

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2170 advertise independently in Craigslist. One such referral to
2171 police in Toronto resulted in the arrest of six Craigslist
2172 sellers.

2173 Mr. {Murphy.} Mr. Clark, I have to ask you to wind up.

2174 Mr. {Clark.} That is it. I will be glad to take
2175 questions.

2176 [The prepared statement of Mr. Clark follows:]

2177 ***** INSERT 5 *****

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|

2178 Mr. {Murphy.} Thank you. I have to step out for a
2179 while, and Dr. Burgess will take over, but I just want to ask
2180 one clarifying question, Mr. Clark, before I go. If you
2181 compare money counterfeiting to electronic counterfeiting to
2182 drug counterfeiting, tell me about the different ratios and
2183 profitability.

2184 Mr. {Clark.} We had 3 years ago seen German customs
2185 refer to a study from the University of Bonn that did just
2186 that. For a \$1,000 base investment by a counterfeiter, they
2187 compared what they estimated would be the return on
2188 investment. They went through several levels of different
2189 commodities. I think cash was the lowest. For \$1,000
2190 invested, they estimated that there would be a \$5,000 return
2191 on investment for counterfeiting cash. I think credit cards
2192 were second with \$10,000 return. The second highest level
2193 commodity counterfeited for return on investment was
2194 electronics. They estimated for \$1,000 investment, the
2195 return would be \$100,000. The highest on that list by the
2196 University of Bonn was pharmaceutical products. For \$1,000
2197 invested, they estimated that the return on investment would

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2198 be \$500,000.

2199 Mr. {Murphy.} Thank you. I appreciate that.

2200 Mr. Moreau, you are recognized for 5 minutes.

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|

2201 ^TESTIMONY OF JEAN-LUC MOREAU

2202 } Mr. {Moreau.} Mr. Chairman and members of the
2203 subcommittee, my name is Jean-Luc Moreau and I am the global
2204 head of product security at Novartis International. My
2205 primary responsibility is to protect the company, its
2206 products, and most importantly, the persons who rely on
2207 Novartis medicines from counterfeits.

2208 Modern counterfeiting is an industrial global business
2209 which in 2010 generated an estimated \$75 billion for
2210 organized crime. In 2002, the Pharmaceutical Security
2211 Institute recorded 196 product incidents worldwide. In 2012,
2212 the same Pharmaceutical Security Institute recorded 2,018
2213 cases representing a 10-fold increase in only one decade.

2214 Counterfeit drugs are most of the time extremely
2215 dangerous. For example, the World Trade Organization has
2216 estimated that counterfeit antimalarial drugs kill 100,000
2217 Africans annually. My own experience tells me that this
2218 number is basically underestimated.

2219 Counterfeit drugs are generally indistinguishable from

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2220 the genuine drugs. Some examples are displayed on the
2221 monitors. Russian counterfeiters have gone so far as to add
2222 holograms to the packaging of their fake drugs which say
2223 ``protected against counterfeit.''

2224 Counterfeit drugs are made in clandestine facilities
2225 which are downright filthy. As the pictures on the monitor
2226 show, Novartis products are made in state-of-the-art
2227 facilities. By contrast, as the pictures on the screen
2228 demonstrate, counterfeiters manufacture their illicit
2229 products in decrepit conditions. Counterfeiting operations
2230 generally ship and/or store their fake products in unsanitary
2231 and improper conditions, more examples on the screen.

2232 Counterfeiting today is frequently highly organized,
2233 transnational, and businesslike. Counterfeiters operate
2234 industrial production facilities with the capacity to
2235 saturate markets with fake products. They target low-volume,
2236 high-specialty medicines, as well as high-volume, low-margin
2237 products as over-the-counter drugs or generics. They reach
2238 persons directly through the internet or illicit retailers or
2239 they infiltrate legitimate supply chains, as in many
2240 countries.

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2241 The scope of sophistication of this modern
2242 counterfeiting is clearly illustrated by the two following
2243 examples. The first example, in May 2006, customs officers
2244 at London Heathrow seized a shipment from Dubai en route to
2245 the Bahamas which contained thousands of packs of eight
2246 confirmed counterfeit drugs from seven pharmaceutical
2247 companies, including more than 3,000 packs of a counterfeit
2248 Novartis medicine for hypertension. The counterfeit product
2249 had been manufactured in China, transported by road to Hong
2250 Kong, flown to Dubai while they were stored in a duty-free
2251 warehouse before being shipped to the Bahamas via the U.K.
2252 In the Bahamas, an illicit fulfillment center established by
2253 Rx North, an internet drug website, process orders placed on
2254 the internet by American and Canadian patients. The fake
2255 products were shipped directly to the Bahamas to customers in
2256 the U.S. and Canada.

2257 The second example, Novartis manufactures Coartem, which
2258 is a breakthrough drug for malaria. Novartis has made over
2259 500 million Coartem treatments available without profit in
2260 malaria-endemic countries through programs such as the U.S.
2261 President's Malaria Initiative and the Global Fund to Fight

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2262 AIDS, Tuberculosis, and Malaria.

2263 In March 2010, I organized a market survey in three
2264 Nigeria basin countries, Cameroon, Nigeria, and Benin, which
2265 concluded that around 25 percent of our Coartem donated to
2266 Eastern African countries was being stolen and shipped 5,000
2267 miles away to Western Africa where it was sold on the street
2268 not for free but for an average of \$5 per treatment.

2269 This large-scale diversion scheme created a mass-market
2270 for Coartem which attracted an extensive counterfeiting
2271 operation. In July 2012, a container ship from Guangzhou,
2272 China, to Luanda in Angola was seized by customs officers.
2273 It contained Hi-fi speakers hiding 1.5 million treatments of
2274 fake Coartem. Subsequent investigations in Western Africa
2275 confirmed that this counterfeit version of Coartem contained
2276 nothing but flour, cornstarch, dextrose, and an industrial
2277 colorant. There is no question in my mind that the Coartem
2278 diversion and counterfeiting schemes grievously undercut
2279 efforts to eradicate malaria and have led directly to the
2280 deaths of hundreds of thousands of Africans.

2281 The United States and other countries should develop
2282 comprehensibility of criminal laws to confront

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2283 counterfeiting, impose stiffer sanctions for pharmaceutical
2284 crimes, and make the commitment to vigorously enforce those
2285 laws.

2286 Thank you.

2287 [The prepared statement of Mr. Moreau follows:]

2288 ***** INSERT 6 *****

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|

2289 Dr. {Burgess.} [Presiding] Mr. Longbottom, you are

2290 recognized for 5 minutes.

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|

2291 ^STATEMENT OF BRUCE LONGBOTTOM

2292 } Mr. {Longbottom.} Good morning, Mr. Chairman, Madam
2293 Ranking Chairman, and members of the subcommittee. My name
2294 is Bruce Longbottom. I am assistant general counsel for
2295 trademarks at Eli Lilly and Company. We are a global
2296 pharmaceutical manufacturing company based in Indianapolis.
2297 And like my colleagues here, our company also invests heavily
2298 to research, develop, and produce safe and effective
2299 medicines which treat many diseases and save lives.

2300 First, let me thank the chairman, ranking member, and
2301 members of the subcommittee for your focus on this important
2302 issue and for inviting Eli Lilly to testify today about
2303 fighting counterfeit drugs and illegal supply chains. We do
2304 appreciate the attention you are devoting to investigate the
2305 problem of counterfeit medicines, which pose an ongoing risk
2306 to patient safety. And this threat of counterfeit medicine
2307 is an issue that is near and dear to Lilly and to also the
2308 heart of our CEO Dr. John Lechleiter, who has spoken on this
2309 on several occasions.

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2310 At Lilly, like the other companies here, we have seen
2311 counterfeit copies of our own branded medicines around the
2312 world and we have seen counterfeiters target a range of
2313 medicines from our medicines for mental illness to our
2314 medicines for cancer as well. Some of the medicines that are
2315 fake may contain over amounts and excess amounts of the API,
2316 the active pharmaceutical ingredients, or perhaps contain the
2317 wrong APIs or none at all. Some counterfeit drugs contain
2318 toxic dangerous ingredients, and we are not alone in this
2319 experience, again, as heard already today. We view this as a
2320 global health threat that we must work diligently to solve
2321 with others in partnership.

2322 We would like to congratulate this committee for its
2323 hard work in passing the Drug Quality Security Act of 2013,
2324 or DQSA. That new law's establishment of a track-and-trace
2325 system for pharmaceuticals will serve greatly to close gaps
2326 in the supply chain for prescription drugs in the traditional
2327 supply chain, which is from the legitimate manufacturer to
2328 the wholesaler to the pharmacies and then to patients.

2329 But while DQSA establishes important requirements for
2330 good guys, I believe today's hearing is to look at the bad

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2331 guys. And as such, I will focus my remarks today on the most
2332 common way that counterfeit drugs reach U.S. patient, and
2333 that is of course through the internet, a topic already
2334 mentioned several times today and rightfully so I would add.

2335 Obviously, more and more of us are becoming more
2336 comfortable with purchasing products online. We are very
2337 easily doing that, and e-commerce is projected to grow at
2338 over 10 percent every year. And as more and more Americans
2339 do look online for their medicines, and there have been some
2340 examples even in this hearing this morning of looking online
2341 for medicines, what are we finding? Forty to fifty thousand
2342 active illegal online drug sellers, and 97 percent, according
2343 to the National Association of Boards of Pharmacy do not meet
2344 pharmacy and drug safety standards. So tens of thousands of
2345 fake online pharmacies put patients at risk. Now, is that
2346 okay? Of course not. I think no one here is satisfied with
2347 that. We don't want to stay at that position.

2348 When we interact with a pharmacy, what should we be
2349 expecting as we go to a pharmacy whether in the real world or
2350 online? I think there are two basic things. One is a drug
2351 approved by the FDA and the second is a pharmacist who has

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2352 been licensed by their state pharmacy board. So that
2353 prescription medicine has been blessed by the FDA and that
2354 pharmacist has been blessed by the state licensing authority.
2355 And I would like to coin the term if I could the sanctity of
2356 the pharmacy. I think that is the standard that we should
2357 work towards whether in the real world or online.

2358 With regard to the online world, there is no one easy
2359 bullet to take care of the problem. There is no one easy
2360 solution. There are several elements that are critical to
2361 adding towards that solution and there are more details in my
2362 submitted written materials, but just at the very high level,
2363 some of those themes are patient education, stronger laws,
2364 more aggressive enforcement of existing laws, and also
2365 voluntary cooperation by internet-based companies.

2366 Now, just as the DQSA used one tool primarily to tighten
2367 defenses in the brick-and-mortar supply chain, and that tool
2368 was of course serialization, I believe there are one or more
2369 tools that could also be used to tighten the illegitimate
2370 supply chain, the online supply chain. And one of those
2371 tools I would like to mention is delisting. That is a tool
2372 that could be used to exclude these bad illegal rogue online

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2373 pharmacies from natural search results found using search
2374 engine. In other words, if a website selling medicines did
2375 not sell only FDA-approved drugs or do not provide those
2376 services using a state licensed pharmacist, you would not
2377 find that website in the search results after it was
2378 delisted. The online pharmacy would still be on the
2379 internet, probably hosted in a foreign country, but would not
2380 be found by the patient in the U.S. doing an internet search.

2381 If natural search results were cleaned up in this way,
2382 that would be the internet equivalent, I believe, of what the
2383 DQSA has done to tighten the traditional supply chain.

2384 And there are other tools that could be discussed as
2385 well. Search optimization for the NABP-approved pharmacies
2386 may be another helpful tool to boost those in the search
2387 rankings.

2388 The internet is here to stay. The number of fake online
2389 pharmacies is growing, and Eli Lilly and Company stands
2390 committed to patient safety in both the brick-and-mortar
2391 pharmacies and the internet-based pharmacies, and I very much
2392 appreciate the opportunity to speak with you today and I am
2393 happy to answer any questions.

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2394 Thank you.

2395 [The prepared statement of Mr. Longbottom follows:]

2396 ***** INSERT 7 *****

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|
2397 Dr. {Burgess.} Ms. Jungman, you are recognized for 5
2398 minutes.

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|

2399 ^STATEMENT OF ELIZABETH JUNGMAN

2400 } Ms. {Jungman.} Thank you. Chairman Murphy, Ranking
2401 Member DeGette, and members of the subcommittee, thank you
2402 for the opportunity to present testimony. My name is
2403 Elizabeth Jungman. I direct drug safety and innovation work
2404 at The Pew Charitable Trusts.

2405 Dr. {Burgess.} May I ask, is your mike on?

2406 Ms. {Jungman.} Pardon me. My name is Elizabeth
2407 Jungman. I direct drug safety and innovation work at The Pew
2408 Charitable Trust, which is an independent, nonpartisan
2409 research and policy organization dedicated to serving the
2410 public.

2411 Counterfeit drugs are far more than an intellectual
2412 property problem; they are a public health problem with real
2413 human costs. Counterfeit and other unsafe drugs have entered
2414 our drug supply numerous times over the past few decades.
2415 Three recent incidents of fake cancer drugs are one example.
2416 My testimony for the record and our website have others.

2417 I am grateful to Congress for recently enacted two

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2418 import laws that have been discussed by other panelists,
2419 Title VII of the FDA Safety and Innovation Act, which focused
2420 on upstream supply chain security; and Title II of the Drug
2421 Quality and Security Act, which laid the groundwork for
2422 tightening the downstream drug distribution system.

2423 My testimony today will focus on next steps, how
2424 policymakers and stakeholders can make full use of these new
2425 tools.

2426 Meaningful penalties for drug counterfeiting and
2427 diversion are important, but the best way to prevent unsafe
2428 products from reaching patients is a tightly closed
2429 distribution system. So that is my focus today.

2430 By passing the Drug Quality and Security Act last year,
2431 Congress created a national serialization and traceability
2432 system that will fundamentally change drug distribution in
2433 this country.

2434 Beginning in late 2017, each package of prescription
2435 drugs will bear a unique serial number enabling it to be
2436 verified and eventually allowing for its distribution history
2437 to be traced. The DQSA contains some requirements for
2438 companies in the supply chain to check serial numbers but in

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2439 most cases only when there is an existing belief that the
2440 product is suspect.

2441 A more powerful use of serial numbers would be as a
2442 routine proactive check. Counterfeiters can be sophisticated
2443 but falsifying a serial number is much harder if that number
2444 is routinely checked against a manufacturer's database.
2445 Pharmacists, physicians, payers, and border agents could use
2446 this important new tool to help stop fake products from
2447 reaching patients.

2448 It is important to underscore that the risks go beyond
2449 counterfeit drugs. In 2009, thieves stole a tractor-trailer
2450 containing at least 120,000 vials of insulin, an injectable
2451 drug that must be refrigerated. After several months, the
2452 stolen drugs were sold to chain drugstores. We don't know
2453 how many patients received compromised medicines, but only a
2454 small percent of the drugs were ever recovered. Regular
2455 checking could have identified them immediately.

2456 Verification should become routine in pharmacies. To
2457 achieve that, a system must be designed to ensure that
2458 verification is practical and efficient. Waivers of the
2459 DQSA's requirements should be rare lest we exempt businesses

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2460 like the pharmacist in Chicago indicted last year for
2461 substituting Chinese counterfeits for legitimate products.

2462 Patients can also make use of this new tool. Doctors
2463 who purchased a counterfeit cancer drug last year may not
2464 have known that it was fake. While the DQSA does not require
2465 physicians to check serials, patients deserve this safety
2466 check. Physician societies and payers should consider the
2467 potential for authentication to protect patients.

2468 Proactive verification of serial numbers is not without
2469 precedent. Other countries like Turkey and Italy already use
2470 it to protect their citizens and to prevent fraud. The U.S.
2471 is behind the curve in this case, but our law creates the
2472 tools necessary for similarly robust protections if Congress,
2473 regulators, and payers take action to encourage them.

2474 Payers can also explore the use of serial numbers as a
2475 condition of reimbursement both to ensure product legitimacy
2476 and to reduce fraud. Large-scale fraud against government
2477 programs is well-documented yet preventable through serial
2478 checks. To be fully effective, such an approach would
2479 require another system element not explicitly contemplated by
2480 the DQSA: decommissioning serial numbers so that they cannot

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2481 be reused.

2482 Serial numbers could also be used by agents at the
2483 border. Spot-checks of incoming products could help
2484 determine legitimacy, and this will complement the progress
2485 in regulating drug imports that was made in the 2012 FDA
2486 Safety and Innovation Act.

2487 The DQSA requires in 10 years an electric interoperable
2488 system for tracing each unit of medicine. There is an
2489 opportunity now to build in strong features that will allow
2490 for more comprehensive automated use in the future. But
2491 stakeholders do not have to wait 10 years to begin using the
2492 DQSA. Starting next year, FDA will stand up a public
2493 database of licensed wholesalers, and all stakeholders will
2494 pass pedigree information. So long before the law is fully
2495 implemented, dispensers can check to ensure that their
2496 sources are legitimate.

2497 The DQSA and the FDA Safety and Innovation Act are
2498 important steps in securing our pharmaceutical supply chain,
2499 but alone they will not solve the problem. Congress,
2500 regulators, border agents, and supply chain stakeholders can
2501 help create a safer drug supply by supporting robust and

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2502 implementation of these laws and full use of the tools that
2503 they provide.

2504 Thank you.

2505 [The prepared statement of Ms. Jungman follows:]

2506 ***** INSERT 8 *****

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|
2507 Dr. {Burgess.} Thank you. And I thank the witnesses,
2508 each and every one of you, for your testimony. And we will
2509 now move to questions. Each Member will be recognized for 5
2510 minutes. I will begin.

2511 Dr. Crosse and Dr. Yadav, I appreciated your testimony.
2512 You heard my questions to the FDA and to ICE. I mean cost is
2513 a big driver here and people are looking at pharmacy bills
2514 that they may never have seen before. I have got to feel
2515 that there is right over the horizon this problem is going to
2516 crescendo in size.

2517 One of you referenced people who go online because they
2518 are bargain hunters or they are self-prescribing. Self-
2519 prescribing means they are avoiding a doctor visit to get a
2520 prescription. So basically cost is the driver there. Has
2521 there been any study on, say, one of the popular proton pump
2522 inhibitors for acid reflux disease went over-the-counter.
2523 Did you see a drop-off in internet activity with the purchase
2524 of other brands that remained on patent and were therefore
2525 more expensive? Was cost reflected in the internet activity?

2526 Ms. {Crosse.} I am not aware of any studies that have

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2527 directly addressed that. We certainly do know that activity
2528 has increased across time in general and the number of sites
2529 I think reflects that. Internet purchases originally were
2530 focused more in the so-called lifestyle drugs. That has
2531 moved increasingly into individuals seeking to save money,
2532 you know, on their blood pressure medicine or whatever other
2533 medications they may regularly be on. But I don't know of
2534 studies that specifically looked at that change when
2535 something goes from prescription to over-the-counter.

2536 Dr. {Burgess.} And, Dr. Yadav, did the Institute of
2537 Medicine do any of that sort of investigative work?

2538 Mr. {Yadav.} So the short answer is no. I think we
2539 looked at various studies and I think we will submit to the
2540 committee some of the findings which show which type of
2541 categories were being purchased more, what kinds of factors
2542 and root causes were leading to that. But there was no study
2543 which showed how does this change when the product goes from
2544 being prescription to over-the-counter.

2545 Dr. {Burgess.} Do any of our representatives from the
2546 industry have any experience with that?

2547 Well, Mr. Clark, I just noticed on your website some of

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2548 the things you have in the pipeline, the Phase III and Phase
2549 II drugs, I mean some pretty exciting stuff already on the
2550 horizon, PCSK9 for lipid control. Is the development of
2551 those products in any way going to be impacted by the fact
2552 that the diversionary activities that you described are going
2553 on? Is that going to have a direct effect on your research
2554 and development side?

2555 Mr. {Clark.} It could and it is one of the worries we
2556 have had in rolling out just last year some of the newer
2557 medicines. They need a track record to build up success and
2558 to prove to the world how good they are. We went out ahead
2559 of several of them to start checking the internet sites to see
2560 if in terms of Eloquest, Xeljanz, a few others that were
2561 coming out, worried that, you know, if competed with by
2562 counterfeits and there are reports of they don't work because
2563 of the counterfeit effect, it could indeed actually the
2564 reputation of the medicine themselves and stuff.
2565 Fortunately, the ones we have been looking at so far haven't
2566 had that much competition on the internet.

2567 Dr. {Burgess.} How about for any of you does it affect
2568 your R&D budget, the fact that you are obviously losing

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2569 sales?

2570 Mr. {Clark.} I can speak for my shop. We have never
2571 been held to task by the company for, you know, return on
2572 investment for sales. You know, it is a reputational thing,
2573 which obviously has a collateral, you know, sales impact, but
2574 it is really a patient health and safety issue for us.

2575 Mr. {Moreau.} The very same at Novartis.

2576 Dr. {Burgess.} And, Mr. Moreau, your description of the
2577 antimalarial drug, I mean the United States taxpayers spent a
2578 lot of money in the PEPFAR program to buy the drug to prevent
2579 the disease to save the children in other countries and human
2580 tragedy because of the counterfeit drugs making it into the
2581 pipeline and the American taxpayers being ripped off. I mean
2582 this is something that just absolutely has to be stopped and
2583 we certainly appreciate your vigilance to that and we will
2584 welcome your input back to the committee.

2585 Mr. {Moreau.} Yes, Congressman. On a more positive
2586 note, I just want to inform the committee that we have been
2587 working, we are still working very closely with federal
2588 agents attached to USAID on this case, and there are reasons
2589 to believe that the criminal gang responsible for this

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2590 counterfeiting operation will one day or another be arrested
2591 in China.

2592 Dr. {Burgess.} All right. Very well. And, Mr.
2593 Longbottom, you heard my description of the little research
2594 project I did here on the committee dais where I put into a
2595 search engine a name of a cheap pharmaceutical project. I
2596 got a lot of results, a lot of hits. And then you talked
2597 about delisting and in fact are those types of activities
2598 actually in process where you are working with the search
2599 engines to try to minimize this?

2600 Mr. {Moreau.} We are currently looking at a program,
2601 especially here in the States and with the plan to liaise
2602 directly with authorities and exchange information and
2603 intelligence.

2604 Dr. {Burgess.} All right. Thank you.

2605 Mr. {Longbottom.} Mr. Chairman, may I answer your
2606 question?

2607 Dr. {Burgess.} Sure.

2608 Mr. {Longbottom.} Thank you. Yes, we are not currently
2609 working on those tools but I do know that the Center for Safe
2610 Internet Pharmacies, or CSIP, referred to earlier by another

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2611 committee member, is at work to develop proposals to work
2612 together, and those are the e-commerce companies, the search
2613 engines, the payment card companies, the main name
2614 registrars. So it might come out of that group. But
2615 wouldn't it have been nice if had you done the search, the
2616 first 35 results would have been the NABP-certified--

2617 Dr. {Burgess.} Yes, sir.

2618 Mr. {Longbottom.} --online pharmacies? I think that is
2619 where we really want to move to. I would love to see that
2620 for my family members going online, constituents as well. I
2621 think that is where we are headed.

2622 Dr. {Burgess.} Absolutely. My time is expired. I
2623 recognize the ranking member for 5 minutes.

2624 Ms. {DeGette.} Thank you very much, Mr. Chairman.

2625 And I want to thank all of you for coming here today and
2626 working collaboratively with us to try to resolve this very
2627 difficult and international problem.

2628 I am concerned because we recognize this issue of
2629 counterfeit drugs. We have been trying to work on it
2630 assiduously with the track-and-trace legislation, with the
2631 FDA, giving more resources with all of the private companies

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2632 giving more resources.

2633 But yet, according to the testimony that I am hearing
2634 from all the witnesses today, the prevalence of these
2635 counterfeit drugs, particularly on the internet, just
2636 continues to grow and to get more sophisticated. And so what
2637 I would like to examine in just a short period of time I have
2638 is what we can really do to try to bend this curve and to
2639 solve the situation.

2640 So I would like to start with you, Dr. Crosse. You
2641 testified, as did the others on the last committee, that the
2642 sentences are really ridiculously low for these federal
2643 offenses, and I agree with that. I think the sentences need
2644 to be increased, but I am trying to figure out, and this is
2645 what I was talking to the chairman about, is how much is
2646 increasing sentences really going to prevent this kind of
2647 conduct, especially as Mr. Moreau and Mr. Longbottom and
2648 others have testified. Some of these people are renegade
2649 gangs in foreign countries.

2650 And so one thing I want to ask you, did the GAO find
2651 that these prosecutors who were able to prosecute people
2652 under other statutes, money laundering, wiretap, et cetera,

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2653 would there have been more prosecutions and more convictions
2654 if they had been able to get felony convictions and higher
2655 sentences?

2656 Ms. {Crosse.} We did hear from prosecutors that
2657 increasing the penalties or clarifying what was required to
2658 be the threshold for criminal activity might make this a
2659 higher priority among all of the competing cases--

2660 Ms. {DeGette.} Okay.

2661 Ms. {Crosse.} --that they have. If they are having to
2662 pick something that is really difficult and that carries low
2663 penalties, it has a lower priority.

2664 Ms. {DeGette.} And so even though they have these other
2665 statutes they could charge them, this would help?

2666 Ms. {Crosse.} Right. They indicated that it would be
2667 helpful.

2668 Ms. {DeGette.} Okay. But it alone would not help? We
2669 are going to need to do other things, right?

2670 Ms. {Crosse.} That is correct.

2671 Ms. {DeGette.} Okay. And what would some of those
2672 other things be?

2673 Ms. {Crosse.} Well, there have been a number of

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2674 settlements that have been undertaken to get at some of the
2675 service providers to these internet sites. The Google
2676 settlement was mentioned earlier. All that did though was
2677 remove the sponsored links at the top--

2678 Ms. {DeGette.} Right.

2679 Ms. {Crosse.} --of the page. That doesn't eliminate
2680 those.

2681 Ms. {DeGette.} So internet vigilance like Mr.
2682 Longbottom and others have been talking about would be
2683 helpful?

2684 Ms. {Crosse.} That can be helpful. Also the NABP is
2685 engaged--

2686 Ms. {DeGette.} Um-hum.

2687 Ms. {Crosse.} --in getting a top-level domain name, a
2688 .pharmacy, where there would be controls in place on which
2689 websites could have a .pharmacy extension as opposed to a
2690 .com. That would require educating consumers to go to those
2691 links and not others.

2692 Ms. {DeGette.} And let follow up on that, educating
2693 consumers. Mr. Clark, I was actually talking to you
2694 yesterday about this. It seems to me one of the real keys is

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2695 educating consumers that they shouldn't be going on these
2696 websites. Can you describe for me what kinds of efforts the
2697 industry is taking to do that consumer education?

2698 Mr. {Clark.} Sure. I know from our experience and my
2699 colleagues have done similarly, I mean, you know, we are
2700 always working with media to try and highlight issues,
2701 whether it is a case or just background information, speaking
2702 at conferences. We do a lot of training of law enforcement
2703 along the same lines to educate them because I think it is
2704 not only just the consumers. First and foremost it is the
2705 medical community. I mean it is astounding how doctors and
2706 nurses aren't so familiar with this and law enforcement as
2707 well. So there is a huge outreach by most of the companies
2708 to try and get to all of the constituents within those
2709 sectors and stuff to try and raise awareness because--

2710 Ms. {DeGette.} And, I am sorry, are you also working
2711 with the various federal agencies to increase this education?

2712 Mr. {Clark.} Absolutely.

2713 Ms. {DeGette.} The FDA and the--okay.

2714 Now, I wanted to ask you, Ms. Jungman. By the way, I am
2715 the co-chair of the Diabetes Caucus, so I was horrified to

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2716 hear your insulin example. And what you really focused on is
2717 what more can we do? Does Congress need to do anything to
2718 help improve this serial number issue? Because that sounded
2719 like a very intriguing and relatively successful way to help
2720 to identify these counterfeit drugs.

2721 Ms. {Jungman.} I think that Congress definitely could
2722 have a role here. I think oversight as the system is
2723 implemented both to ensure that all stakeholders are fully
2724 participating but also to be sure that as a system,
2725 architecture is built up. There are ways that the system
2726 could be built that are more robust or just barebones, and I
2727 think congressional oversight could play a real role in
2728 ensuring that it is built to have the functionality that
2729 would allow for serial checking in a way that is automatic
2730 and simple for people to use.

2731 Ms. {DeGette.} Thank you.

2732 Thank you very much, Mr. Chairman. And if you can help
2733 convey with me to Mr. Murphy that we should continue this
2734 oversight, I think that would be great.

2735 Dr. {Burgess.} I thank the gentlelady.

2736 I would be willing to go for one supplemental question

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2737 if you were.

2738 Ms. {DeGette.} Okay. One.

2739 Dr. {Burgess.} Well, it just so happens I have one.

2740 Has the Ryan Haight Act been effective in reducing the number
2741 of internet pharmacies selling controlled substances,
2742 Dr. Crosse?

2743 Ms. {Crosse.} DEA tells us that it has been effective
2744 in reducing the number of domestically located websites
2745 selling controlled substances. However, they haven't been
2746 doing a lot of looking overseas. They have had a small
2747 sample of websites that they looked at and ordered controlled
2748 substances, and 40 percent of the websites where they placed
2749 those orders actually provided them with controlled
2750 substances. They tell us, though, that they are more likely
2751 to be schedule III or schedule IV, drugs like Vicodin or
2752 Xanax, rather than oxycodone, which is a schedule II
2753 substance. So they do believe it has been effective in
2754 pushing the activity offshore.

2755 Dr. {Burgess.} I recognize the ranking member for an
2756 additional question.

2757 Ms. {DeGette.} I am fine. I thank the panel.

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2758 Dr. {Burgess.} And to be bipartisan I would join in
2759 that thanks for all the witnesses, all the members who
2760 participated in today's hearing. I remind Members they have
2761 10 business days to submit questions for the record and I ask
2762 all the witnesses to agree to respond promptly to written
2763 questions.

2764 With that, the subcommittee shall stand adjourned.

2765 Thank you.

2766 [Whereupon, at 12:30 p.m., the Subcommittee was
2767 adjourned.]