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4 PRESCRIPTION DRUG DIVERSION: COMBATING THE SCOURGE

5 THURSDAY, MARCH 1, 2012

6 House of Representatives,

7 Subcommittee on Commerce, Manufacturing, and Trade

8 Committee on Energy and Commerce

9 Washington, D.C.

10 The Subcommittee met, pursuant to call, at 11:10 a.m.,
11 in Room 2322 of the Rayburn House Office Building, Hon. Mary
12 Bono Mack [Chairwoman of the Subcommittee] presiding.

13 Members present: Representatives Bono Mack, Blackburn,
14 Stearns, Harper, Lance, Cassidy, McKinley, and Butterfield.

15 Staff present: Paige Anderson, Commerce, Manufacturing,
16 and Trade Coordinator; Charlotte Baker, Press Secretary;
17 Brian McCullough, Senior Professional Staff Member, Commerce,
18 Manufacturing, and Trade; Gib Mullan, Chief Counsel,

19 Commerce, Manufacturing, and Trade; Shannon Weinberg,
20 Counsel, Commerce, Manufacturing, and Trade; Michelle Ash,
21 Democratic Chief Counsel; and Will Wallace, Democratic Policy
22 Analyst.

|
23 Mrs. {Bono Mack.} Good morning. If statistics hold
24 true, by the time this hearing is over 10 Americans will have
25 tragically and I believe needlessly died from prescription
26 drug overdoses. Today prescription drug abuse is a deadly,
27 serious, and rapidly-escalating problem all across our
28 Nation. We have a solemn obligation to tackle this growing
29 epidemic head on, and I am going to keep beating the drums
30 until Congress, the FDA, and the DEA come up with a
31 comprehensive plan for action.

32 The Chair now recognizes herself for an opening
33 statement, and the clock is not working. That is all right
34 for me. It won't be all right for you all, though, so don't
35 get too comfortable.

36 But as Americans we rally around efforts to fight breast
37 cancer, childhood diseases, and other serious health threats.
38 But for far too long there have been only hushed whispers
39 about prescription drug abuse, now the fastest-growing drug
40 problem in America according to the CDC.

41 Today as the death toll from prescription drug overdoses
42 continues to rise sharply, it is time to move the story from
43 the obituary page to the front page where it belongs. It is
44 time to realize that we can't simply wish this horrific
45 problem away, not with nearly 30,000 people a year dying from

46 it. See no evil, hear no evil often leads to a society's
47 unspoken evil, indifference.

48 We can do better than that, and we must. Just about
49 everyone knows someone who is affected by prescription drug
50 abuse which impacts an estimated 12.5 million Americans and
51 is now considered a health epidemic by the CDC. According to
52 a recent, ``Monitoring the Future,'' national survey nearly
53 one in four twelfth graders have abused prescription drugs.

54 Today two classes of medicines, painkillers and insomnia
55 and anxiety drugs, are responsible for about 70 deaths and
56 nearly 3,000 emergency room visits a day. These are stunning
57 numbers, but here is what is even more alarming. The death
58 toll from overdoses of these powerfully-addictive medicines
59 is now more than double the death toll from heroin, cocaine,
60 and all other illegal drugs combined. As a result, for the
61 first time ever drug deaths outnumber traffic fatalities and
62 has become the leading cause of accidental death in America.

63 So what is the answer? When it comes to prescription
64 drug abuse, where are the safety belts and the airbags that
65 we need to deploy? First, like anyone in recovery knows we
66 have to admit we have a serious problem. Americans today
67 simply are prescribed too many medicines. There is a pill
68 for just about every ache, pain, and malady.

69 So what is wrong with that? Well, consider this. Not

70 long ago the DEA conducted three national drug take-back
71 days, and I applaud them for that, and at those 3 take-back
72 days they collected an astonishing 995,815 pounds of unused
73 and unneeded medicines. That is 995,000 pounds, not pills,
74 in just 3 days.

75 Today doctor shopping is a widespread problem which
76 contributes to our Nation's alarming prescription drug
77 addiction rate, increases costs to all of us through higher
78 insurance rates, and makes it extremely difficult for the DEA
79 to crack down on abusers. Compounding the problem is an
80 oftentimes false sense of security. ``If it is approved by
81 the FDA and prescribed by a doctor, then it must be okay.''
82 Wrong. Too many pills taken at once or combining them with
83 other drugs and alcohol can have a serious and even deadly
84 consequence.

85 But the issue confronting us today is much more complex
86 and involved than just what have you found lately in
87 Grandma's medicine cabinet. The black market sale of
88 powerful and highly-addictive narcotic painkillers such as
89 OxyContin and Vicodin is big business, prompting the DEA to
90 attack the problem on multiple fronts from street-level sales
91 all the way to the top of the supply chain. Targeted first
92 were the so-called, ``pill mills'' in Florida which were
93 largely unregulated until last year, and they routinely

94 dispensed painkillers like they were M&Ms from a gumball
95 machine.

96 There is yet another more insidious side of the story as
97 well. After becoming addicted to prescription painkillers,
98 law enforcement authorities say more and more people are now
99 switching to heroin. In San Diego County, which borders my
100 district, drug treatment experts say the use of heroin by
101 young adults has more than tripled since 2006. Much of this
102 growth is due to people who have switched to heroin as a
103 cheaper alternative to OxyContin, now going on the street for
104 as much as \$80 for an 80-milligram tablet. By contrast,
105 OxyContin sells for about \$6 a tablet in pharmacies.

106 Personally, I will never forget the very chilling phone
107 call I received one night from a constituent of mine who told
108 me that his son had had a gun put to his head because he
109 couldn't pay the street price any long for his OxyContin.

110 So what is the answer? I believe my legislation, the
111 Ryan Creedon Act, H.R. 2119, and the Stop Oxy Abuse Act, H.R.
112 1316, are good starting points. My goal is to improve
113 prescriber education by getting doctors, dentists, nurse
114 practitioners, and other prescribers up to speed on the
115 dangers of addiction and to make certain that powerful and
116 seductive narcotic prescription drug such as OxyContin are
117 used to treat severe pain only, not moderate pain like a

118 toothache or a sore knee. In far too many cases addiction
119 becomes a much greater health threat than the original pain
120 itself, and in far too many cases death is the final result
121 of a failed rehab.

122 So let us not continue to blame this on Grandma and her
123 medicine chest. She knows better, and in our hearts
124 Americans do, too.

125 [The prepared statement of Mrs. Bono Mack follows:]

126 ***** COMMITTEE INSERT *****

|
127 Mrs. {Bono Mack.} And I am happy to recognize the
128 gentleman from North Carolina, the Ranking Member of our
129 Subcommittee, Mr. Butterfield, for his 5 minutes.

130 Mr. {Butterfield.} Thank you. Let me thank the
131 Chairman for holding today's hearing on this very important
132 subject of prescription drug diversion, and I know that this
133 issue is very important to you, and I admire your work on it.

134 Prescription drug diversion is an ever-growing problem
135 in our country. In fact, a couple years ago in 2010, seven
136 million people, seven million, over the age of 12 were
137 considered current users of a prescription pain reliever;
138 tranquilizers, stimulant, or a sedative, that was not
139 prescribed to them. Sadly, it has become clear that as
140 legitimate prescription drug use rises, so, too, does the
141 number of people who abuse these drugs and so, too, does the
142 number of people who accidentally die from prescription drug
143 overdose. It is unconscionable that since 1990, a little
144 over 20 years ago, the deaths resulting from an overdose of
145 prescription drugs have risen. It has risen five-fold.
146 Sometimes must be done, and I agree with that.

147 But the question is what, and by whom. Some of the
148 testimony we will hear today comes from manufacturers and
149 distributors of prescription drugs. It seems to me that the

150 security and safeguards these entities employ is very
151 impressive and goes beyond what might be expected. The use,
152 layers upon layers of--they use layers upon layers of
153 security. They hire third parties to audit the processes and
154 make immediate changes if a vulnerability is indentified.
155 They track shipments with GPS precision and have built in a
156 lot of redundancy in their security procedures.

157 Understandably, though, the further down the supply
158 chain a particular drug travels the greater are the
159 opportunities for diversion. The National Survey on Drug Use
160 and Health reported that 76 percent, more than three-quarters
161 of people who use prescription drugs non-medically, gain
162 access to them from someone they know. I think this needs to
163 be our focus as we go forward.

164 To that end, we need to focus on anti-diversion efforts,
165 and I am pleased that the director from the White House
166 Office of National Drug Control Policy is here today to tell
167 us about their action plan.

168 In a perfect world the answer to this problem is
169 personal responsibility, but in the real world it is clear
170 the Federal Government does have a defined role to play. We
171 need to provide greater support for education programs for
172 young people so they can learn at an early age the dangers of
173 misusing prescription drugs. We need to provide greater

174 support for rehabilitation initiatives so those who are
175 addicted to prescription drugs have access to the help they
176 medically need, and we need to make sure DEA has access to
177 the resources it needs to scrutinize all the players involved
178 and the manufacturer, distribution, and dispensing of
179 controlled substances. Most involved in this process are
180 good and honest people. DEA needs to find the ones who are
181 not.

182 And so I would like to personally on behalf of the
183 Democrats on this Committee thank all of you for coming
184 today, and I look forward to your testimony. I stand ready
185 to work with each of you, Madam Chair, and our colleagues and
186 witnesses to curtail prescription drug abuse in the United
187 States of America.

188 Thank you so very much. I yield back.

189 [The prepared statement of Mr. Butterfield follows:]

190 ***** COMMITTEE INSERT *****

|
191 Mrs. {Bono Mack.} Thank you, Mr. Butterfield. Chairman
192 Upton has yielded his 5 minutes for an opening statement to
193 me in accordance with Committee rules, and as his designee I
194 now recognize Mr. Stearns for 2 minutes for an opening
195 statement.

196 Mr. {Stearns.} Thank you, Madam Chair, and just wanted
197 to compliment you for this hearing on prescription drug
198 diversion. Very important and I am also very pleased to have
199 and welcome our Attorney General, Florida's own Attorney
200 General Pam Bondi. She is here to testify on this important
201 hearing. She is Florida's 37th Attorney General, sworn in in
202 January of last year. She is a native of Florida, and she
203 graduated from the University of Florida, which I represent,
204 so I am proud to have her as a so-called constituent. She
205 also graduated from Stetson Law School and was a prosecutor
206 for almost 18 years.

207 Among her top priorities is strengthening penalties to
208 stop pill mills in the Sunshine State, which from our last
209 hearing, Madam Chair, on this issue was a prevalent problem
210 in our state, and with her dedication and leadership against
211 prescription drug abuse, Florida went from having 98 of the
212 top 100 dispensing physicians for oxycodone pills to have 13
213 dispensing physicians residing in Florida.

214 So frankly her success in this effort resulted in
215 recognition from the National Association of Drug Diversion
216 Investigators, Florida Police Chiefs Association, and from
217 the Florida Board of Medicine. So I want to welcome her, and
218 I thank you, Madam Chair, for the opportunity to do so.

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

220 ***** COMMITTEE INSERT *****

|
221 Mrs. {Bono Mack.} Thank you, and I just want to point
222 out that there is a hearing going on in the Health
223 Subcommittee with the Cabinet Secretary. So a lot of members
224 are bouncing in and out. If they are able to attend, I just
225 want to thank the members who are here.

226 Mr. {Butterfield.} Madam Chairman, that is where I was
227 until I figured out I was in the wrong place.

228 Mrs. {Bono Mack.} I am glad you figured it out. But we
229 do have three panels before us today. Each of our witnesses
230 has prepared an opening statement. They will be placed into
231 the record. Each of you will have 5 minutes to summarize
232 that statement in your remarks. The good news is the clock
233 is working, and there is a timer in front of you now.

234 On our first panel we have the Honorable Gil
235 Kerlikowske, Director of the Office of National Drug Control
236 Policy. Good morning, Director, and once again, thank you
237 very much for being here. I am happy to recognize you now
238 for 5 minutes for your statement.

|
239 ^STATEMENT OF RICHARD GIL KERLIKOWSKE, DIRECTOR, OFFICE OF
240 NATIONAL DRUG CONTROL POLICY

241 } Mr. {Kerlikowske.} Thank you, Chairman Bono Mack and
242 Ranking Member Butterfield and distinguished members of the
243 Subcommittee. It is a great opportunity for us to update you
244 on this important issue of prescription drug abuse in the
245 United States.

246 Prescription drug abuse has been a major focus of the
247 Office of National Drug Control Policy since my confirmation.
248 I am particularly indebted to Chairman Bono Mack for calling
249 me up to her office in the first week that I was in the
250 office to really begin to educate me about an issue that,
251 frankly, 3 years ago was not on the public's radar screen,
252 but it is clearly in front of the public today.

253 I included prescription drug abuse as a signature
254 initiative as part of the Administration's National Drug
255 Control Strategy. As been mentioned, it has been categorized
256 as a public health epidemic by the Centers for Disease
257 Control and Prevention.

258 The scope of non-medical use of pharmaceuticals is
259 striking. CBC found in 2008, that the opioid pain relievers
260 were involved in 14,800 deaths, and opioid pain relievers are

261 now involved in more overdose deaths as has been mentioned in
262 heroin and cocaine combined. The vast majority of abused
263 pharmaceutical drugs originally enter into circulation
264 through a prescription. The quantity of prescription
265 painkillers sold to pharmacies, hospitals, and doctors'
266 offices has quadrupled from 1999, to 2010.

267 When I testified last year before this Subcommittee in
268 April, the Administration had just released that month its
269 Comprehensive Prescription Drug Abuse Prevention Plan. The
270 plan focuses on four major pillars.

271 The first pillar is education. Most prescription
272 painkillers are prescribed by primary care doctors,
273 internists, and dentists, not pain specialists. The FDA is
274 requiring manufacturers of these opioids to develop
275 educational materials and training for prescribers. The
276 Administration is working with Congress to amend the federal
277 law to require mandatory education and training for
278 prescribers, and we are also working very hard to educate the
279 general public about the risks and the prevalence of
280 prescription drug abuse and about the safe use and proper
281 storage and disposal of these medications.

282 The second pillar, monitoring. We focused on expanding
283 and improving state prescription drug monitoring programs.
284 Forty-eight states have those laws. Despite the progress,

285 some states lack operational programs. Many states operate
286 PDMPs that lack interoperability with other states. But I am
287 pleased to report the Administration worked with Congress to
288 secure legislative language to allow the Department of
289 Veterans' Affairs to share prescription drug data with these
290 PDMPs.

291 Our third pillar focuses on safe disposal of unused and
292 expired medications and through the National Prescription
293 Drug Take Back Days that the DEA has collected and was talked
294 about by the chair. The Administration also recognizes the
295 significant role that pill mills and rogue prescribers play
296 in this issue. Our surveys and research show that with
297 chronic addiction to prescription drug they are more likely
298 to obtain their drugs from the pill mills than the recent
299 initiates.

300 And final pillar of the Administration's plan focuses on
301 improving law enforcement capabilities to address diversion.
302 Across the country law enforcement regulatory and legislative
303 actions are forcing doctors and shoppers and doctor shoppers
304 and others seeking these sources of prescription drugs to be
305 apprehended.

306 The problem, of course, was highlighted in the State of
307 Florida, which was in 2010, the epicenter of the Nation's
308 pill mill epidemic, but I have to tell you that working with

309 the attorney general in the State of Florida has led to
310 marked changes in that state, and I couldn't be more pleased
311 that not only she, but Attorney General Conway are also here.

312 In 2011, ONDCP, our office, supported training events
313 because we know if you are going to do the enforcement, it
314 can't be just at the federal level. It has to be at the
315 state and local level also, and experts in law enforcement
316 need that kind of training in order to investigate these
317 complex cases.

318 We are undertaking a data analysis project right now to
319 examine the ways that prescription drugs are purchased,
320 purchasing behaviors, and whether those patterns are
321 indicative of suspicious behavior. We held a round table
322 with members of the pharmacy community and law enforcement to
323 discuss pharmacy robberies and burglaries. We called in the
324 heads of organizations that worked on the security of the
325 manufacturers and distributors to make sure that we were
326 knowledgeable about what they were doing to secure these very
327 potent pharmaceuticals.

328 In closing just let me thank the members of Congress for
329 their support on the ONDCP and my Executive Branch colleagues
330 who know that without your efforts and without your support
331 we would not make a difference in this very important area.

332 Thank you.

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

334 ***** INSERT 1 *****

|
335 Mrs. {Bono Mack.} Thank you very much, Director. I
336 will recognize myself now for 5 minutes for questioning.

337 And just ask you with everything that your office is
338 doing together, the DEA and the FDA, why are we losing this
339 battle against the prescription drug epidemic, and you have
340 mentioned a lot of progress we have made, but you do live in
341 Florida, but prescription drug abuse has not decreased. What
342 is the next step?

343 Mr. {Kerlikowske.} I think the fact that all of these
344 things are coming together, that we actually are starting to
345 see some fruition to all of the work that has been going on.
346 For instance, in the most recent Monitoring the Future
347 Survey, eighth, tenth, and twelfth graders have actually
348 reduced their level of use of prescription drugs, but I
349 couldn't agree with the chair more that it is an epidemic,
350 that it is so wide spread and that people still don't get it.
351 They don't understand that these are dangerous, they can be
352 deadly, and they can certainly be addictive.

353 I think that one of the greatest hopes will be in the
354 next step forward, and that is mandatory prescriber
355 education. Physicians must be told and must have unequivocal
356 information about the dangers of addiction, pain management,
357 tolerance, dependence, and they really don't get that in

358 medical school. The second part I know you will hear from
359 the Drug Enforcement Administration as non-enforcement. The
360 laws have to be enforced, and people have to be prosecuted.

361 Mrs. {Bono Mack.} I appreciate that and especially your
362 viewpoint on prescriber education, but a problem for me, too,
363 is we examined this problem. There are clearly gaps in the
364 data, and we don't really know the extent of the problem.

365 What are the gaps, and how can they be filled?

366 Mr. {Kerlikowske.} Well, quite often we rely, for
367 instance, on fatality data to come from the individual
368 states, and we know that depending on the particular state,
369 whether it is a medical examiner system or others, those
370 states can often be delayed.

371 We also know that at times, whether it is from
372 fatalities from driving accidents or others, that the level
373 of examinations to determine what the cause and whether or
374 not that person had the drugs in their system is not always
375 as thorough as it can and should be. There are data gaps,
376 but I will be happy at another time to tell you about this
377 new initiative to take some of the data and really identify
378 and drill down into it.

379 Mrs. {Bono Mack.} I would be happy to work with you on
380 that. I think they are critical even for policymakers. We
381 need that data critically.

382 The DEA is going to testify that there are 1.4 million
383 DEA registrants. That seems awfully high. Do you think that
384 1.4 million registrants is about right for America, or is
385 that kind of a crazy number?

386 Mr. {Kerlikowske.} Chairman, I actually wouldn't know
387 what the right number would be, but I think when you look at
388 nurse practitioners, physicians, and all of the other people
389 that hold those DEA registration licenses across the country
390 in the healthcare field, that the number doesn't seem
391 completely out of line to me. I think more importantly is
392 how they are policed.

393 Mrs. {Bono Mack.} Thank you, and lastly, should we be
394 thinking about creating new classification schedules under
395 the Controlled Substance Act with stricter regimes for the
396 drugs that are clearly the biggest problems?

397 Mr. {Kerlikowske.} I know that issue has come up before
398 to put those into the higher schedule. I think the more
399 important part is to try and keep them out of the hands of
400 the abusers but not at the same time they get so restrictive
401 that the issues that led us to where we are today 15 years
402 ago, which was the clear indication that pain was not being
403 adequately treated in the United States, I think the pendulum
404 was too far over there. Clearly today the pendulum is too
405 far over here when it comes to the availability of these.

406 I am not sure scheduling would be the right answer, but
407 we have to bring this back to some equilibrium.

408 Mrs. {Bono Mack.} Are you working with the physicians
409 who are saying that pain shouldn't always be treated solely
410 with opioids and that there have to be other ways of treating
411 pain, that this is creating an epidemic that is hurting more
412 people than it is saving?

413 Mr. {Kerlikowske.} I have. I have heard from a number
414 of physicians that want to be much more flexible and
415 understanding and treating pain rather than writing
416 prescriptions for 30, 60, or 90 days worth of very powerful
417 painkillers. They also want to make sure that there are
418 systems in place where they can be adequately reimbursed for
419 treatments other than what right now seems to be a very
420 simple and quick method but not always particularly effective
421 in treating pain by writing a script.

422 Mrs. {Bono Mack.} In the last 22 more seconds that I do
423 have something Attorney General Bondi cares deeply about are
424 the opiate babies. Can you speak briefly to what you have
425 learned about opiate babies?

426 Mr. {Kerlikowske.} I can. I can tell you that in the
427 past and having visited in one of the centers for newborns in
428 Seattle the issue always centered around newborns and the
429 addiction through heroin. Today when I met and saw all of

430 those infants and actually held one of those infants, the
431 issue was all about prescription drugs, and there was very
432 little discussion about mothers using heroin.

433 And so we are building some tremendous healthcare costs
434 as a result of not treating this adequately.

435 Mrs. {Bono Mack.} Thank you very much, Director, and
436 happy to recognize Mr. Butterfield for 5 minutes.

437 Mr. {Butterfield.} Thank you. Again, thank you very
438 much for coming forward today with your testimony. We have
439 heard your testimony, and we appreciate so much what you do.

440 I have a question that I would like to ask, and I may
441 even ask it of the other panels as well, but I believe it is
442 very critical, and it is central to the problem that we are
443 dealing with.

444 Efforts in one state may yield declines in the number of
445 pills dispensed, hospitalizations, or deaths, any of which
446 are very commendable achievements within that state's border,
447 but how can we be sure that addicted individuals simply don't
448 go to another state?

449 Mr. {Kerlikowske.} I think the key would be on the
450 example would be the fact that Florida had become such as has
451 been talked about, so publicly an epicenter for not only the
452 use of these very powerful, misuse and abuse of these very
453 powerful prescription drugs for people within the State of

454 Florida but for people traveling all the way through
455 Appalachia and actually New York, Connecticut, and other
456 places.

457 The regulation of medicine is done at the state level.
458 It is not done at the federal level, and we have to provide
459 the training, the technical assistance, the start-up money
460 for the computer systems, and the assistance to law
461 enforcement, particularly state and local law enforcement to
462 understand how to investigate these complex cases.

463 I would tell you that greater use of the PDMPs is
464 necessary. Not as many physicians or people in the
465 healthcare industry utilize them as should and that they need
466 to be real time and that they need to be interoperable across
467 states.

468 When those things come together and I think we are
469 seeing some of this in the number of states that are sharing
470 the information, I think that that way we can stop that
471 balloon effect that you were talking about, Congressman.

472 Mr. {Butterfield.} We have been looking at the data in
473 our office, and the data seems to suggest that the total
474 number of illicit drug users was constant for 2 years, even
475 though we have seen great strides in states like Kentucky and
476 Florida and even Ohio.

477 Are we on the right path with this?

478 Mr. {Kerlikowske.} I think we are on the right path
479 with this with what I believe is a very balanced way and a
480 very comprehensive way of looking at this. I think that if I
481 go back and look at where we were, and believe me, I am the
482 first one to tell you that a lot more has to be done,
483 particularly in redoubling our efforts in some of these
484 areas, but I look at where we were 3 years ago. As a chief
485 of police of a city of almost 700,000 people, I was really
486 unaware of this prescription drug problem. I think that my
487 colleagues who were sworn to protect people in the city and
488 learn about what are the dangers when you don't realize it,
489 when we didn't realize it and prosecutors and judges and many
490 others did not realize it, we weren't paying attention to it
491 because after all, it is a prescription, it is coming out of
492 the medicine cabinet. It was a huge mistake.

493 This is on the front page of every major newspaper on a
494 regular basis. It is on television. We are moving in the
495 right direction.

496 Mr. {Butterfield.} Let me talk about tribal communities
497 for a minute, and I only have a minute 50 left. As the
498 National Drug Control Strategy points out, tribal communities
499 have been particularly hard hit by unemployment and combined
500 with problems accessing healthcare, education, and other
501 services, tribal communities can be disproportionately

502 vulnerable to prescription drug abuse.

503 A 2009, study by the Substance Abuse and Mental Health
504 Administration found that American Indians are more than
505 twice as likely as whites to abuse prescription drugs. What
506 is the Administration doing to help tribal communities
507 address these unique challenges?

508 Mr. {Kerlikowske.} We started looking at that almost
509 immediately and a couple things that are done. First
510 Assistant Secretary Echo Hawk from the Department of Interior
511 has been a great partner, along with the Indian Health
512 Service and along with the Bureau of Indian Affairs. We have
513 made trips to a number of the tribal lands, for example, the
514 Tohono O'odham Nation in Arizona, and the issues around
515 dietary issues, alcohol issues, and illegal drugs was
516 significant, but the growing problem that was pointed out to
517 us is exactly as you said, and that is around the
518 prescription drug issues.

519 Mr. {Butterfield.} But are you working with them to set
520 up databases?

521 Mr. {Kerlikowske.} Education, so the education and
522 prevention and working through the Indian Health Service and
523 the Treatment Service, and let me just mention on the
524 enforcement side for the first time one of our high-intensity
525 drug trafficking groups, HIDTA, in Portland includes a member

526 of--a tribal chief to help direct those needed enforcement
527 resources back onto tribal lands.

528 Mr. {Butterfield.} That includes databases and other
529 resources?

530 Mr. {Kerlikowske.} I don't know about the database in
531 particular. I would think that the health service would
532 probably be more knowledgeable about that.

533 Mr. {Butterfield.} All right. Thank you. You have
534 been very kind.

535 Mr. {Kerlikowske.} Thank you.

536 Mrs. {Bono Mack.} Thank you, Mr. Butterfield.

537 The Chair recognizes Mr. Stearns for 5 minutes.

538 Mr. {Stearns.} Thank you, Madam Chair.

539 Is it true that prescription drug overdose deaths now
540 surpass our car-related fatalities?

541 Mr. {Kerlikowske.} It is true that all overdose deaths
542 are now the leading, from drugs, misuse and abuse, not
543 accidental, are the number one cause of accidental death in
544 this country, ahead of gunshot wounds and ahead of car crash
545 deaths, driven by prescription drugs.

546 Mr. {Stearns.} That is a startling fact, don't you
547 think?

548 Mr. {Kerlikowske.} Yes.

549 Mr. {Stearns.} Do you think based upon that that we

550 should have a radical change in our approach?

551 Mr. {Kerlikowske.} I think that we haven't gotten
552 anywhere near the attention or near the traction to something
553 that is killing more people in this country than car--

554 Mr. {Stearns.} And, in fact, 10 or 20 years ago I
555 wouldn't find the statistics like it is today?

556 Mr. {Kerlikowske.} Not at all.

557 Mr. {Stearns.} And why do you think that occurred?

558 Mr. {Kerlikowske.} One, I think that the driver of the
559 prescription drugs as we have been, as has been mentioned a
560 little bit, people don't see them as addictive, they don't
561 see them as dangerous, and they don't see them as deadly,
562 because they are, after all, a prescription.

563 Mr. {Stearns.} I think in your opening statement you
564 were talking about opiates were sold in 2010, to medicate
565 every American adult six times a day for a month. That was
566 in your statement.

567 Mr. {Kerlikowske.} Yes.

568 Mr. {Stearns.} Doesn't that put a line to the claim
569 that we are just getting better at pain management?

570 Mr. {Kerlikowske.} When I have spoken with the
571 physicians who looked at and were instrumental in the early
572 days of under-treating and the recognition of under-treating
573 pain, I think that a clear recognition, and as I mentioned a

574 minute ago I think that the pendulum was there and that in
575 very good faith ways they worked very hard to make sure that
576 people actually were adequately treated for pain.

577 A few things were missing. One is the amount of
578 education that a physician would need to clearly understand
579 and recognize some of the dangers of these. The other is
580 that as many people have mentioned, we have become kind of an
581 overmedicated society.

582 Mr. {Stearns.} How would we educate Americans to not be
583 an overly medicated society?

584 Mr. {Kerlikowske.} It is a pretty tough issue. It is
585 kind of like dealing with the obesity issue.

586 Mr. {Stearns.} Do you think it is something to do with
587 our culture today that--

588 Mr. {Kerlikowske.} I think that the more important part
589 is to educate the physicians around this, as physicians are
590 so much more knowledgeable about dietary issues and the
591 causes, I don't see the same level of knowledge among them
592 and among healthcare practitioners when it comes to the
593 addictive properties of these drugs.

594 Mr. {Stearns.} Could you from your department make it
595 more difficult for the doctors to provide prescription drugs
596 in the areas that are causing the overdoses? Is there
597 something that you could do?

598 Mr. {Kerlikowske.} I--we are kind of a small policy
599 shop that--

600 Mr. {Stearns.} You couldn't make any recommendations?

601 Mr. {Kerlikowske.} --we bring all of these folks
602 together. I think the key will be education and then making
603 sure that they follow the rules, and I think that we are well
604 on the way to hopefully getting that done.

605 Mr. {Stearns.} You mentioned in your opening statement
606 the actual cost to society is estimated at \$56 billion in
607 2007, and maybe likely higher today. Do you have any idea
608 what the cost in terms of devastating affects on families and
609 communities--so if it is \$56 million [sic] in 2007, what do
610 you think it is today?

611 Mr. {Kerlikowske.} Well, and I think that the most
612 recent study on the costs to the United States taxpayer on
613 drug abuse is well around \$190 billion that--

614 Mr. {Stearns.} One hundred and ninety billion.

615 Mr. {Kerlikowske.} For--and that includes all types of
616 heroin, cocaine, marijuana issues, et cetera, but I think
617 that you couldn't be more correct in putting forward the fact
618 that it is not only a huge cost in our healthcare system, it
619 is a huge personal cost and a huge personal tragedy the child
620 that doesn't graduate from high school, the employer that
621 wants to start a new business and can't find people that are

622 drug free so that they will have less accidents and be more
623 productive. All of these things play a huge part, and so the
624 dollar cost is one thing. The tragedy to this country is
625 another important part.

626 Mr. {Stearns.} Lots of times all of us talk about the
627 legal war on drugs, but we are also--I think we have to
628 consider a war on prescription drugs, and so I guess the
629 question is where does the current prescription drug war rank
630 compared to our war on illegal drugs?

631 Mr. {Kerlikowske.} I think my colleagues, particularly
632 in the Drug Enforcement Administration, when they set their
633 goals and they move forward each year in recognizing what the
634 drug threat is, several years ago they recognized this issue
635 much more quickly and actually changed their direction and
636 focus. I think you will hear about the number of what are
637 called tactical diversion squads, the number of
638 investigations, the number of local law enforcement and
639 prosecutors that have been trained in how to investigate
640 these complex cases, because these are actually legal drugs
641 that are manufactured and often through prescriptions or pill
642 mills. So those are important steps forward.

643 Mr. {Stearns.} Are we winning or losing?

644 Mr. {Kerlikowske.} We are moving ahead. I am
645 encouraged by a couple of things. One, the number of

646 dispensed opioid prescriptions has flattened, and if you
647 looked at the charts in a number of years, it looked like the
648 space shuttle taking off. The amount of opioids manufactured
649 has flattened, and the fact that in this most recent monitor
650 in the future, eighth, tenth, and twelfth graders actually
651 decreased in their use of one of the very powerful
652 painkillers, Vicodin.

653 I think we are moving there, but as the chair and others
654 know so well, it is not enough, and it is not fast enough.

655 Mrs. {Bono Mack.} Thank you very much, Mr. Stearns, and
656 I am pleased to recognize Mr. McKinley for 5 minutes for his
657 questions.

658 Mr. {McKinley.} Thank you, Madam Chairman.

659 Briefly, I think you and I had a little conversation
660 beforehand, before we began, and we were concerned about
661 privacy. I still would, I would like you to expand a little
662 bit about that. What--to me from an engineering for small
663 business perspective, I am a little concerned about, very
664 concerned about the privacy, but I know and I think you would
665 recognize that if there were a national registry of all the
666 prescription drug used in America, the pharmacies would be
667 held responsible to check that registry to find out that they
668 just got OxyContin just one day earlier for a 3-months'
669 supply, and they would be able to say no.

670 Isn't there something, some form, I know we don't want
671 to have FDA, because as we have had other hearings here,
672 someone being able to hack into that information.

673 Mr. {Kerlikowske.} Right.

674 Mr. {McKinley.} There were penalties according--that
675 are related to that, but we all know if we had a list, if
676 someone had a list, we could go hold those people responsible
677 more so than the distributors that are doing the best they
678 can to curtail that.

679 Tell me a little bit about what efforts we can do in
680 security privatizing those names so that individuals can't be
681 identified but yet we--a pharmacy would be able to know that
682 they have now, this is their third prescription for the same
683 medicine in the last 2 weeks. Isn't there something you are
684 doing on that?

685 Mr. {Kerlikowske.} I think--

686 Mr. {McKinley.} I saw this the other night. I just
687 think that is just great, education. It works so well with
688 teenage pregnancies and everything else, hasn't it?
689 Sanctions against governments that they continue to--so I
690 really want something with more substance to it that is going
691 to solve the problem.

692 Mr. {Kerlikowske.} Sure. I think the answer is the
693 prescription drug monitoring plans that are done by the

694 state. Since the Federal Government doesn't regulate the
695 practice of medicine and the state does, having the PDMP,
696 that electronic database that would be used by all physicians
697 and healthcare professionals that would be real time and that
698 in states, particularly neighboring states, that information
699 could be shared across the states.

700 When it is led and directed and the start-up money comes
701 from the Federal Government but led and directed by the state
702 government, they can put in the protections about patient
703 confidentiality and privacy. I think in the best of all
704 worlds that national database would be a wonderful thing. I
705 think it would be difficult to implement because of the
706 protections that would be needed to prevent exactly as you
707 said hacking, and I think that part of that national database
708 would be the fact that it would be 5 or 6 or 7 years in the
709 making. Right now we have all but two states that have
710 PDMPs, and as they become more well used and more well
711 robust, it will actually make a difference with their use.

712 Mr. {McKinley.} So are you suggesting, and I think I
713 understand, something that would not work with mail orders
714 because they are ordered someplace else other than just in
715 the state, but tell me again, you think that if pharmacists
716 knew by looking at computer screen that that person got--
717 would he or she still fill that prescription if he knew it

718 was being violated?

719 Mr. {Kerlikowske.} When I speak with all of the
720 different groups and the individual pharmacists, and you look
721 at their ethical standards and their patient safety practices
722 and the number of pharmacists that have picked up the phone
723 and either said, either called the physician saying something
724 isn't right or the ones that have told that patient, you know
725 what, I am not going to fill that because I have that
726 information, I am pretty heartened by where the pharmacists
727 are.

728 But I think going upstream a little bit, that doctor
729 that realizes that that patient that has come into his or her
730 office has been to two or three other physicians or that
731 patient that walks in on Friday evening to an emergency
732 department and says, gee, I am traveling or I have lost my
733 prescription or I need something like that, when that
734 frontline, upstream person can take a look at that system and
735 say, well, this is the third hospital you have been to this
736 weekend or you are seeing two other doctors with a similar
737 complaint, I am not going to be dealing with this, I think
738 that is a help also.

739 Mr. {McKinley.} So what do we do with that individual
740 when they come in? Are they held?

741 Mr. {Kerlikowske.} They are not held because I think

742 that unless they actually get, unless there is a law
743 violation, they are not going to be charged or they are not
744 going to be held, but I think the other important part of
745 this education piece is that they need to get into the
746 treatment. I have met so many people now across this country
747 on these travels that have become addicted to prescription
748 drugs, have received proper quality treatment, and they are
749 back. I mean, they are back taking care of their families,
750 they are back paying taxes, they are back working, and I
751 think that this is the entry point to get them the help that
752 they are needed, because we are talking about a disease. We
753 are talking about addiction.

754 Mr. {McKinley.} Okay. I guess we have run out of time.
755 Thank you very much.

756 Mr. {Kerlikowske.} Thank you, Congressman.

757 Mrs. {Bono Mack.} Thank you. Mr. Harper, you are
758 recognized for 5 minutes.

759 Mr. {Harper.} Thank you, Madam Chair.

760 Director Kerlikowske, thank you for your time here and
761 all that you are trying to do in a very serious situation.
762 You know, with regard to the PDMPs, what do you think the
763 biggest barrier is in the implementation of a drug-monitoring
764 program for states whose programs have yet to go online?

765 Mr. {Kerlikowske.} One of the barriers is the fact that

766 it needs to be real time, and it needs to be ease of use.
767 Physicians have about, as I have been told, about 16 minutes
768 with a new patient to assess everything. These are busy
769 practices and busy offices, and they need to be given a tool
770 that is easy, that is accessible in order to use it and of
771 course, once they do and they become schooled in it and rely
772 on it, the physicians that I have spoken with tell me that it
773 is a patient safety tool.

774 Mr. {Harper.} Okay. Now, we have 48 states that have
775 authorized programs, 40, I understand, have operational
776 programs. Are all of these state PDMPs created equal?

777 Mr. {Kerlikowske.} No.

778 Mr. {Harper.} Okay.

779 Mr. {Kerlikowske.} They are not, but we are fortunate
780 at Rice University to have a center of excellence that takes
781 the best practices that helps those that are--and of course,
782 the heads of each of these agencies come together several
783 times a year for us to be able to speak with them. We want
784 to be able to make them as robust and helpful as possible,
785 but I would be the first to tell you that some are better
786 than others.

787 Mr. {Harper.} Well, are there some that you would hold
788 out as a role model for the other states or for those that
789 have yet to go operational?

790 Mr. {Kerlikowske.} I think you will hear from Attorney
791 General Conway, and I think Kentucky is clearly one of those
792 states that has addressed this not just with a very robust
793 and smart PDMP and some pending changes that they have
794 planned in their laws to make it an even better system. I
795 would tell you that from what I have looked at in California,
796 the CURES System, is another one. The Center for Excellence,
797 they have done a very good job of putting in the hands of the
798 people that use these, develop these systems, information
799 that is necessary.

800 Mr. {Harper.} What are you seeing as strengths and
801 weaknesses as communication between the various states with
802 their monitoring programs? Is that a weak link? Do you feel
803 like that the communication between those states can be
804 improved, and if so, what would you suggest?

805 Mr. {Kerlikowske.} Now, you ask the million dollar
806 question, and I think you are exactly right. Some states are
807 easier to get along with amongst each other on this
808 particular issue and to work together. Some states when you
809 look at these systems and it is not a huge amount of money
810 but every state is facing difficult budget times, how much of
811 a priority is it. But when I talked to these physicians or
812 listen to these physicians in all these states, I said, look.
813 If I am in eastern Kentucky, I really don't want to spend the

814 time to check Ohio, West Virginia. I need to get to a system
815 that is already linked to those neighboring states.

816 Mr. {Harper.} Uh-huh. Do you--are the PDMPs the only
817 option out there for states to implement the sharing of this
818 information?

819 Mr. {Kerlikowske.} Right now on the prescription drug
820 abuse issue, those are the options. I think the healthcare
821 technology in the future, e-prescribing, all of these other
822 things will play a big role in the future and make it easier
823 and more helpful.

824 Mr. {Harper.} We want to thank you for your work on
825 this very important topic, and with that I yield back, Madam
826 Chair.

827 Mrs. {Bono Mack.} Thank you, Mr. Harper.

828 Director Kerlikowske, thank you so much for being here
829 today and all of your hard work. You have been generous not
830 only today but every day in working with me on these issues.
831 I applaud you for raising the profile for many years and
832 especially coming from somebody who said you didn't know 3
833 years ago, you certainly know now. I don't know that we have
834 all the answers, but at least we are finally starting to
835 confront it, and I look forward to working with you.

836 Thank you, again, very much for being here today. Is
837 there anything you would like to close--rather than a second

838 round of questions, something you just need to say that you
839 didn't get to say?

840 Mr. {Kerlikowske.} Madam Chair, one--I am indebted to
841 the Committee and the members of Congress that take this
842 issue on. You have so many issues in front of you, and yet
843 as I mentioned to the President on the drug issue, when we
844 think about keeping our kids in school and we think about who
845 is going to be the workforce that we are all going to depend
846 on in the future, I think about healthcare costs, I think
847 about law enforcement issues.

848 The more that we can do on the drug prevention side and
849 the more that we can do to get people adequate treatment and
850 get them back into the--into being productive members of
851 society, none of that could happen without the will and the
852 support and the help of members like you all.

853 Thank you.

854 Mrs. {Bono Mack.} Thank you very much.

855 And with that we are going to take a very, very brief
856 recess just while we seat the second panel. Hopefully it is
857 30 seconds or so, and we ask the second panel to join the
858 table.

859 [Recess]

860 Mrs. {Bono Mack.} All right. On our second panel we
861 have four very distinguished witnesses who are very deeply

862 involved in the issues of prescription drug abuse and
863 prescription drug diversion, which clearly go hand in hand.
864 We are honored today to have with us the Honorable Pamela Jo
865 Bondi, Attorney General for the State of Florida, the
866 Honorable Jack Conway, Attorney General for the State of
867 Kentucky. Also joining us are Aaron Haslam, Senior Assistant
868 Attorney General for the State of Ohio, and Joseph
869 Rannazzisi, Deputy Administrator for the Drug Enforcement
870 Administration.

871 Thank you all, again, for being with us this morning.
872 To help you keep track of time there is a timer light on your
873 table. When it turns yellow, you have a minute to wrap up.
874 So, again, you don't have to come to a screeching halt when
875 it turns red, but if you can wrap up your comments, we would
876 appreciate it.

877 So with that we are happy to recognize Attorney General
878 Bondi for her 5 minutes, and please just remember to turn
879 your microphones on, and you may begin.

|
880 ^STATEMENTS OF PAMELA JO BONDI, ATTORNEY GENERAL, STATE OF
881 FLORIDA; JACK CONWAY, ATTORNEY GENERAL, STATE OF KENTUCKY;
882 AARON E. HASLAM, SENIOR ASSISTANT ATTORNEY GENERAL, STATE OF
883 OHIO; AND JOSEPH T. RANNAZZISI, DEPUTY ASSISTANT
884 ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION

|
885 ^STATEMENT OF PAMELA JO BONDI

886 } Ms. {Bondi.} Thank you, Congresswoman Bono Mack, and
887 thank you for championing this cause on behalf of our
888 country, and thank you as well, Ranking Member Butterfield,
889 for having us here today and also to Congressman Stearns from
890 Florida and to all the Committee members. We truly
891 appreciate this.

892 I am here to tell you about what Florida is doing to try
893 to stop prescription drug abuse. As Congressman Stearns told
894 you, just to put it in perspective, of the top 100 oxycodone
895 dealers in the entire country, 98 of them were in Florida.
896 Now we have 13, and that is with legislation that has been in
897 effect barely a year. So last year we had over 900 pain
898 management clinics registered within our state. Today we
899 have 580, and I guarantee you that number is going to
900 continue to plummet.

901 I want to outline now briefly our comprehensive
902 legislation and what we have done in our state. As you know,
903 we have become the Oxy Express, and that is why I worked so
904 closely with General Conway, with General DeWine in Ohio
905 because what was happening, people were buying their drugs in
906 Florida, taking them to Kentucky. I had to hug a mother in
907 Kentucky when I was with General Conway who lost her daughter
908 2 years ago to prescription drugs that were bought in
909 Florida, and that had to stop.

910 So we passed, with that we passed tough new legislation
911 in our state, and we are very proud of that legislation.
912 Long, long overdue, let me tell you that.

913 The common characteristics of a pill mill in Florida
914 were cash business, \$200 to \$300 cash, armed guards at the
915 door, little to no medical equipment at all. Just shelves
916 and shelves of pills. These doctors who we call drug dealers
917 wearing white coats are sitting in a back room just signing
918 prescription pads, and it was legal, and it was killing our
919 kids.

920 So we had very weak regulatory oversight of the pain
921 management clinics. We had limited oversights of the
922 physicians who were dispensing, which was very important, and
923 we had a non-operational prescription drug monitoring
924 program.

925 So with that we have now passed some very tough
926 legislation, and we are very proud of that. One of the most
927 important things to me was that we banned doctors from
928 dispensing most abused narcotics, and we made that a
929 violation of the ban, both a third degree felony and how do
930 you hurt a bad doctor? Take their license away. So with
931 that dispensing ban we feel that we have been very successful
932 as well.

933 We also have--we created a standard of care for
934 physicians prescribing controlled substances. We require
935 these doctors to either electronically prescribe or to use
936 counterfeit-proof prescription pads, none of which had been
937 done in our state. We also added, as I said, enhanced
938 criminal penalties, which were very important and required
939 all of these pharmacies to be re-permitted by the State of
940 Florida.

941 We did great things. We now have the PDMP up and
942 running, which if you have any questions, I can discuss that
943 with you as well, and with that, you know, we can always
944 create tough new laws and onto something else, but what we
945 did in Florida with Governor Scott's help, we started a
946 strike force, and that is joint with federal, state, and
947 local officials all working together. You can pass these
948 laws and move on, and it is not going to work. We are

949 targeting these guys, and we are putting them out of
950 business.

951 And with that just--we have seven strike forces
952 throughout our state, and if you have questions about the
953 strike force, I can explain that in greater detail, but what
954 we have done, since we have had the strike force is we have
955 truly gone in and started putting these guys out of business.
956 We are targeting them, and we are not letting up on them.

957 We also have an educational component of this
958 legislation, and that involves narcotics overdose prevention
959 education, NOPE, and this task force, these remarkable people
960 have done an amazing job of going into our schools and
961 educating our children about this.

962 We have also instituted along with DEA state drug take
963 back days. I have participated personally in as many of
964 those as I could. You would not believe the drugs that are
965 being turned in, and it has gotten so successful that we plan
966 on putting permanent drop boxes up at our police stations and
967 our sheriff's offices as well. At two drug take back days
968 alone we seized over five tons of prescription drugs.
969 Unbelievable.

970 So and we are very pleased to announce that as of
971 February, 2012, our strike force efforts have resulted in
972 2,040 arrests, 34 of those are doctors. We have seized 390

973 weapons, almost \$5 million, but there is one other problem.
974 I have run out of time, but that is the babies being born
975 addicted to prescription drugs, and that is our newest fight
976 this session, and we are not going to give up on that as
977 well.

978 Thank you for all of your efforts, and we do know we
979 have a long way to go, but I don't think any of us in this
980 room are going to stop.

981 Thank you.

982 [The prepared statement of Ms. Bondi follows:]

983 ***** INSERT 2 *****

|
984 Mrs. {Bono Mack.} Thank you very much.

985 And General Conway, you are recognized for 5 minutes.

|
986 ^STATEMENT OF JACK CONWAY

987 } Mr. {Conway.} Well, thank you, Chairwoman Bono Mack and
988 Representative Butterfield for your commitment to this issue.
989 I also want to recognize Congressman Guthrie, who is not
990 here, but who is a fellow Kentuckian who works with our drug
991 task forces on this very important issue.

992 Prescription pill abuse is a reality that has touched
993 the lives of just about every Kentucky family. It has touch
994 my family's life in a very personal way. It has ravaged our
995 communities, it has shattered families, and it has fueled
996 crime.

997 Depending on which study you believe Kentucky is either
998 the most third or fourth most medicated state in the entire
999 country, and the four you always hear at the top of the list
1000 are Kentucky, West Virginia, Tennessee, and Oklahoma. Last
1001 year in Kentucky we had over 1,000 people that we documented
1002 died from prescription painkiller overdoses. That is more
1003 than we lost to auto accidents.

1004 And Madam Chairman, we actually think that is
1005 underreported, because our estimates are that only about half
1006 the people that actually die from overdoses autopsied by a
1007 medical examiner's offices. And when you take a look at the

1008 unnatural deaths in the Commonwealth of Kentucky, what you
1009 see over and over is not heroin or not cocaine, not even
1010 alcohol as much as you see Xanax, oxycodone, Methadone, and
1011 hydrocodone. Last year, Kentucky hospitals treated over
1012 5,000 overdose patients.

1013 Now, this is an epidemic we first started to see in the
1014 1990s in eastern Kentucky. Eastern Kentucky is a region of
1015 heavy industry, of laborers, of coal mines. We have more
1016 injury-prone jobs, but it is also an area of economic
1017 depression, and we have too many doctors who overprescribed
1018 and too many people became hooked. And because of the
1019 economic depression, people figured out they could sell their
1020 pills on the street, and a black market was born. And today
1021 when you go through eastern Kentucky, which I do on a regular
1022 basis, you will find that about 80 percent of the crime
1023 according to law enforcement and prosecutors is fueled by the
1024 abuse and the insidious addiction to prescription
1025 painkillers.

1026 The problem has spread across the Commonwealth. It is
1027 not just in eastern Kentucky. According to a ``Lexington
1028 Herald'' leader study not too long ago in 120 of our counties
1029 which we have total, 118 were up in the number of schedule
1030 two and three narcotics prescribed, and I am sad to report
1031 that estimates from law enforcement and those in the

1032 healthcare community say that we have only about 10 percent
1033 of the treatment beds that we actually need in the
1034 Commonwealth of Kentucky.

1035 You know, I am sick and tired of hearing about losing an
1036 entire generation to prescription pill abuse in the
1037 Commonwealth of Kentucky, so we have started a public
1038 education program for doctors and also for school children in
1039 Kentucky. I actually travel across the Commonwealth with two
1040 mothers from Morehead, Kentucky, who lost their daughters to
1041 prescription pill abuse, and it is really important to get
1042 people like that who look like the mothers of these kids to
1043 tell them their story, because they will listen to an elected
1044 official for 5 minutes or so, but when the mothers talk, they
1045 really listen.

1046 And here is what is disheartening. You can look at
1047 these kids, middle schoolers, high schoolers, and say, okay,
1048 you know, tell the truth. Just because I am the Attorney
1049 General, tell the truth. How many of you have used a
1050 prescription pill or your best friend has used it for an off-
1051 label purpose. I am sad to report 70 or 80 percent of the
1052 hands go up. I ask them how many think that prescription
1053 pills are easy to get. Seventy or 80 percent of the hands
1054 will stay up. Then I will ask them how many of their parents
1055 lock up their medicine cabinets. All the hands will go down.

1056 I realize it is not a problem that starts with Grandma, but
1057 in some instances, particularly in Kentucky, it is an
1058 addiction that is starting in our homes.

1059 I have tried to do all I can. I have created the
1060 state's first prescription pill task force. That is my drug
1061 investigators working with local law enforcement. We are
1062 trying to collaborate and share resources in a time of
1063 dwindling law enforcement resources. We participated in
1064 Operation Flamingo Road, where we partnered with the DEA and
1065 the Kentucky State Police to round up 500 individuals who
1066 were vanning pills up from Florida in 2009.

1067 At that point we thought about 60 percent of our pills
1068 in our streets were coming from Florida. Pam Bondi told me a
1069 story one time that they executed a search warrant on a pain
1070 management clinic in Broward County, Florida, and they seized
1071 1,700 patient records. Of those 1,700 individuals they
1072 seized the records 1,100 of them are from the Commonwealth of
1073 Kentucky. That is what we in law enforcement call ``a
1074 clue.'' We had people by the vanload going to Kentucky to
1075 bring pills back.

1076 And that is why I am not only happy to a friendship with
1077 Pam or General Bondi I should say, I am grateful that she
1078 came along at this time. She has done a tremendous job of
1079 taking on these pill pushers in her state. As she said,

1080 Florida was home to 97 or 98 of the Nation's top 100
1081 prescribers of oxycodone. Now they are down to 13.

1082 This issue knows no party. It is an American tragedy.
1083 We are doing all we can. We have new legislation in the
1084 Commonwealth of Kentucky to reregulate our pill mills. We
1085 have entrepreneurs getting in the pill mill business. We
1086 need to stop them. We have the issue of the mail order forms
1087 cease shipping 90-day supplies of schedule two and three
1088 narcotics. I understand the issue of efficiency in our
1089 healthcare system, but that needs to be 30 days, and we need
1090 to make certain that we get doctors using these systems.
1091 Yes, we have KASPER, our PDMP. It is a good system, but only
1092 about 25 percent of our doctors are using it, and on top of
1093 that those of us in law enforcement can't see the data to do
1094 the investigations that we need to do, and I would be happy
1095 to talk with you a little bit more about that.

1096 I have heard the questioning here today, and I am out of
1097 time, so I am going to wrap up, but if you want to know what
1098 you can do to help, help us get all 50 states up with PDMPs
1099 and with systems that talk to one another. We can do our
1100 jobs if we can get those systems up and running and if we can
1101 get the doctors to use them.

1102 Thank you very much for the opportunity to appear.

1103 [The prepared statement of Mr. Conway follows:]

1104 ***** INSERT 3 *****

|
1105 Mrs. {Bono Mack.} Thank you very much, General Conway.

1106 Mr. Haslam, you are recognized for 5 minutes.

|
1107 ^STATEMENT OF AARON E. HASLAM

1108 } Mr. {Haslam.} Thank you Chairman Bono Mack, Ranking
1109 Member Butterfield, and distinguished members of this
1110 Committee. I thank you on behalf of Ohio Attorney General
1111 Mike DeWine and all of Ohio for the opportunity to address
1112 you today.

1113 As the Chief Assistant Prosecutor and later the elected
1114 Prosecutor in Adams County, Ohio, I had a front row seat for
1115 the devastation that this scourge can cause on a community.
1116 In February, 2011, Ohio Attorney General Mike DeWine
1117 recruited me to lead his prescription drug task force.
1118 Attorney General DeWine has been committed to using every
1119 resource Ohio has to fight this scourge.

1120 In Ohio we have taken nationwide--a nationwide stance in
1121 fighting back through changes in legislation, proactive law
1122 enforcement actions, partnering with prescribers and
1123 dispensers and being proactive with awareness, education, and
1124 treatment.

1125 Through this effort Ohio has raised public awareness,
1126 increased public education, and improved Ohio's
1127 investigations and prosecutions in both criminal and
1128 regulatory cases.

1129 However, to make a real difference we must limit the
1130 availability of prescription drugs to those individuals in
1131 actual need and in the proper quantities. In Ohio
1132 unintentional fatal and non-fatal drug poisoning has cost
1133 Ohioans \$3.6 billion annually. Between the years of 1999,
1134 and 2007, Ohio's rate of opioid distribution increased 325
1135 percent. During that same time period Ohio's unintentional
1136 drug overdose death rate increased 305 percent. If you will
1137 look to my left, you can see this remarkable correlation on
1138 the graph located closest to the back of the room.

1139 In 1997, Ohio averaged seven doses of opioids per
1140 capita. In 2010, our average dose of opioid per capita
1141 increased to 67. In less than 15 years Ohio watched that
1142 average dose of opioids per capital increase almost 900
1143 percent.

1144 The chart to my left, the closest to the front of the
1145 room, will illustrate that the death rates during the current
1146 prescription drug scourge is much higher in Ohio than the
1147 death rates in Ohio during the heroin epidemic in the '70s
1148 and the crack cocaine epidemic in the 1990s.

1149 Ohio's leaders recognize the seriousness of Ohio's
1150 prescription drug problem. On February 8, 2011,
1151 Representatives Terry Johnson and Dave Burke, a physician and
1152 a pharmacist, introduced what is known as House Bill 93 in

1153 Ohio. The bill passed through the House and the Senate
1154 unanimously. With the support of the Attorney General,
1155 Governor John Kasich signed the bill into effect on May 20,
1156 2011, and it became law.

1157 Much like Florida, our pain clinics, our pill mills were
1158 not regulated. House Bill 93 for the first time regulated
1159 pain clinics in Ohio. It required physician ownership of
1160 pain clinics. It required prescribers to review our PMDP--
1161 sorry, our Prescription Drug Monitoring Program, which is
1162 known as OARRS in Ohio, and they had to do that when they
1163 were treating chronic pain patients.

1164 Attorney General DeWine has worked tirelessly to create
1165 a multidisciplinary approach to the investigation and
1166 prosecution of prescription drug cases. Attorney General
1167 DeWine has worked with law enforcement at the local, state,
1168 and federal levels in Ohio to investigate prescription drug
1169 cases. We are currently working with county prosecutors and
1170 federal prosecutors all across Ohio to prosecute these cases.
1171 He is proud to be a part of the state-wide team in an effort
1172 to protect Ohio's families.

1173 Our next step the Attorney General believes is to build
1174 a bridge with state and federal officials across the Nation.
1175 To have a true impact we must collaborate on a multi-state
1176 approach to combat this scourge. Ohio and the Nation must be

1177 proactive working with all the stakeholders to tackle this
1178 epidemic. When this happens you will see success.

1179 For example, in Scioto County, one of Ohio's hardest hit
1180 counties, also a border county to Kentucky, the last pill
1181 mill was closed this past December. Scioto County has a
1182 population of approximately 78,000 residents. At one time it
1183 housed 12 pill mills prior to Ohio's efforts. Today it
1184 houses zero pill mills. Just last week Scioto County learned
1185 that accidental overdoses decreased 17 percent and drug-
1186 related deaths decreased 42 percent in 2011. This was the
1187 first decrease Scioto County had seen in the past decade in
1188 these numbers. It had been a steady increase prior to 2011.

1189 I will end with a quote from Reverend Martin Luther King
1190 Jr., who said, ``We may have all come on different ships, but
1191 we are in the same boat now.'' Each of us may have arrived
1192 at the prescription drug scourge on a different ship, but
1193 today we are all in the same boat, and more importantly,
1194 people will die if we continue to ignore the scourge.

1195 Thank you.

1196 [The prepared statement of Mr. Haslam follows:]

1197 ***** INSERT 4 *****

|
1198 Mrs. {Bono Mack.} Thank you very much.

1199 Mr. Rannazzisi, you are recognized for 5 minutes.

|
1200 ^STATEMENT OF JOSEPH T. RANNAZZISI

1201 } Mr. {Rannazzisi.} Thank you. Chairman Bono Mack,
1202 Ranking Member Butterfield, distinguished members, on behalf
1203 of Administrator Michele Leonhart and the men and women of
1204 the Drug Enforcement Administration, I would like to thank
1205 you for the opportunity to appear today to discuss
1206 prescription drug diversion and the critical role the DEA
1207 plays in securing the integrity of the controlled substance
1208 supply chain and delivery system.

1209 Before I get going I would just like to thank the
1210 Chairman and this Committee for their leadership on this
1211 problem, and I also want to thank you for promoting the
1212 National Take Back Program. If I may throw in a plug, we
1213 will doing it again April 28, Saturday, state, federal, local
1214 agencies with community groups working together to collect
1215 those drugs, and I want to thank you again for that.

1216 Also, I would like to thank the leadership of Director
1217 Kerlikowske, who has gone out of his way to ensure that we
1218 get the--all of the resources that we need to do our job.

1219 The abuse of pharmaceuticals continues to be a
1220 significant problem in the United States, and it is based on
1221 pharmaceutical diversion from the supply chain and the

1222 medication delivery system, and we believe that is the major
1223 reason. There is just holes in the system. Over the last
1224 few years individuals and organizations have created schemes
1225 within the healthcare delivery system that appear legitimate
1226 but are nothing more than illegal operations to facilitate
1227 the illegal distribution of pharmaceuticals. Pharmaceutical
1228 diversion facilitated by these operations can be prevented if
1229 DEA registrants would just fulfill their obligations under
1230 the Controlled Substances Act.

1231 The act was designed so that each DEA registrant is a
1232 link in the closed system of distribution. Each registrant,
1233 manufacturers, wholesalers, distributors, practitioners, and
1234 pharmacies have a critical role to play in keeping the
1235 distribution chain closed.

1236 Two major schemes have emerged to divert millions of
1237 dosigents, powerful addictive drugs. The first one a few
1238 years back was the internet pharmacy scheme. You could go
1239 online, and you could purchase pretty much any schedule
1240 three, four, or five controlled substance you would like.
1241 hydrocodone was the drug of choice, and it came out of the
1242 distribution chain, and really no one fulfilled their
1243 obligations to the chain. You had distributors that weren't
1244 doing due diligence on pharmacies that were ordering huge
1245 amounts of hydrocodone. The pharmacists weren't checking

1246 those prescriptions to ensure they were valid, that is they
1247 were issued for legitimate medical purposes in the usual
1248 course of professional practice, and the doctors weren't
1249 doing the same thing. They were just prescribing without a
1250 legitimate reason for prescribing. There was no medical
1251 determination made. It was a major breach in the system.

1252 But because of law enforcement's focus on that problem
1253 and then Congress coming in and passing the Ryan Haight Act,
1254 we basically shut down that system. Unfortunately, that
1255 system moved back to Florida and turned into pain clinics,
1256 and pain clinics grew.

1257 Now, these pain clinics, besides the fact that they are
1258 operating illegally, they were doing the same thing that the
1259 internet pharmacies did. The only difference is on the
1260 internet pharmacies there was no face-to-face visit. In pain
1261 clinics they actually see patients, but, again, the doctors
1262 are moving huge amounts of prescriptions out the door.
1263 Pharmacists are not checking the validity of those
1264 prescriptions. They are not ensuring they are valid
1265 prescriptions, and the wholesalers and distributors just
1266 continue to ship large amounts of drugs to those pharmacies
1267 without doing due diligence, without knowing their customer,
1268 without saying, well, why are you ordering? Why are you
1269 ordering this amount of drug when every other average

1270 pharmacy in the U.S. only orders this, and you are ten, 12,
1271 14 times more than that? They have a responsibility under
1272 the act. They choose not to comply with that obligation.

1273 We are fighting this problem through education and
1274 regulatory control and enforcement. Since 2005, we have a
1275 distributor initiative that has educated distributors of
1276 their obligations under the act. When distributors fail to
1277 adhere to their obligations, DEA takes administrative or
1278 civil action against their registration. From mid 2010,
1279 through the end of 2011, we took action against five
1280 wholesaler distributors for unlawfully supplying Florida-
1281 based pain clinics or associated pharmacies with controlled
1282 substances. These actions included the issuance of immediate
1283 suspension orders and result in the restriction and loss of
1284 DEA registrations.

1285 We also focus our resources on practitioners that issue
1286 those prescriptions not for legitimate medical purpose.
1287 These practitioners feed the addiction of drug seekers and
1288 allow drugs to enter the illicit market and facilitate
1289 overdose and death. Rogue practitioner activity is not
1290 limited to Florida. In fact, rogue pain clinics are moving
1291 northward, and they operate in Georgia, Tennessee, Kentucky,
1292 and southern Ohio now in addition to out west. A DEA
1293 investigation with state and local and federal agencies of a

1294 pain clinic doctor operating in Portsmouth, Ohio, culminated
1295 this February with the doctor being sentenced to four life
1296 terms for overdose deaths of four individuals.

1297 I have to wrap it up here, but we are making progress.
1298 DEA is using its regulatory authority to ensure compliance
1299 with the CSA and its implementing regulations. These
1300 measures that we are taking are beginning to show promise.
1301 We are strengthening the integrity of the system through
1302 registrant compliance.

1303 In closing I want to assure you that DEA is working
1304 closely with all of our counterparts; federal, state, and
1305 local, and our regulatory counterparts as part of the
1306 Administrator's comprehensive approach to combating
1307 prescription drug abuse. We are committed to balancing the
1308 need for diversion control enforcement with the need for
1309 access to these important medications by legitimate users.

1310 Thank you for this opportunity to appear, and I look
1311 forward to answering any questions.

1312 [The prepared statement of Mr. Rannazzisi follows:]

1313 ***** INSERT 5 *****

1314 Mrs. {Bono Mack.} Thank you very much.

1315 I am going to recognize myself for 5 minutes of
1316 questioning, and I would like to begin with General, Attorney
1317 General Bondi, and I know you care passionately and you and I
1318 have spoken about the opiate babies, and it is my belief that
1319 when people dabble with heroin or cocaine, they understand
1320 they are dabbling with a potential addiction. They don't
1321 necessarily think that when they start playing around with
1322 pharmaceuticals.

1323 Can you speak to why you are so focused on the opiate
1324 babies? I mean, you really are passionate about it. I would
1325 love for you to--you ran out of time, so please talk about it
1326 for a little bit if you could.

1327 Ms. {Bondi.} Absolutely. You know, right after we
1328 passed our legislation last session I started getting calls
1329 from neonatal intensive care nurses, neonatologists, and said
1330 there is another problem, and you have got to come see this.
1331 I went to Saint Joseph's Hospital in Tampa. Twenty percent
1332 of the babies going through the neonatal intensive care unit
1333 are born addicted to prescription drugs.

1334 Now, imagine the worst addict you can see on TV going
1335 through those withdrawals, that is how these babies are born
1336 into this world. Their incubators have to be covered with

1337 blankets. They are sensitive to light, to sound, to touch.
1338 Instead of milk, they are getting morphine or methadone.
1339 That is how these kids are coming into this world.

1340 All Children's Hospital in St. Petersburg, that is a
1341 premiere hospital for children, 30 percent of the babies
1342 going through the neonatal intensive care unit born addicted
1343 to prescription drugs, and it has to stop. Take it from a
1344 cost perspective. I take it from a life, babies' lives, but
1345 if you look at it from a cost perspective, Saint Joe's had to
1346 expand their NICU just to accommodate these babies. So it is
1347 costing taxpayers a fortune, and I think a lot of it really
1348 has to do with education, and that is why we have legislation
1349 proposed this session. I have talked to adoption lawyers, I
1350 have talked to nurses, we brought in the Board of Health, we
1351 brought in the Board of Medicine. It is all about working
1352 together to educate these women, because unfortunately, I
1353 think some of these women will say I have stopped drinking
1354 alcohol, I have stopped smoking marijuana, but because it is
1355 the word prescription drugs, they don't realize the harm that
1356 it is doing to their unborn child.

1357 What scared me to death, Chairman Bono Mack, was when I
1358 asked a doctor, I said, we can't let this become the next
1359 crack baby epidemic, and he said, we have already surpassed
1360 it.

1361 Mrs. {Bono Mack.} Thank you. I just wanted to say we
1362 don't even know the long-term consequences for these opiate
1363 babies, and I just want to turn with my limited time to Mr.--
1364 and hopefully we will have a second round of questioning, but
1365 Mr. Rannazzisi, you and I have had multiple discussions, and
1366 we are not always on the same page, but I applaud some of
1367 your efforts recently.

1368 You and I have talked about quotas. If Florida is
1369 having success at shutting down their pill mills, wouldn't
1370 the quotas show a correlating reduction in the quotas that
1371 you do allow the manufacturing of these drugs? Are you
1372 seeing that?

1373 Mr. {Rannazzisi.} Actually, we are seeing a decrease
1374 somewhat in Florida, but we are seeing the expansion of these
1375 pill mills throughout the country. If you go to Tennessee,
1376 Kentucky, southern Ohio, and most of those in southern Ohio
1377 were shut down, but we still continue to see those flow out,
1378 and I just right now, even though Florida is on the going
1379 downhill, states north of Florida are starting on the rise.
1380 This problem is just, again, just moving north and west.

1381 Mrs. {Bono Mack.} Well, I am just glad you hear you
1382 admit that and to say that. That is encouraging to me, but
1383 can you speak briefly about the Cardinal Case? Now that the
1384 district court has dissolved the temporary restraining order,

1385 what are the next steps in the Cardinal Case, and apparently
1386 Cardinal plans to appeal. If the district court's order is
1387 upheld, what is the next step?

1388 Mr. {Rannazzisi.} Because that case is in active
1389 litigation, I am not allowed to answer questions, however, I
1390 can tell you we have had cases similar to Cardinal in the
1391 case in the last 2 or 3 years. They are exercising their
1392 appeal rights, and we respect that. We will continue on with
1393 this program. Looking at our distributors, making sure that
1394 they meet their obligations under the act, and if they don't
1395 meet their obligations under the act, we will take the same
1396 action that we have taken.

1397 Mrs. {Bono Mack.} I am just encouraged because long ago
1398 you and I argued that it was all coming out of Grandma's
1399 medicine chest. Correct?

1400 Mr. {Rannazzisi.} Yes, ma'am, and not that I don't
1401 still believe it is coming out of the medicine chest, but I
1402 believe that we are handling it upstream now to prevent it
1403 from getting down to that level.

1404 Mrs. {Bono Mack.} Thank you for that.

1405 Mr. Haslam, you talk about shipments, whole cargo
1406 containers that go missing but they are unreported. Do you
1407 want to speak to that?

1408 Mr. {Haslam.} Anecdotally, law enforcement throughout

1409 Ohio has told us that they, that cargo shipments are falling
1410 off the trucks. We have heard--

1411 Mrs. {Bono Mack.} Just magically.

1412 Mr. {Haslam.} Just magically. We have heard--

1413 Mrs. {Bono Mack.} Yes.

1414 Mr. {Haslam.} --through conversations with
1415 manufacturers about their security measures, and they do seem
1416 to be very good security measures as Director Kerlikowske
1417 alluded to earlier.

1418 However, there seems to be a point as it gets further
1419 down the chain that the security measures either weaken or
1420 are not as efficient, and once it gets to the distributors
1421 and then they send it to their distributors who send it out,
1422 there appear to be security measures that aren't in place
1423 that allow shipments to fall off of trucks.

1424 Mrs. {Bono Mack.} Thank you very much. My time is up,
1425 and I would like to recognize Mr. Butterfield for 5 minutes.

1426 Mr. {Butterfield.} Thank you. Let me go to the
1427 gentleman from the DEA. How do you pronounce your name? Is
1428 it Rannazzisi?

1429 Mr. {Rannazzisi.} Rannazzisi. Yes.

1430 Mr. {Butterfield.} Yes. All right. Thank you. Let me
1431 talk with you about the security procedures followed by the
1432 prescription drug manufacturers, specifically how the drug

1433 moves from raw materials to usable medicine, then to
1434 distributors, and then down to the wholesalers. Are you
1435 comfortable, sir, with the security mechanisms employed by
1436 these companies?

1437 Mr. {Rannazzisi.} The physical securities for the most,
1438 the physical security systems for the most part I am. We do
1439 onsite inspections every 3 years or so for manufacturers,
1440 importers, exporters, any other raw material holders, and if
1441 there is problems in physical security, we handle it onsite.
1442 We make suggestions, and generally it is corrected.

1443 Mr. {Butterfield.} All right. What kind of
1444 relationship does the DEA have with the prescription drug
1445 industry? Specifically, what programs does DEA employ to
1446 educate DEA manufacturers and distributors? How closely, if
1447 at all, does DEA audit or approve security measures employed
1448 by the manufacturers and distributors, and is there a
1449 difference in procedure for authorized distributors versus
1450 secondary distributors?

1451 Mr. {Rannazzisi.} Well, first of all, we are on site
1452 for these distribution and manufacturing facilities every 3
1453 years. In addition, for instance, the wholesalers and the
1454 distributors, we have a program called the Distributor
1455 Initiative where we sit down, not as a group, but
1456 individually with each company, and we go over their

1457 distributions, and we talk to them about what to look for
1458 when they are sending their drugs downstream. We offer them
1459 assistance to help them identify what diversion is and where
1460 it is, and that is done individually by company.

1461 The manufacturers, we have an open door as far as the
1462 manufacturers go. I don't think we have ever had a problem
1463 with the manufacturers where we haven't rectified that
1464 problem.

1465 So we are regulators. We have a relationship between
1466 regulators and the industry, and we oversee them and make
1467 sure that they are operating under the act, in compliance
1468 with the act.

1469 Mr. {Butterfield.} All right. Technology advances have
1470 enabled new abuse deterrent drugs to take the place of
1471 conventional pills. I am encouraged by the addition of
1472 abuse-deterrent drugs into the marketplace, and while it is
1473 not a silver or magic bullet in completely stopping
1474 prescription drug abuse, it seems to be a tool that can
1475 greatly help.

1476 Some medications have been reformulated to be extremely
1477 difficult to crush and dissolve. These are what we call
1478 abuse deterrent drugs and new additions to the prescription
1479 drug marketplace and have not yet been widely adopted. But
1480 things are moving in the right direction.

1481 Question. How do you think abuse-deterrent formulations
1482 will have an impact on reducing opiate abuse, and how do we
1483 ensure that those who are addicted do not just switch to a
1484 new drug such as Fentanyl or heroin?

1485 Mr. {Rannazzisi.} I think that the abuse, well, first
1486 of all, we are very supportive of these assistance
1487 formulations. We think that is the future that will curb
1488 drug abuse.

1489 However, we also know that abuse-resistance formulations
1490 tend to stop drug abusers from ingesting the drug in certain
1491 manners, for instance, injection or snorting the drug. When
1492 they need to, they take it orally, and abuse-resistant
1493 medication generally does not affect how you take it orally.

1494 What we are seeing in the field is they are taking the
1495 drug orally with an agent that will give it a synergistic
1496 property to enhance the, for instance, for a drug like
1497 oxycodone, they will take it with an Alprazolam product or
1498 Carisoprodol, which is a muscle relaxant to enhance the
1499 product, the effects of the product.

1500 Mr. {Butterfield.} Thank you. I yield back.

1501 Mrs. {Bono Mack.} Thank you, Mr. Butterfield.

1502 Mr. Harper, you are recognized for 5 minutes.

1503 Mr. {Harper.} Thank you, Madam Chair, and if I could,
1504 Mr. Rannazzisi, if you I could ask you a few questions.

1505 First, what regulation does DEA have that specifically
1506 outlined the legal requirements that pharmacies,
1507 distributors, and manufacturers are required to take to avoid
1508 drug diversion?

1509 Mr. {Rannazzisi.} Well, for starters, pharmacists are
1510 held pretty much to the same standard that doctors are under
1511 1306.04, 1306.04 says a prescription is not valid unless it
1512 is issued for legitimate medical purpose and use, of course,
1513 a professional practice. It also goes on to say that a
1514 corresponding responsibility exists with the pharmacist to
1515 ensure that the prescription is valid.

1516 Mr. {Harper.} Okay.

1517 Mr. {Rannazzisi.} The manufacturers under 1301.71 and
1518 1301.74 have to maintain a system that stops diversion or the
1519 diversion of controlled substances into other than a
1520 legitimate marketplace. And it also goes on to say that you
1521 also have to maintain a system of suspicious ordering
1522 monitoring, and they leave it up to the manufacturers and
1523 distributors to determine how to set up that system of
1524 suspicious ordering and monitoring.

1525 Mr. {Harper.} You know, I know the DEA has the ability
1526 to see unusual ordering patterns. Are there certain
1527 thresholds or levels that you pass on to the distributors to
1528 look for? Are you giving them guidelines to--that you pass

1529 off?

1530 Mr. {Rannazzisi.} No. I think what distributors have
1531 to do is look at their customers. They know their customers.
1532 I don't know all of their customers. They do. If they went
1533 onsite and looked at their customers, they could make a
1534 determination of what thresholds should be maintained for
1535 those individual registrant customers.

1536 The problem is is I don't believe that the distributors
1537 and the wholesalers are actually looking at their customers
1538 as closely as they should. If you have customers that on the
1539 average purchase, I don't know, 70,000 oxycodone tablets a
1540 year and you have customers purchasing well in excess of a
1541 million a year, I think that would trigger something where
1542 you should go onsite and find out why that is the issue.

1543 Mr. {Harper.} Does the DEA have those volume parameters
1544 that it uses but are not shared with manufacturers or
1545 distributors?

1546 Mr. {Rannazzisi.} No. We--no, we don't share, we don't
1547 give them volume parameters. That is up to them. It is
1548 their system that they are setting up.

1549 Mr. {Harper.} All right. Well, what guidance has DEA
1550 provided to the manufacturers, distributors, pharmacies, or
1551 whatever on the specific steps that they should be taking to
1552 identify fraudulent prescriptions? What advice are you

1553 giving them to look for or suggestions?

1554 Mr. {Rannazzisi.} Well, there are certain red flags.

1555 Mr. {Harper.} Okay.

1556 Mr. {Rannazzisi.} For instance, a pharmacy. If you
1557 have, if you are sitting in we will say Portsmouth, Ohio, and
1558 all of your customers are coming from, I don't know, 80 or
1559 100 miles away, and the doctor you are filling for is 100
1560 miles the opposite way, and it is all cash transactions, and
1561 you are seeing this over and over again, you know, I am not
1562 the smartest guy, but red flags pop up in my mind when that
1563 happens.

1564 Mr. {Harper.} Yes.

1565 Mr. {Rannazzisi.} And I think those are typical red
1566 flags, and Attorney General Bondi I am sure, or any one of
1567 these distinguished gentlemen could tell they are seeing the
1568 same thing that I am seeing. So over and over again we see
1569 these red flags. The pharmacists should see them, too.

1570 Mr. {Harper.} Would you favor under the Controlled
1571 Substance Act to create a stricter requirement, legal
1572 requirement for the most problematic drugs?

1573 Mr. {Rannazzisi.} I think the requirements that are in
1574 place right now for these drugs are fine if the individuals
1575 within the supply chain and healthcare delivery system would
1576 follow them. The problem is that the doctors continue, not

1577 all doctors, 99 percent of the doctors are perfect. It is
1578 that small percentage of doctors that just don't want to
1579 fulfill their obligation. What they do is prescribe for
1580 illegitimate purposes, or they don't make a medical
1581 determination. They just go with patient-directed
1582 prescribing, which is just wrong. I think that if everybody
1583 within that supply chain would just police each other, we
1584 wouldn't have the problem that we have right now.

1585 Mr. {Harper.} I thank each of the witnesses for being
1586 here today and for your insight, and with that I yield back.

1587 Mrs. {Bono Mack.} Thank you, Mr. Harper.

1588 Mr. McKinley, you are recognized for 5 minutes.

1589 Mr. {McKinley.} Thank you again.

1590 Let us go back to Florida or maybe Kentucky, but let us
1591 start with Florida. When you have your program, your PDMP,
1592 do you have an identification system? Is that how--is that
1593 included in it?

1594 Ms. {Bondi.} We, as I am sure you are aware, we had
1595 some very difficult problems getting our PDMP in place, our
1596 Prescription Drug Monitoring Program. It was, you know, 48
1597 states have a PDMP but many weren't up and running, and ours
1598 was one of them.

1599 We received some resistance. What we have done now is
1600 that it is up and running. We had some issues with getting

1601 it funded. Do you know who came forward?

1602 Mr. {McKinley.} Wait a minute. Do you have an
1603 identification so when someone comes in, is this--do they
1604 enter their name or something into--

1605 Ms. {Bondi.} Yes.

1606 Mr. {McKinley.} --a file?

1607 Ms. {Bondi.} Yes, and it used--

1608 Mr. {McKinley.} It is available for everyone in the
1609 State of Florida?

1610 Ms. {Bondi.} Absolutely, and it used to be 15-day
1611 reporting, and now we have limited that down to 7-day
1612 reporting.

1613 Mr. {McKinley.} Okay. So--

1614 Ms. {Bondi.} So we have shortened the reporting period.

1615 Mr. {McKinley.} --if it works in your state, why
1616 wouldn't that work nationally?

1617 Ms. {Bondi.} Well, and this is, like I said, brand new
1618 in our state because it had never been funded. So now it is
1619 funded by forfeiture funds from our sheriff for the next few
1620 years.

1621 Mr. {McKinley.} What about Kentucky? What are you
1622 doing in Kentucky? Do you have the database or names?

1623 Mr. {Conway.} We have the database, and what happens in
1624 Kentucky, we were one of the first states to bring a PDMP

1625 online, Congressman, but our doctors will go in and enter a
1626 patient name to see if that particular patient is doctor
1627 shopping. The problem we have in Kentucky is, it is a pretty
1628 good system, but only about 25 percent of our doctors are
1629 using it. It is not mandatory. It is not mandatory that ER
1630 docs, for example--

1631 Mr. {McKinley.} Okay. Thank you.

1632 What concerns me some is you have done a great job in
1633 Florida. You just chased them to another state. That is
1634 what I am hearing from the other testimony here, and what we
1635 are hearing from around the country is that you did a great
1636 job. It happens in law enforcement when you start performing
1637 your duties, they go someplace else because they are not
1638 going to change their behavior. They just transfer to
1639 another state.

1640 I am looking to see how we can capture them nationally.

1641 Ms. {Bondi.} And we still have a long way to go in
1642 Florida, but I think what we are doing is we are working
1643 together, and as long as I can tell you the two of us are
1644 still alive, we are going to put this, we are going to put
1645 these guys out of business. I mean, we work together
1646 constantly, we share ideas, we share thoughts, and we frankly
1647 in Florida we work great with the DEA. We--you have to work
1648 as a team, and I don't know if you were here earlier for that

1649 part of it, but you have to bring state, local, and federal
1650 authorities and now wrap all of our states into this, because
1651 this is a national crisis, and I mean, we are in a war with
1652 drugs, and just the drug has changed.

1653 Mr. {Conway.} If I may address that point, Congressman,
1654 not to take up too much of your time, but Kentucky borders
1655 seven states, and the pharmacists when they fill a script,
1656 enter the data that goes into the system that doctors later
1657 check.

1658 The problem for us has been that the docs feel like it
1659 is too time consuming. The docs don't want to be forced to
1660 do this, and they don't have a system that they think is user
1661 friendly that they can type in, takes 30 seconds or less, and
1662 tells you if you are in eastern Kentucky whether or not this
1663 patient has been to West Virginia, Ohio, or Virginia or
1664 Tennessee.

1665 And that is what we don't have, and really a state like
1666 Kentucky can't get to where we need to be. We can't get 50
1667 states with a good system that is interoperable unless we
1668 have the help of the Federal Government.

1669 Mr. {McKinley.} And Ohio, do you have the names up on--
1670 do you have with your program, do you have the names, the
1671 individual, so they know, we know what prescription drug they
1672 are acquiring?

1673 Mr. {Haslam.} We do, Congressman, and our program has
1674 been up and running for many years as well just as Kentucky's
1675 has.

1676 Mr. {McKinley.} Do you see a problem with that going
1677 nationally?

1678 Mr. {Haslam.} I don't. I think it is one of the
1679 necessary tools that we are going to need to fight this
1680 epidemic.

1681 Mr. {McKinley.} How do you deal with the privacy
1682 matter, because that seems to be the hang up, the
1683 confidentiality of people to access. What--how did you get
1684 around that for the State of Ohio?

1685 Mr. {Haslam.} Well, it is very protected by--our Ohio
1686 State Pharmacy Board houses that program, and they are very
1687 protective over the information and who it goes to and how it
1688 is distributed, and that is how they get around it. They
1689 make sure that it is protected, but it is, it is a necessary
1690 tool in this battle as we move forward.

1691 Mr. {McKinley.} So you are saying some states, in your
1692 three states, you all have that. You are doing something
1693 along that line.

1694 Mr. {Conway.} The information is protected. Only the
1695 doctor is going to see it, and if we have a designated case
1696 open on a specific target, we can ask to see the KASPER data,

1697 but one of the problems we have seen is that the Board of
1698 Medical Licensure when they see disturbing trends are not
1699 forwarding onto law enforcement. We have that problem in
1700 Kentucky.

1701 Mr. {Haslam.} That is the same issue in Ohio,
1702 Congressman. It is a great tool. It is under-utilized by
1703 our physicians. House Bill 93 required physicians that are
1704 treating pain management to utilize it, but as, exactly as
1705 you have alluded to, as we have success in law enforcement,
1706 we are squeezing the balloon and people are just moving to
1707 other states.

1708 And what has happened, the three states represented here
1709 today have all worked wonderfully together to tackle this
1710 issue and to share that information and investigations.

1711 Mr. {McKinley.} I know the time. I think you are great
1712 models. I just want to see it replicated in all 50 states so
1713 we can protect this thing. We can't have you operating in
1714 the middle. So thank you. I yield back my time.

1715 Mrs. {Bono Mack.} Thank you, and Dr. Cassidy, you are
1716 recognized for 5 minutes.

1717 Dr. {Cassidy.} Thank you, Madam Chair. First I will
1718 say that we are introducing Mike Ross and I from the other
1719 side of the aisle, H.R. 4095, which is the Stop Online
1720 Pharmacy Safety Act, which attempts to close down or at least

1721 prevent the publicizing of these rogue pharmacies. So
1722 hopefully we will get some cosponsors on this.

1723 Secondly, Mr. Rannazzisi, man, I keep on thinking with
1724 the databases you all have, if we gave them to Google, I have
1725 no doubt that Google knows what color dress my daughter has
1726 on today. And so it seems like data mining could really go a
1727 long way to pinpointing these problems for a specific
1728 intervention. I am told by industry that you all have lots
1729 of data forwarded to you regularly.

1730 My question is why not?

1731 Mr. {Rannazzisi.} I think the data they are referring
1732 to is our ARCOS System.

1733 Dr. {Cassidy.} Yes.

1734 Mr. {Rannazzisi.} Yeah. Under 827(D) they are required
1735 to send all narcotic control substance transactions to us to
1736 be put in a database, and we do have that information, and
1737 quite frankly, we use that information to assist us in
1738 investigations.

1739 However, that information is proprietary. It is
1740 protected information. I can't release that information to
1741 industry, and they have asked--

1742 Dr. {Cassidy.} But you could release it to local law
1743 enforcement.

1744 Mr. {Rannazzisi.} If local law enforcement is involved

1745 in investigation and they request the information, yes, we
1746 can.

1747 Dr. {Cassidy.} Let me ask because as I go through the
1748 testimony you have rank ordered states in which there is the
1749 highest prescriptions per capita of controlled substances,
1750 you have related it to over 65 how many people on Medicare
1751 Part D are getting X amount per, in a certain region. I also
1752 see other statistics where you speak about three or four
1753 physicians moving from one state to another, so you have
1754 physician level, and I am sure you also have a pharmacy
1755 level. It just seems, again, if Google had that or some
1756 other data miner had that, we could have a specific
1757 intervention here. Boom. And then there and then there. I
1758 seems like there is missed opportunities. What am I missing
1759 on this?

1760 Mr. {Rannazzisi.} I don't believe there is missed
1761 opportunities. The data that we have is very narrow. It is
1762 for the narcotic controlled substances. For instance, I am
1763 dealing with a pharmacy or a group of pharmacies and
1764 manufacturers or distributors that are selling Fentermine or
1765 Alprazolam or drugs like that. I have no way of tracking
1766 because it is not entered into the system.

1767 Dr. {Cassidy.} But if we just took those which are
1768 narcotics, I mean, probably there is going to be a

1769 correlation between somebody getting an illegal prescription
1770 for Ativan as well as an illegal prescription for OxyContin.
1771 So I am not saying you have to do the breath, but, again, if
1772 you have reported to you the narcotics for OxyContin--

1773 Mr. {Rannazzisi.} Uh-huh.

1774 Dr. {Cassidy.} --again, knowing that you just from here
1775 have a heck of a lot of data--

1776 Mr. {Rannazzisi.} Uh-huh.

1777 Dr. {Cassidy.} --why aren't we doing every week another
1778 intervention at another pharmacy because it seems like it is
1779 a target-rich environment.

1780 Mr. {Rannazzisi.} We are. We have active
1781 investigations across the country based on complaints and our
1782 ARCOS data. Now, sometimes the ARCOS data might show up with
1783 a pharmacy that is, indeed, a legitimate pharmacy that does
1784 have a high volume, and the reason they have a high volume is
1785 because they are next to a hospital or oncology--

1786 Dr. {Cassidy.} And that is a fair statement. I can
1787 imagine a cross tab which would say, okay, here are the
1788 variables that we find associated with, you know, again, I
1789 can see Google with an algorithm that you give them.

1790 Mr. {Rannazzisi.} Right.

1791 Dr. {Cassidy.} Which would data mine. Are you all data
1792 mining on that, formally data mining?

1793 Mr. {Rannazzisi.} Yes. We look at that, we look at
1794 ARCOS data on a regular basis. We look at the top 50, top
1795 100 in different areas of the country. We make sure that,
1796 you know, we do background and make sure those pharmacies and
1797 wholesalers are operating within the confines of the law, and
1798 if we have further information on it, we open investigations.
1799 Yes. That is what ARCOS is for. ARCOS is a targeting tool.

1800 Dr. {Cassidy.} How many active investigations do you
1801 all have right now?

1802 Mr. {Rannazzisi.} I would have to get back. I don't
1803 want to throw out a number.

1804 Dr. {Cassidy.} Ballpark, 50, 100, or 1,000?

1805 Mr. {Rannazzisi.} Oh, we have a lot. Many more than
1806 1,000.

1807 Dr. {Cassidy.} Now, kind of a recurring theme from
1808 these folks is that people go from one state, they go to
1809 another. I live in Louisiana, my pain doc is legitimate and
1810 tell me that illegitimate patients, if you will, go to
1811 Mississippi or Houston and then back again.

1812 So is federal, in your mind is federal legislation
1813 required that would almost mandate some sort of standard so
1814 that Texas, Louisiana, Mississippi, Arkansas, or Kentucky
1815 with every state bordering it would be in some sort of
1816 interchangeable information?

1817 Mr. {Rannazzisi.} I think--my personal opinion is, yes,
1818 I would love to see that because I think doctors need that
1819 additional tool. I think there as a practitioner you would
1820 agree that I want to know what my patient is doing and who my
1821 patient is seeing, whether it is in Kentucky, Ohio, or, you
1822 know, four states over.

1823 The problem is interconnectivity, and the problem is is
1824 a lot of these states have different state laws and different
1825 laws regarding the information and how it could be
1826 distributed. So I don't think it is--I think the problem
1827 lies within the states. They have to work it out. This is
1828 not a Federal Government system, and while we support the
1829 states and we want the states to get that interconnectivity,
1830 that is a question better asked to the states. It is their
1831 decisions.

1832 Dr. {Cassidy.} Just if I may have a few more seconds, I
1833 will say that after Hurricane Katrina and all my patients
1834 were displaced to other states, I found that those, there is
1835 something that happened, a switch was turned, and a doctor in
1836 Oklahoma could find out the drugs I was prescribing for my
1837 patients in Louisiana, and so it does seem as if that
1838 interoperability could occur in a fairly straightforward
1839 fashion if we had, you know, a little direction.

1840 Mr. {Rannazzisi.} I remember that, and that state

1841 boards were working extremely well together, and I don't know
1842 how that information was passed because we don't have
1843 dispensing information, but I do know that we were working
1844 with the--

1845 Dr. {Cassidy.} I think it was through E-scripts. I
1846 think that there was something like that.

1847 Mr. {Rannazzisi.} But the state boards really came
1848 together, and they did a fine job getting everybody in line.

1849 Dr. {Cassidy.} So there is a chance we just need those
1850 folks to talk to their state boards.

1851 Thank you. I yield back.

1852 Mrs. {Bono Mack.} Thank you, Dr. Cassidy.

1853 The chair recognizes Ms. Blackburn for 5 minutes.

1854 Mrs. {Blackburn.} Thank you so much, and I want to
1855 thank you all for your patience today. As you know, we have
1856 had other hearings downstairs. We had Secretary Sebelius and
1857 looking at the budget that is there, and I know that those of
1858 you at the state level are quite concerned about the Obama
1859 Care impact that is coming to a state near you very quickly.

1860 Mr. Rannazzisi, am I saying your name correctly?

1861 Mr. {Rannazzisi.} Yes, ma'am.

1862 Mrs. {Blackburn.} I am close enough.

1863 Mr. {Rannazzisi.} Perfect.

1864 Mrs. {Blackburn.} Okay. On the Ryan Haight Act how

1865 many online pharmacies have registered under that act? What
1866 is--how is that being built out?

1867 Mr. {Rannazzisi.} Currently I--we have no registered
1868 pharmacies under the act. We have I think four or five
1869 applications pending but no pharmacies have been registered.
1870 Now, remember there are a lot of provisions in the act that
1871 allow you to do certain things online that is not, that you
1872 don't--the Act was written so it would prevent the rogue
1873 pharmacies from jumping online and continuing practice, and
1874 it has done that. There is no domestic pharmacies currently
1875 there operational that are under--

1876 Mrs. {Blackburn.} Okay. Then let me ask you this
1877 another way. How many enforcement actions has DEA taken
1878 against online pharmacies or rogue pharmacies under the act?

1879 Mr. {Rannazzisi.} I would have to get back to you,
1880 ma'am. Very few because the act pretty much shut down the
1881 domestic online pharmacy problem, and the problem moved
1882 overseas.

1883 Mrs. {Blackburn.} Okay. Are you having difficulty in
1884 sorting and finding out which are the rouge foreign-based
1885 pharmacies or--I would like to visit with you more about
1886 that. I think that it is an issue that is of concern to us
1887 and being able to see where we have these online pharmacies,
1888 find out who is registering or not. That would be helpful

1889 and instructive to us.

1890 So let us look at that a little bit and then if you
1891 could quantify the kind of actions that have been taken
1892 against some of these rogue pharmacies, just--it allows us to
1893 do a little bit of due diligence and see if decisions we are
1894 making are working or having an impact or not. So I would
1895 appreciate having that time with you.

1896 I want to talk with you for just a little bit, if you
1897 can answer this within the allotted time, that is great, and
1898 if you need to get back to me, that would be great. I am no
1899 cheerleader for the FDA, but I understand their philosophy
1900 and approach that, in that an agency as it applies to
1901 controlled substances seems much more measured than that of
1902 the DEA at times, and my understanding is I want to talk
1903 about this post-inspection feedback in the form of what is
1904 known as the FDA form 483, Inspection Report.

1905 And my understanding on this FDA form 83 [sic] is that
1906 it sets out with specificity the agency's concerns and the
1907 parties have the opportunity to meet with the FDA and discuss
1908 any issues that may be before them, that companies are given
1909 the opportunity to address issues and solve problems in a
1910 collaborative dialogue.

1911 And if the company were to choose not to address the
1912 issues, the agency then typically takes further action in the

1913 form of a warning letter and proceeds with prosecution and
1914 consent decrees as appropriate. And I think that that FDA-
1915 type approach is different from the DEA approach when there
1916 are problems, which his just enforcement and not the
1917 opportunity to address concerns.

1918 So it seems like DEA there is no post-inspection give
1919 and take or dialogue that may be there and no information
1920 sharing or the opportunity to address issues or--that are out
1921 there. So my question to you is this, and you mentioned
1922 Tennessee as one of the states with the pill mills, and you
1923 know, we all are concerned about patients that are in pain
1924 that need medication, companies that are trying to meet those
1925 needs, and here, again, want companies to do the right thing,
1926 want them to spend the money wisely, want individuals to be
1927 safe, want there to be protections that are in place.

1928 So my question is is there a more surgical approach?
1929 Should we be thinking of a more surgical approach to
1930 addressing the issue of prescription drug abuse rather than
1931 just looking at suspension of licenses? You know, where is
1932 the right balance in a vetting process? Is there a more
1933 proportional approach to take rather than just going to an
1934 immediate suspension?

1935 Mr. {Rannazzisi.} Yeah. I would love to answer that
1936 question. First of all, the FDA deals mostly with legend

1937 drugs, and they do have manufacturing processes they do with
1938 controlled substances, but the vast majority of their
1939 authority is over legend drugs and prescription drugs, making
1940 sure they have good manufacturing processes, maybe making
1941 sure that labeling is correct, putting the drug through the
1942 appropriate validation process.

1943 My responsibility under the act is to ensure that there
1944 is no diversion of highly-addictive medications into an
1945 illicit marketplace. We do give chances to companies. If you
1946 look at our history, we went onsite on many of these
1947 companies that we have taken action against and pharmacies
1948 and explained to them what their obligations were. We sat
1949 down with them and talked to them of what their obligations
1950 were. They just--

1951 Mrs. {Blackburn.} Okay. So your response then would be
1952 that you all are carrying out that dialogue?

1953 Mr. {Rannazzisi.} Yes.

1954 Mrs. {Blackburn.} Okay. All right.

1955 Mr. {Rannazzisi.} Yeah. I look at Florida and the
1956 millions of tablets that are going into the illicit
1957 marketplace in Florida, not only from the pharmacies but also
1958 from the distributors and the doctors. And I think we have
1959 to hold the line somewhere. These are drugs that are killing
1960 people. It is not Amoxicillin, and you know, we have to take

1961 a stand.

1962 Mrs. {Blackburn.} Okay. Do any of the others of you
1963 want to make a response to that? No? Okay.

1964 Madam Chairman, I will yield back.

1965 Mrs. {Bono Mack.} Thank you, and I am going to
1966 recognize myself for 5 minutes for a second round and any
1967 other member who wants to ask a second round, I will yield to
1968 you for your own 5, and then we will move to the third panel.

1969 My, first of all, my comment on what Dr. Cassidy had to
1970 say, I think he brought up a good point, and I think it is
1971 fair to ask if the DEA data mining capabilities are as robust
1972 and clever as you would suspect. Googles are and perhaps we
1973 can visit that in the days ahead, but this is a, sort of a
1974 general question to each of you, and thank you, Mr.
1975 Rannazzisi, for mentioning my support of your take back days,
1976 but 995,000 pounds of drugs in 3 days.

1977 The question I want to ask each of you if you would care
1978 to comment or weigh in is who is paying for those pills? Are
1979 we paying for them in the form of healthcare premiums? Are
1980 we paying for them through diversion out of Medicare Part D
1981 and Medicaid? Who is paying for all of those pills? Why are
1982 there 995,000 pounds of extra pills being turned back in?
1983 What is the overall toll in healthcare in our country just
1984 from this problem?

1985 Anybody?

1986 Ms. {Bondi.} I can tell you from our local take back
1987 days these are good, solid citizens who are coming in with
1988 brown paper bags filled with prescriptions that they have had
1989 and that they are concerned because they know you cannot
1990 flush prescription drugs down your toilet, and they don't
1991 know what to do with them, and they don't want their
1992 grandkids to get a hold of them, and you know, when I speak
1993 to people, I say, no one ever wants to believe it is their
1994 kids, so I say, your kid's friends can get into your medicine
1995 cabinet.

1996 So people--it is our citizens, and I think a lot of them
1997 are getting them from their doctors, their dentists for
1998 legitimate purposes. They are taking one or two of them, and
1999 they are just stockpiling them because they don't know what
2000 to do with them, but we have had remarkable results with good
2001 citizens turning them in to have them properly disposed of.

2002 Mrs. {Bono Mack.} But the question is is why is there
2003 so many left over in the medicine chest to turn back in? Who
2004 is paying for--what is the cost, and General Conway, you
2005 mentioned this is an American tragedy, and I couldn't agree
2006 with you more. There is no question our doctors are working
2007 too hard, and ultimately this comes out of their patient
2008 visit, they are scrambling because healthcare is squeezed

2009 more and more and more, and this is a part of the problem.
2010 But \$148 million diverted out of Medicare Part D in 2008,
2011 alone.

2012 So are we really, I mean, General Conway, do you want to
2013 weigh in on--

2014 Mr. {Conway.} Well, I don't know that I can quantify
2015 the cost. I mean, sitting here as the Attorney General of
2016 Kentucky I can't quantify the cost, but my experience is
2017 similar to General Bondi's. When I go to one of our drug
2018 take back days and sit there with my plastic gloves on, it is
2019 the concerned mother who doesn't want her kids and realized
2020 she saw something on TV and her hydrocodone she got for a
2021 broken arm is expired.

2022 The cost comes in crime. People are committing thefts
2023 to get access to resources to buy pills. The cost comes in
2024 cash. A lot of these pill mills deal on a purely cash basis.
2025 When you have healthcare companies that are trying to get
2026 more efficient in mandating 90-day supplies of some of these
2027 mail order pills, a 90-day supply in Kentucky of hydrocodone
2028 or oxycodone, chances are about 50 percent of that is hitting
2029 the streets. That is what my law enforcement officials are
2030 telling me. That is something that we need to quantify.

2031 And certainly Medicare and Medicaid are paying some of
2032 that.

2033 Ms. {Bondi.} And Chair Bono Mack, I think what you are
2034 saying is if you go in for a routine dental surgery, why do
2035 you need 60 oxycodone pills.

2036 Mrs. {Bono Mack.} Exactly.

2037 Ms. {Bondi.} You don't.

2038 Mrs. {Bono Mack.} Thank you. Thank you, and Mr.
2039 Haslam, you speak on this, to this in your testimony, too.
2040 You suggest that maybe they have sort of a tiered approach
2041 into needing the drugs. Do you want to speak a little bit
2042 about your beliefs on this, too?

2043 Mr. {Haslam.} Absolutely, Madam Chairman. The--what we
2044 see in Ohio we see--to answer your original question, the
2045 taxpayers at some level is paying for the problem. No matter
2046 how you look at it when you boil it down to the common
2047 denominator, it is the taxpayer that is paying for it,
2048 whether it is Medicaid costs in Ohio, especially in southern
2049 Ohio, which is economically depressed, it borders eastern
2050 Kentucky as we have heard Attorney General Conway elude to is
2051 an economically-depressed area. That--it is a huge burden on
2052 the Medicaid System there, and as you move across the State
2053 of Ohio, though, it is not limited to that socioeconomic
2054 class. It goes all through all the way to the middle class
2055 up to the upper class, and whether it is a company that has
2056 to pay increased healthcare premiums that is I providing for

2057 its employees because of the number of pills their employees
2058 are receiving as part of a prescription or the insurance
2059 companies, the cost to those folks. The insurance companies
2060 in Ohio have recently reached out to the Attorney General's
2061 office to talk with us and say what role do we play in this?
2062 This is a huge cost to our bottom line. It touches
2063 everybody.

2064 So at the end of the day it is the taxpayer that is
2065 footing the bill for this prescription drug problem and for
2066 those large amounts of pills that are on the street.

2067 Mrs. {Bono Mack.} Thank you. So when we win the day
2068 with the arguments of the human suffering of the budgetary
2069 tolls, there is no rhyme or reason why we wouldn't be
2070 tackling this head on as a Nation, and again, Mr. Rannazzisi,
2071 one last question to you.

2072 This committee has been investigating nano encryption,
2073 intagence, and other technologies coming out. Can you speak
2074 briefly about future technologies that you might be exploring
2075 like this on tracking drugs?

2076 Mr. {Rannazzisi.} Ma'am, I can't take that question for
2077 the record. I am not an expert on--

2078 Mrs. {Bono Mack.} Okay.

2079 Mr. {Rannazzisi.} But I do have experts on staff.

2080 Mrs. {Bono Mack.} That is fair. You know we will be

2081 submitting plenty of questions to each of you for the record.

2082 Mr. Butterfield, did you have--

2083 Mr. {Butterfield.} I have one.

2084 Mrs. {Bono Mack.} All right. I will yield to you--

2085 Mr. {Butterfield.} Thank you.

2086 Mrs. {Bono Mack.} --for 5 minutes.

2087 Mr. {Butterfield.} Thank you. Under the careful

2088 supervision of a doctor, prescription drugs can alleviate

2089 severe pain or help those suffering from mental disorders

2090 like psychosis or depression or anxiety or insomnia or

2091 attention deficit disorder. Unfortunately, there are true

2092 stories of these drugs being prescribed inappropriately or

2093 not for their intended use.

2094 Only 54 percent of physicians ask about prescription

2095 drug abuse when taking a patient's medical history, and only

2096 55 percent regularly contact their patients' previous doctor

2097 before prescribing controlled pain medication.

2098 Question. State entities certify and regulate both

2099 doctors and pharmacies. Through this role, General Conway,

2100 what do you think state authorities can do to educate medical

2101 practitioners?

2102 Mr. {Conway.} Well, the thing about the medical

2103 community, Congressman, is that it is not a one-size-fits-all

2104 approach, and we have a piece of legislation we are

2105 considering right now in the general assembly that I am
2106 supportive of that would require anyone who wants to
2107 prescribe a schedule two or three narcotic to mandatorily
2108 register with our PDMP.

2109 But I think that the education component for the medical
2110 community is important. The Chairwoman talked about what
2111 needs to happen with short-term prescriptions. Our ER docs
2112 need to have standards for how much should they prescribe if
2113 someone shows up at the ER. They ought to do mandatory PDMP
2114 checks.

2115 The problem for us in law enforcement and in Kentucky,
2116 and I can't speak to it in other states, but in Kentucky we
2117 have a little bit of a battle with our medical community in
2118 that the KASPER System, our PDMP, is housed over in a cabinet
2119 of Health and Family Services. They have the data. They
2120 observe the trends that are problematic. They are supposed
2121 to take actions against licenses if they spot problematic
2122 trends and then refer them to law enforcement if necessary.

2123 Until this issue received increased scrutiny here in the
2124 last couple of months, in my first 4 years as Attorney
2125 General, I didn't have a single law enforcement referral from
2126 the Board of Medical Licensure.

2127 So the doctors, if they are going to be prescribing, you
2128 know, there are different standards for an oncologist or pain

2129 management doctor from a podiatrist and an allergist. But
2130 the doctors that are going to be prescribing have an
2131 obligation to use the system, to check their patients, and to
2132 help us police their profession, because they are under-
2133 utilizing the system right now, and they need to work with us
2134 so that we can see the data.

2135 I cannot ask who are the two largest prescribers of
2136 schedule two and three narcotics in Pike County. I would
2137 love to, but the law prohibits me from doing it, and the
2138 Board of Medical Licensure is not sending me the data. So I
2139 am using old-fashioned surveillance and talking to people
2140 about where are they getting the pills in order to figure it
2141 out, and we have a great system, and all the data is right
2142 there. We are just under-utilizing it, and we are under-
2143 utilizing it because we don't have the partnership we need
2144 with the medical community to make certain that that is
2145 getting addressed in Kentucky.

2146 Mr. {Butterfield.} Would it be helpful to work with
2147 some of the medical schools, the dental schools to develop a
2148 curricula in this area?

2149 Mr. {Conway.} Oh, absolutely. I speak to the pharmacy
2150 students, and I speak to a lot of medical students on an
2151 annual basis to tell them how big the problem is and to look
2152 out for this. You know, it is a balance here. The medical

2153 community gets nervous whenever an Attorney General or a
2154 lawmaker gets in the middle of the doctor, patient
2155 relationship, and I respect that. I respect that, but there
2156 ought to be some way for us to see the disturbing trends so
2157 that we can do our job in law enforcement, and right now in
2158 Kentucky our data monitoring law says I have to have a
2159 designated case, a bona fide case open on a designated
2160 target. I can't look at trends. I can't see where the
2161 problems are. I have to ask about Mr. Smith, and the data is
2162 all there, and I can't use it, and I can't tell you how
2163 incredibly frustrating that is.

2164 Mr. {Butterfield.} Do you believe the Federal
2165 Government should consider certain minimum standards for
2166 doctors, for doctor education or training in the area of
2167 addiction medications?

2168 Mr. {Conway.} I don't think it is a bad idea.
2169 Traditionally the regulation of the practice in medicine has
2170 been left to the states. I respect that. I think we are
2171 doing all we can in the Commonwealth of Kentucky to educate
2172 doctor. A lot of the healthcare organizations are starting
2173 to set up--some of our larger hospital companies are starting
2174 to set up standards for their ER docs. I think that is
2175 great. I think it is something probably best left to the
2176 states, but I would welcome some federal guidance on that.

2177 Mr. {Butterfield.} All right. Thank you. I understand
2178 you may have spent some time at Duke University.

2179 Mr. {Conway.} I did, sir. I did, sir, and I don't know
2180 your allegiance. One of the toughest things I have to do is
2181 get elected statewide in the Commonwealth of Kentucky being a
2182 graduate of Duke University. It is--basketball passions
2183 being what they are.

2184 Mr. {Butterfield.} The state legislature has just added
2185 Duke University to my district.

2186 Mr. {Conway.} Well, Roy Cooper and I have a running
2187 argument every time we see each other, and I am going to see
2188 him this weekend. I am sure we will be arguing over that
2189 little game this weekend.

2190 Mr. {Butterfield.} All right. Thank you.

2191 Mrs. {Bono Mack.} Thank you. Mr. McKinley? No?

2192 Okay. Well, we--the next panel. Okay. We want to
2193 thank you all very, very much for your expertise and your
2194 hard work on this. We look forward to working with you.
2195 Please anticipate further questions in writing. We look
2196 forward to getting your responses.

2197 Again, thank you for fighting this battle, and we look
2198 forward to partnering with you in the future. Safe travels
2199 home.

2200 Ms. {Bondi.} Thank you, Chair.

2201 Mr. {Conway.} Thank you.

2202 Mrs. {Bono Mack.} We will take quick 30-second break
2203 while we seat the next panel.

2204 [Recess]

2205 Mrs. {Bono Mack.} On our third panel we have five
2206 witnesses. First is John Gray, President and CEO of
2207 Healthcare Distribution Management Association. Our next
2208 witness is Joseph Harmison, a Pharmacist and Owner of DFW, it
2209 sounds like Dallas Fort Worth Airport--oh, it is. Okay. Of
2210 DFW Prescriptions, who is testifying on behalf of the
2211 National Community Pharmacists Association. Hopefully I will
2212 be flying through DFW later today.

2213 We also have another pharmacist joining us, Kevin
2214 Nicholson, Vice President of the National Association of
2215 Chain Drug Stores. Next is Kendra Martello, Assistant
2216 General Counsel, Pharmaceutical Research and Manufacturers of
2217 America, and our final witness is David Gaugh, Vice President
2218 for Regulatory Science of the Generic Pharmaceuticals
2219 Association.

2220 Welcome everyone. I think you know the drill. The 5
2221 minutes. There is the timer, and with that we will be happy
2222 to turn to you, Mr. Gray, for your 5 minutes. Please make
2223 sure your microphone is on.

|
2224 ^STATEMENTS OF JOHN M. GRAY, PRESIDENT AND CEO, HEALTHCARE
2225 DISTRIBUTION MANAGEMENT ASSOCIATION; JOSEPH H. HARMISON,
2226 OWNER, DFW PRESCRIPTIONS, ON BEHALF OF NATIONAL COMMUNITY
2227 PHARMACISTS ASSOCIATION; KEVIN N. NICHOLSON, R. PH., VICE
2228 PRESIDENT, NATIONAL ASSOCIATION OF CHAIN DRUG STORES; KENDRA
2229 A. MARTELLO, ASSISTANT GENERAL COUNSEL, PHARMACEUTICAL
2230 RESEARCH AND MANUFACTURERS OF AMERICA; AND DAVID GAUGH, R.
2231 PH., VICE PRESIDENT FOR REGULATORY SCIENCE, GENERIC
2232 PHARMACEUTICALS ASSOCIATION

|
2233 ^STATEMENT OF JOHN M. GRAY

2234 } Mr. {Gray.} Now it is greener. Thank you. Good
2235 afternoon, Chairman Bono Mack and Ranking Member Butterfield
2236 and members of the Energy and Commerce Subcommittee on
2237 Commerce, Manufacturing, and Trade. I am John Gray,
2238 President and CEO of the Healthcare Distribution Management
2239 Association, and I want to thank you all for the opportunity
2240 to come here today and talk about this critically important
2241 problem of prescription drug abuse and diversion, and most
2242 importantly, what my members are doing to combat that
2243 problem.
2244 The pharmaceutical distribution industry's primary

2245 mission is operate the safest, most secure, and efficient
2246 supply chain in the world. As part of this mission HDMA and
2247 its members are committed to addressing the serious national
2248 problem of prescription drug abuse and to being a part of the
2249 solution.

2250 HDMA members have not only statutory and regulatory
2251 responsibilities to detect and prevent diversion and control
2252 prescription drugs, but to undertake such efforts as
2253 responsible members of our society.

2254 To address the issue of prescription drug abuse,
2255 distributors have developed complex systems to help prevent
2256 diversion of medicines and to comply with the DEA's expanded
2257 expectation for suspicious order in monitoring and reporting.

2258 To aid in the development and implementation of these
2259 systems, in 2008, HDMA and its member companies developed the
2260 Industry Compliance Guidelines to support the distribution
2261 industry practices on the evaluation of customer orders for
2262 controlled substances and the reporting of so-called
2263 suspicious orders to the DEA. The ICGs, as we call them,
2264 were vetted with the DEA in advance to their publication.

2265 These guidelines emphasize the concept of ``know your
2266 customer.'' That is obtaining and reviewing thorough
2267 background information about a perspective healthcare
2268 provider prior to doing business with them. Therefore, in

2269 many cases potential problems can be avoided even before an
2270 order is placed.

2271 Because the advanced systems now in place and the
2272 industry's proactive efforts, the DEA reported last year that
2273 since 2006, and 2011, distributors in this country stopped
2274 shipping controlled substances to more than 1,500 customers
2275 that could have posed an unreasonable risk of diversion.

2276 Let me add it is critical that the anti-diversion
2277 efforts of our industry, as well as the enforcement actions
2278 of DEA, should always carefully balance the need to cut off
2279 supply to any customer engaged in diversion while not
2280 limiting access to appropriately-prescribed and legally-
2281 dispensed medicines for seriously ill patients or potentially
2282 putting legitimate pharmacies out of the business.

2283 Despite the best efforts of our industry, we find
2284 ourselves today in a conundrum. Pharmaceutical distributors
2285 do not manufacture legal controlled substances. We do not
2286 license pharmacies or healthcare providers. We do not write
2287 prescriptions for patients. We do not dispense these
2288 products to patients. We do not see the prescription a
2289 patient presents for filling at a pharmacy. A single
2290 pharmaceutical distributor does not know and has no way of
2291 knowing if a pharmacy customer is purchasing prescription
2292 drugs from other distributors.

2293 Furthermore, we do not determine or set prescription
2294 drug fill rates.

2295 However, the DEA receives information from each
2296 distributor that sells controlled substances to a particular
2297 pharmacy or prescriber. The agency also sets annual
2298 allowable production quotas for manufacturers of these
2299 controlled substances. Distributors are often held
2300 accountable with incomplete information for diversion from
2301 parts of the supply chain they simply do not control.

2302 To comply with DEA's expectations, distributors are
2303 being asked to judge the diagnosis, intent, medical
2304 knowledge, experience of doctors and pharmacists.

2305 Furthermore, the DEA's emphasis on volumes and national
2306 averages to determine suspicious orders may simply over
2307 simplify the problem for schedule two controlled prescription
2308 drugs. Our members have found the analysis of a single
2309 pharmacy's controlled substance ordering pattern is simply
2310 far more complex and includes critical factors such as the
2311 size of the pharmacy, the patient demographics, the
2312 geographic proximity to the hospitals or surgery centers,
2313 nursing homes, cancer clinics, hospice providers, and other
2314 major urban areas.

2315 Now, as was stated earlier today, I need to correct
2316 that. We do not choose not to comply with these laws of

2317 suspicious ordering. The fact is our members have many
2318 questions about the compliance. You have heard this is a
2319 relatively new process, a new procedure, and unfortunately,
2320 today with the questions we have remaining each distributor
2321 essentially operates in an information silo. We are unaware
2322 if a new pharmacy customer may have been cut off by another
2323 distributor who had concern about potential diversion at the
2324 pharmacy, or we are unaware that an existing pharmacy
2325 customer is ordering controlled substances from multiple
2326 distributors. Or we are also unaware that specific
2327 pharmacies may be dispensing controlled substances for
2328 physicians who are writing prescriptions for patients when
2329 there is no legitimate medical need.

2330 So in an effort to break down these walls and get this
2331 new program going, HDMA has asked DEA in face-to-face
2332 meetings over the last several years as well as in written
2333 communications to provide some clarification and guidance on
2334 the agency's expanded expectations of an anti-diversion
2335 program for wholesale distributors, and we have sought
2336 greater information sharing in the process between the agency
2337 and our industry.

2338 Throughout these communications HDMA and its members
2339 have also asked DEA to provide aggregated and critically-
2340 important blinded data from the ARCOS System that could be

2341 used to further assess product orders and provide supportive
2342 information for the agency and for the members.

2343 A distributor does not have the independent ability to
2344 determine whether a pharmacy or a physician customer is
2345 ordering from multiple distributors. Only the DEA possesses
2346 that information.

2347 In closing, we strongly believe that all stakeholders,
2348 doctors, pharmacists, distributors, manufacturers, and
2349 indeed, the government must work together to achieve this
2350 shared goal to ensure a sufficient, safe supply of medicines
2351 for legitimate patients while keeping those same drugs out of
2352 the hands of individuals who will abuse them.

2353 Ms. Chairman, thank you for your time.

2354 [The prepared statement of Mr. Gray follows:]

2355 ***** INSERT 6 *****

|

2356 Mrs. {Bono Mack.} Thank you, Mr. Gray.

2357 Mr. Harmison, you are recognized for 5 minutes.

|
2358 ^STATEMENT OF JOSEPH H. HARMISON

2359 } Mr. {Harmison.} Thank you, Madam Chairwoman.

2360 Mrs. {Bono Mack.} Turn the mic on and pull it close to
2361 you, please.

2362 Mr. {Harmison.} Does it help if I get it closer?

2363 Mrs. {Bono Mack.} Yes. Thank you.

2364 Mr. {Harmison.} I am sorry. I have a hearing deficit,
2365 and people say I talk too softly. Sorry. Good afternoon,
2366 Madam Chairwoman Bono Mack, Ranking Member Butterfield, and
2367 Members of the subcommittee. I am Joe Harmison. I am a
2368 practicing pharmacist. I am a pharmacy owner and past
2369 President of the National Community Pharmacists Association.
2370 NCPA is a national organization representing the owners and
2371 pharmacists of the non-publically traded community
2372 pharmacies.

2373 Everyone here today is in agreement that the United
2374 States has a problem with drugs abuse, misuse, and diversion.
2375 I hope we will also acknowledge that the drugs we are
2376 discussing today when used appropriately are extremely
2377 beneficial. When they are not used as intended, they are
2378 destructive in many ways.

2379 As has been stated over and over, the majority of people

2380 that abuse prescription drugs get them from the family
2381 medicine cabinet or friends. This shines a very bright light
2382 on how we need to destroy these drugs. The community
2383 pharmacists in the United States have been excited, willing
2384 participants in the Drug Take Back Program for Destruction.

2385 The problem we have, we are not allowed to take back the
2386 controlled substances of what--those are the drugs we really
2387 want to get off the street. We can't handle that. We are
2388 anxiously awaiting the rules we have been told with DEA they
2389 are promulgating to allow us to participate in this process.

2390 The pharmacists of America interact with millions of
2391 patients every day and advises them on how to use their
2392 medicine correctly and what can happen if they don't. We
2393 cannot cure the problem we are addressing today by ourselves.
2394 We use the tools we have, but we need more tools.

2395 There have been many suggestions on how you can get more
2396 or people can get more information to us. I am very much in
2397 agreement that the most readily-implementable procedure we
2398 have out now is the PDMPs. Every pharmacist in I believe it
2399 has been stated 48 states has to submit on a regular basis
2400 the information on the controlled substances they dispense.
2401 This goes into some giant computer somewhere.

2402 The problem the pharmacists have with it is most of us
2403 don't have access to that information. It is certainly not

2404 in real time, and it is not able to be incorporated into our
2405 workflow systems. If you can find a way to get that to us,
2406 we will be your greatest advocates in using it. We do not
2407 want to be the drug police. We would be very willing to work
2408 with all parties to prevent abuse, misuse, and diversion.

2409 Another thing with this computer database, it must not
2410 be the deciding factor on whether a patient gets their
2411 medicine. That decision must be left to the responsible
2412 parties, the prescribers and the pharmacists. We are the
2413 ones that know the patients best. We know their conditions.

2414 Another very important part of this equation is pharmacy
2415 burglaries and robberies. In 2010, there were 686 armed
2416 robberies of pharmacies in the United States, and
2417 unfortunately, some of these end up with murders involved
2418 with them. Unfortunately, I have way too much experience
2419 first hand with pharmacy burglaries. One of my pharmacies
2420 has been burglarized three times since December 1, 2011.
2421 This is one small pharmacy, and from what I can determine the
2422 street value of the drugs taken from my pharmacy is in excess
2423 of \$575,000. And more onerous than that, there were almost
2424 10,000 doses of controlled substances potentially put on the
2425 street.

2426 I would like to make a few recommendations for your
2427 consideration. One, require mandatory minimum sentences for

2428 robberies and burglaries involving controlled substances.
2429 Find some way to give federal, state, and local law
2430 enforcement and prosecutors the ability to better communicate
2431 and coordinate their efforts to do their work.

2432 Third, shut down the pill mills. Get the back actors
2433 out of the process. Leave those of us that are trying to do
2434 the best we know how, what we are trained to do, care for
2435 patients, to do our job. Another is consider a change to the
2436 tax code to allow those of us that have put out the money to
2437 have different security systems, to depreciate those in 1
2438 year. Don't make us depreciate it over 7, 10, or more years.

2439 And also we would hope that you might reconsider
2440 allocating some of the money taken from forfeiture from
2441 crimes related to controlled substance, put that in a pot
2442 somewhere and let pharmacists apply for some of that money.
2443 If they can't afford security systems, let them apply to use
2444 some of that forfeiture money.

2445 NCPA and the Community Pharmacists of the United States
2446 will--are committed to working with Congress and law
2447 enforcement to combat drug use, abuse, and diversion, but we
2448 need your help.

2449 Thank you for the ability to be here today and your
2450 attention.

2451 [The prepared statement of Mr. Harmison follows:]

2452 ***** INSERT 7 *****

|
2453 Mrs. {Bono Mack.} Thank you, and Mr. Nicholson, you are
2454 recognized for 5 minutes.

|
2455 ^STATEMENT OF KEVIN N. NICHOLSON, R. PH.

2456 } Mr. {Nicholson.} Chairman Bono Mack, Ranking Member
2457 Butterfield, and subcommittee members, thank you for the
2458 opportunity to testify. My name is Kevin Nicholson. I am a
2459 pharmacist and Vice President of Government Affairs and
2460 Public Policy for the Nationals Association of Chain Drug
2461 Stores. NACDS represents traditional drug stores,
2462 supermarkets, and mass merchants with pharmacies. Our
2463 members operate more than 40,000 pharmacies and employ more
2464 than 3.5 million employees, including 130,000 pharmacists.

2465 Our members are deeply committed to serving the
2466 healthcare needs of Americans. We are serious about the
2467 trust our patients impart upon us and about our
2468 responsibilities to provide the highest quality care. We are
2469 keenly aware of the scourge of prescription drug diversion,
2470 and our members actively work on numerous solutions. We also
2471 support a number of new and federal, state policy
2472 initiatives.

2473 DEA has implemented comprehensive regulations for a
2474 closed system to minimize the diversion of controlled drugs.
2475 Our members have developed extensive policies and procedures
2476 to comply with DEA's regulatory regime and similar

2477 requirements from state agencies such as board's pharmacy and
2478 narcotic drug agencies. A complex regulatory and policy
2479 matrix of checks and balances protects Americans.

2480 Chain pharmacies have zero tolerance for prescription
2481 drug diversion. We have implemented a variety of extensive
2482 and robust loss prevention and internal security systems from
2483 our prescription drug distribution centers to the point of
2484 dispensing to patients. Examples include that we conduct
2485 background checks and random drug testing, extensive DEA
2486 training within 30 days of hire, maintaining electronic
2487 inventories of controlled substances with random auditing,
2488 use of camera surveillance closer to television, heavy-duty
2489 safes, and complete alarm systems, training employees on how
2490 to handle suspicious prescriptions, and internally
2491 investigating unusually large drug orders.

2492 Chain pharmacies support and comply with state
2493 prescription drug monitoring programs. We support policies
2494 to prevent illegitimate internet drug sellers from illegally
2495 selling prescription drugs to consumers, and we support
2496 efforts to provide consumers with the means for proper
2497 disposal of unwanted medications in ways authorized by law
2498 enforcement.

2499 NACDS is pleased to offer our support for the Online
2500 Pharmacy Safety Act, which would take important steps to shut

2501 down the illegitimate internet sellers that prey on
2502 consumers. We applaud subcommittee members Bill Cassidy and
2503 Mike Ross for their strong commitment to protecting the
2504 American public. Approximately 36 million Americans have
2505 purchased prescription medications online without a
2506 prescription. Americans are being harmed by these rouge
2507 internet sites daily.

2508 We also look forward to DEA's upcoming regulations to
2509 allow consumers to safely dispose their unwanted controlled
2510 prescription drugs. DEA recognizes that consumers' inability
2511 to safely dispose of controlled prescription drugs
2512 contributes to prescription drug diversion.

2513 NACDS routinely meets with DEA officials to learn about
2514 diversion trends and to develop strategies to mitigate and
2515 reduce problems, and although we support the mission and
2516 objectives of DEA, we do have concerns with DEA's recent
2517 policies surrounding the volumes of controlled substances
2518 ordered by pharmacies.

2519 Every pharmacy environment is different, and enforcement
2520 action should not be brought against a pharmacy merely based
2521 on the number of controlled substances ordered or dispensed.
2522 Certain pharmacy locations will have higher-than-average
2523 volumes of controlled substances. For the ultimate good of
2524 patients who rely on access to controlled substances for

2525 legitimate purposes such as pain management, we urge DEA to
2526 take a holistic approach when developing policies to pursue
2527 enforcement actions.

2528 We have worked over the past few years to develop
2529 prescription drug risk management programs with FDA called
2530 REMS to reduce the potential for addiction and abuse of
2531 prescription drugs, and we will continue to work with FDA on
2532 future similar risk management programs. We also meet
2533 routinely with the White House Office of National Drug
2534 Control Policy on trends and solutions.

2535 We are proud of the comprehensive approach that our
2536 chain pharmacies have taken and look forward to continuing
2537 our work with federal and state policymakers to implement
2538 solutions, including expanding prescription drug monitoring
2539 programs, shutting down illegitimate internet sites, and
2540 providing consumers with the ability to safely dispose
2541 unwanted prescription drugs.

2542 I thank you for the opportunity to appear and welcome
2543 your questions.

2544 [The prepared statement of Mr. Nicholson follows:]

2545 ***** INSERT 8 *****

|

2546 Mrs. {Bono Mack.} Thank you, Mr. Nicholson.

2547 Ms. Martello, you are recognized.

|
2548 ^STATEMENT OF KENDRA A. MARTELLO

2549 } Ms. {Martello.} Thank you. Chairman Bono Mack, Ranking
2550 Member Butterfield, and distinguished members of the
2551 subcommittee, my name is Kendra Martello, and I am pleased to
2552 offer this testimony today on behalf of the Pharmaceutical
2553 Research and Manufacturers of America or PhRMA. Our members
2554 represent America's leading pharmaceutical research and
2555 biotechnology companies.

2556 Our prescription drug distribution system is a closed
2557 system. This means that all entities engaged in the
2558 manufacture, distribution, and dispensing of pharmaceutical
2559 products, including controlled substances, must be licensed,
2560 registered, or approved by FDA, DEA, or the states. Thus,
2561 each entity has a shared responsibility to prevent diversion
2562 of pharmaceutical products.

2563 When an authentic product is diverted, it could be
2564 mishandled and potentially cause patient harm if reintroduced
2565 into the legitimate supply chain. Additionally, the diverted
2566 medicine can be misused or abused.

2567 The Controlled Substances Act and DEA regulations
2568 require entities handling these products to register and to
2569 have in place effective controls and security measures to

2570 protect against theft, loss, or diversion of controlled
2571 substances. The DEA also has authority over websites
2572 dispensing controlled substances and recent additional
2573 authority to supervise return of unused controlled substances
2574 for disposal.

2575 PhRMA member companies engage in a variety of activities
2576 to help prevent diversion of their products from the
2577 regulated supply chain. Our companies take these efforts
2578 seriously because fundamentally patient safety and the public
2579 health demand no less. Our members employ a range of
2580 measures to prevent diversion from facility security
2581 including uniformed guards, fences, and extensive access
2582 control and video surveillance systems to strict controls
2583 over in-process manufacturing operations to in-transit
2584 security measures such as the use of GPS tracking devices on
2585 18 wheelers that carry medicines across the country to
2586 enhancing enforcement by information sharing with law
2587 enforcement officials and to helping educate other on best
2588 practices. Our companies work to help secure the products we
2589 manufacture in the regulated supply chain.

2590 Because of the number of independent actors in the drug
2591 distribution chain, preventing diversion of medicines from
2592 the regulated supply chain is a shared responsibility.
2593 Recognizing this PhRMA members participate in broad-based

2594 coalitions to help address specific aspects of prescription
2595 drug diversion. These include coalitions to increase
2596 penalties for cargo theft, groups to facilitate information
2597 sharing and best practices, and participation in stakeholder
2598 coalitions that are pursuing new authorities in a variety of
2599 related and significant areas. These activities are detailed
2600 further in my written testimony submitted for the record.

2601 We do believe that there are additional authorities that
2602 could also have a significant impact on reducing diversion as
2603 well as reducing the non-medical use of prescription drugs.
2604 These include, first, increase the use of and improvements to
2605 state prescription drug monitoring programs, which can be an
2606 important tool to prevent and detect abusers and refer them
2607 for treatment.

2608 Second, reauthorize NASPER, which provides grants for
2609 these state's monitoring tools and which is legislation we
2610 have supported. Third, increase penalties for and
2611 enforcement against criminal cargo theft, Rogan mine drug
2612 sellers, and criminal counterfeiters. Fourth, fully
2613 implement DEA authorities over online sales of controlled
2614 substances and responsible secure disposal of unused
2615 controlled substances. And finally, increase licensure
2616 requirements for wholesale distributors to prevent
2617 unscrupulous actors from moving their operations across state

2618 lines.

2619 In conclusion, PhRMA and its member companies are
2620 dedicated to improving the lives of patients. This emphasis
2621 on the patient extends throughout the product life cycle,
2622 from researching and developing new medicines, including
2623 abuse-resistant formulations, to helping ensure medicines are
2624 used appropriately, to helping prevent diversion from the
2625 regulated supply chain.

2626 At the same time addressing the growing problem of
2627 prescription drug abuse is also a shared responsibility, and
2628 patients need continued access to the medicines they need to
2629 allow them to live longer, healthier lives. We remain
2630 committed to addressing the issues surrounding prescription
2631 drug diversion and inappropriate use of prescription
2632 medicines, and we look forward to continuing to work with the
2633 subcommittee, members of Congress, and other stakeholders on
2634 these important issues. Thank you.

2635 [The prepared statement of Ms. Martello follows:]

2636 ***** INSERT 9 *****

|

2637 Mrs. {Bono Mack.} Thank you, Ms. Martello.

2638 Mr. Gaugh, you are recognized.

|
2639 ^STATEMENT OF DAVID GAUGH

2640 } Mr. {Gaugh.} Thank you. Good afternoon, Chairman Bono
2641 Mack, Ranking Member Butterfield, and members of the Energy
2642 and Commerce Subcommittee on Commerce, Manufacturing, and
2643 Trade. I am David Gaugh, Vice President of Regulatory
2644 Sciences at the Generic Pharmaceutical Association and a
2645 licensed pharmacist.

2646 GPhA represents the manufacturers, distributors, the
2647 finished dose generic pharmaceuticals bulk chemicals, and
2648 also suppliers of other goods and services to the generic
2649 pharmaceutical industry. Generic pharmaceuticals now fill
2650 about 80 percent of all prescriptions dispensed in the United
2651 States but consume just 25 percent of the total drugs spent
2652 for the prescriptions. GPhA's member companies manufacture
2653 FDA-approved generic versions of brand-name drugs in all
2654 therapeutic classes, including prescription painkillers. We
2655 share the concern of the members of the committee when
2656 medications that are made to improve the quality of life and
2657 alleviate pain are abused. We believe that addressing this
2658 issue will require continued coordination among federal
2659 agencies, state, local, and federal law enforcement,
2660 healthcare professionals, drug manufacturers, patients, and

2661 even the caregivers. And we will work together to shape
2662 policy.

2663 To control the misuse of pain medications we must
2664 recognize that the overwhelming majority of individuals,
2665 including millions of senior and cancer patients, rely on
2666 these important medications to help treat their pain. In our
2667 collective efforts to curb drug diversion, we must carefully
2668 but not inadvertently punish the patients who need these
2669 medications. Rather we should punish the criminals who
2670 illegally acquire and sell these products outside the normal
2671 chains of distribution.

2672 GPhA member companies are absolutely committed to the
2673 safe and reliable manufacturing and delivery of generic
2674 drugs. As an industry we have invested millions of dollars
2675 in technologies and delivery systems to help assure that our
2676 products reach their destinations safely and securely.

2677 For example, our industry works with the DEA through the
2678 closed system that you have heard about before of
2679 distribution to prevent a diversion and also to assure that
2680 these products do not fall in the hands of abusers.

2681 The DEA also administers drug allotment and
2682 accountability systems to ensure against lost and diversion
2683 of controlled substances. While some have questioned whether
2684 the quota system needs to be reevaluated, we do not believe

2685 that doing so is an appropriate way to address concerns with
2686 prescription drug abuse. Further restrictions of the quota
2687 system could actually hinder access to important medical
2688 therapies for the patients who rely on them.

2689 For example, there are drugs specifically designed for
2690 attention deficit disorder and attention deficit hyperactive
2691 disorder in the quota system that are currently on the FDA's
2692 drug shortage list. Thus we are concerned that if Congress
2693 starts to tip the balance in the quota system, it could
2694 actually have unintended consequences on the patients who
2695 need these medications.

2696 GPhA has also been participating in the Pharmaceutical
2697 Distribution Security Alliance or the PDSA to develop a
2698 consensus technology model for increasing the security of the
2699 drug supply chain in the United States. As part of this
2700 model manufacturers have committed to maintaining a database
2701 that would associate unit level data and lot number
2702 association. GPhA believes this model will deliver greater
2703 safety to the patients and help to achieve FDA's stated goals
2704 of enhancing the identification of suspect products.

2705 But no matter how secure we make the supply chain for
2706 prescription drugs, ensuring safe use of these drugs is a
2707 responsibility that rests on all of us. In fact, recent
2708 studies suggest that the problem with prescription drug abuse

2709 in the United States today primarily stems not from drugs
2710 that are outside the legitimate supply chain or have been
2711 obtained illegally through the black market, but instead from
2712 those who legally prescribe and are available in the homes.

2713 According to a 2010, national survey of health more than
2714 70 percent of people abusing prescription drugs are doing so
2715 with products that were obtained either from friends or
2716 relatives.

2717 The general drug industry has been a leader in
2718 addressing the problem on drug diversion. We believe that
2719 education is the key component to addressing this issue and
2720 as such support efforts such as the American Medicine Chest
2721 Challenge, Smart Rx, and the National Council on Prescription
2722 Information and Education.

2723 In addition, our industry has focused its efforts in the
2724 area by joining the brand industry, patient groups, and the
2725 FDA to develop the REMS Program, which addresses long-acting
2726 and extended-release opioid medications. REMS, which is
2727 short for Risk Evaluation and Medication Strategies, are
2728 special programs that are used by the FDA to help prevent
2729 adverse outcomes for the patients and through the education
2730 of key participants about the risks that are associated with
2731 the medications and the proper and legitimate use of these
2732 medications.

2733 Madam Chairman, thank you for the tireless efforts to
2734 combat the problems of the prescription drug abuse in this
2735 country. You know more than anyone that this is very much a
2736 multi-faceted issue that will require multi-stakeholders to
2737 solution.

2738 Thank you, and I will be happy to answer any questions.

2739 [The prepared statement of Mr. Gaugh follows:]

2740 ***** INSERT 10 *****

|
2741 Mrs. {Bono Mack.} Thank you, Mr. Gaugh, and I recognize
2742 myself for 5 minutes for questioning, and I just want to say
2743 I get very frustrated anytime I hear denial from anybody in
2744 front of this Committee, as if they don't have a role in
2745 this. I think that there is plenty of blame to go around.
2746 There is no doubt, and in the private sector if anybody was
2747 analyzing statistics and looking at the number of overdose
2748 deaths screaming upward, I mean, Donald Trump would say,
2749 ``You are fired.''

2750 These statistics are staggering. The Attorney General
2751 pointed that out. They did a fantastic job. I, you know,
2752 something that really struck me to the pharmacy, the two
2753 pharmacy representatives, the murders of the four people in
2754 New York, how the bad guy, the assailant, whatever you want
2755 to call him, was an addict, too. Correct? And it seems
2756 that--are these robberies, are these crimes on the uptick
2757 because of the prescription drug epidemic? Are they addicts
2758 themselves, and are they actually--which is worse? Are they,
2759 you know, I have seen people trying to go through withdrawal.
2760 They will do anything to get the drug, anything at all. So
2761 are you seeing it because they are addicts or just people who
2762 are trying to divert it to the black market?

2763 Mr. {Harmison.} I can't speak with a great deal of

2764 authority here. I think that it is a combination. To the
2765 best of my knowledge I have never seen a patient come in that
2766 I could say this person is in withdrawal. I think that there
2767 is so much money involved with the black market of this, I
2768 think there are so many people that enjoy the euphoria.
2769 There is a demand, and somebody is going to meet that demand.
2770 Some of them are evil enough they will do whatever it takes
2771 to get it.

2772 Mrs. {Bono Mack.} But it is not the euphoria. They
2773 need a basic level to sustain themselves, so let us make it
2774 clear that it is not to sustain the euphoria. At any point
2775 in time it becomes so that they can live. Correct?

2776 Mr. {Harmison.} Yes, ma'am, but what I mean by
2777 euphoria, it has been proven over and over people in true
2778 organic pain do not get euphoria from the pain-relieving
2779 drugs. If they are an addict, they do--the threshold to keep
2780 down the withdrawal syndromes does keep rising. They do have
2781 to have more and more, probably more often and more often.

2782 Mrs. {Bono Mack.} Right.

2783 Mr. {Harmison.} But I don't know the people committing
2784 the crimes are addicts or salespeople.

2785 Mrs. {Bono Mack.} Mr. Nicholson, do you want to weigh
2786 in on that?

2787 Mr. {Nicholson.} Thank you, Madam Chairwoman. First I

2788 would add that I start off by saying that nothing is more
2789 important to our members than the safety of their patients
2790 and their employees, and I would also add that the incidents
2791 that you are talking about with respect to deaths from
2792 pharmacy robberies, the pharmacy robbery problem is, in fact,
2793 not, from what we are hearing is not at a nationwide spike,
2794 but it is spiking in certain geographic areas such as in the
2795 greater, in the northeast and in the New York metropolitan
2796 area.

2797 To help address these issues, you know, we work on a
2798 number of initiatives. We have been recently meeting with
2799 the officials at the HIDTA Office in that area to develop
2800 solutions that would help pharmacies to prevent these types
2801 of circumstances in the future.

2802 Mrs. {Bono Mack.} Do you all flag and identify
2803 willingly if an addict is willing to disclose to you he is
2804 addicted to opiates and I just want to know in my record that
2805 I am asking for these, I know it presents a whole host of
2806 other problems, but there are these sorts of things that
2807 pharmacies are not addressing right now currently. Correct?
2808 Are you able to say, I know you can say you have an allergy
2809 to iodine, and you can put that on a patient's record.
2810 Correct? But can you say none addiction to a substance with
2811 a patient's willingness to provide that kind of information?

2812 Do you track that data?

2813 Mr. {Nicholson.} Well, we, I mean, the information that
2814 goes to a patient profile is provided either by the patient
2815 themselves--

2816 Mrs. {Bono Mack.} That is what I am asking you. Do
2817 you, but do you specifically if a patient says to you, I am
2818 in recovery for an opiate addiction, if I come to you with a
2819 prescription for Opana, Opana, whatever--

2820 Mr. {Nicholson.} Right.

2821 Mrs. {Bono Mack.} --or Vicodin, whatever opiates--

2822 Mr. {Nicholson.} I mean--

2823 Mrs. {Bono Mack.} --please talk to me, counsel me
2824 first, call my doctor and say, doc, I want you to know. Do
2825 you do that now? I mean, that is a basic, simple step.

2826 Mr. {Nicholson.} The basic practice would be in a
2827 situation where a patient comes to you and says they are an
2828 addict, you would--the ultimate goal would be to refer them
2829 to treatment.

2830 Mrs. {Bono Mack.} Do you keep it on their record? It
2831 is a yes or no question.

2832 Mr. {Nicholson.} I can't answer. I mean--

2833 Mrs. {Bono Mack.} Yes, because the answer is no, but
2834 let me just move on because my time is limited. I just want
2835 to go down the line if I might and get a yes or no answer out

2836 of each of you.

2837 Do you agree with me that there is, is there an epidemic
2838 on prescription drug abuse?

2839 Mr. {Gray.} Yes.

2840 Mr. {Harmison.} Absolutely yes.

2841 Mr. {Nicholson.} Yes.

2842 Ms. {Martello.} Yes.

2843 Mr. {Gaugh.} Yes.

2844 Mrs. {Bono Mack.} Do you agree each of you have a
2845 responsibility in finding a solution to this problem?

2846 Mr. {Harmison.} Yes.

2847 Mr. {Nicholson.} Yes.

2848 Ms. {Martello.} Yes.

2849 Mr. {Gaugh.} Yes.

2850 Mrs. {Bono Mack.} Thank you. Lastly I am just going to
2851 close with this one thought that I am a little bit frustrated
2852 by the notion that a prescription drug monitoring program is
2853 punitive. It shouldn't be. My daughter was a professor of,
2854 I mean, excuse me, my father was a professor of medicine, and
2855 I really hold in very high regard doctors and understand
2856 their limited time. Same with pharmacists.

2857 But when we are thinking this is a cumulative measure
2858 rather than a holistic approach, the ability for each of you
2859 to see a patient in their entirety, perhaps if we changed the

2860 language, it is not punitive but it is supposed to be an
2861 added tool that will actually help you provide better
2862 healthcare to your patients, your consumers, your customers.
2863 I think that that would help if we could change the feeling
2864 and the language, and I am happy to work with all of you on
2865 that.

2866 My time has expired. I am happy to yield to Mr.
2867 Butterfield for 5 minutes.

2868 Mr. {Butterfield.} Thank you. I am happy that the
2869 Chairman went a little bit over time because that kept me
2870 from having to ask each of you the question about whether or
2871 not you feel some shared responsibility in curbing the abuse
2872 of drugs, and each one of you answered the question as I
2873 thought you would. I don't get the sense for 1 minute that
2874 any of you are not sensitive to what we are talking about
2875 today, and so I thank you for coming. I thank you for what
2876 you do in your industry and just encourage you to--let us
2877 work together to try to solve this huge problem that we are
2878 facing.

2879 I asked this question of the first panel, and I am going
2880 to try it again, and then I will close it out and head to the
2881 airport. Law enforcement efforts in one state may certainly
2882 yield reductions in the number of pills dispensed or
2883 hospitalizations or deaths. All of this is commendable if it

2884 happens within the state's border, but how can we be sure
2885 that addicted individuals simply don't go to another state
2886 and continue to commit the crime? We have asked other panels
2887 about that, and it is the elephant in the room. I mean, that
2888 is the big problem. If we fix the problem in one state, it
2889 is very simple for the addict to go to a neighboring state.

2890 Now, help us with some of your ideas on that very
2891 quickly. Mr. Gray.

2892 Mrs. {Bono Mack.} Please make sure your microphone is
2893 on.

2894 Mr. {Gray.} All they have to do is get in a car and go,
2895 and I think ultimately the solution is going to be the
2896 ability to link up these PDMP Systems and what other health
2897 IT record systems can be done across the country, and where
2898 doctors in Florida or doctors in Michigan can look at, you
2899 know, can go online and see what each individual patient is
2900 doing, I mean, that is the only way to kind of link up the
2901 information flow so a pharmacist in Tennessee can look up and
2902 understand that this patient was also just recently at a
2903 pharmacy in Florida, and now they are up here.

2904 But right now as you heard the earlier panel, these
2905 systems are discreet by their states. They are not
2906 connected, so the information flow isn't there.

2907 Mr. {Butterfield.} Thank you.

2908 Mr. {Harmison.} Is it on?

2909 Mr. {Butterfield.} Yes.

2910 Mr. {Harmison.} I don't know why they can't be
2911 connected. There are nationwide systems right now that we
2912 deal with every day with insurance that will feed back to us
2913 in a matter of seconds. There is drug allergy on record to
2914 this. They have had it refilled too soon. It is not on our
2915 formulary. There is all sorts of information that comes back
2916 in seconds. I don't know why something like this--but I am
2917 the most technologically illiterate person in this room, but
2918 I don't know why it can't be done.

2919 Mr. {Nicholson.} I would agree with, you know, my--Mr.
2920 Gray and Mr. Harmison that, yes, I mean, we definitely need,
2921 you know, the mater solution is to connect the prescription
2922 drug monitoring programs. At NACDS we support appropriations
2923 for NASPER and for the Harold Rogers Prescription Drug
2924 Monitoring Program to provide funding to the states so that
2925 they can upgrade and better maintain their prescription drug
2926 monitoring programs and work on programs to interconnect them
2927 with each other.

2928 I also would add that we are hopeful that as the
2929 healthcare delivery system becomes more interoperable that
2930 pharmacies and prescribers and hospitals and you know, other
2931 entities will have better access to patient's full, the

2932 patient's full record so that there won't be gaps that would
2933 allow a patient to go from prescriber to prescriber or from
2934 state to state.

2935 Mr. {Butterfield.} Okay. Counsel.

2936 Ms. {Martello.} Similarly prescription drug monitoring
2937 programs, we think that they can be an efficient and
2938 effective tool in helping to identify folks for treatment as
2939 well, and some of the solutions that have been talked about
2940 today include making sure that information is provided to
2941 these state prescription drug monitoring programs in real
2942 time but also enhancing their interoperability across state
2943 lines so that you can utilize this data to its maximum
2944 effect.

2945 Mr. {Butterfield.} All right. Fifty seconds.

2946 Mr. {Gauth.} I would concur with my colleagues on the
2947 panel that PDMP is a system that is in place, but it does not
2948 cross borders at this point in time, and as Mr. Harmison
2949 said, the reimbursements are instantaneously, why can't this
2950 be instantaneously.

2951 Mr. {Butterfield.} Very well. Thank you.

2952 Mrs. {Bono Mack.} Thank you.

2953 Mr. McKinley, you are recognized for 5 minutes.

2954 Mr. {McKinley.} Thank you. Mr. Gray, I think you
2955 started in a direction, and I want to follow back up again.

2956 Maybe--but then you stopped short of going that direction.

2957 Question. When we have spoken with the DEA, they claim
2958 for the distribution groups they give you very specific
2959 suggestions for improvements or otherwise how to--I have a
2960 feeling that there is a breakdown from what they say they are
2961 doing and what you in the distribution business--are the
2962 distributors getting good advice, good direction when they go
2963 to the DEA and ask for improvements to their delivery system
2964 before they pull the registration?

2965 Mr. {Gray.} That is the big debate, and if you talk to
2966 my members, they would tell you that those meetings,
2967 particularly at the regional level, tend to be deficient in
2968 solid advice at the end of the day as to whether or not a
2969 particular pharmacy should be--have a stop order as far as
2970 delivery.

2971 You know, our members started in this process with the
2972 DEA 4 years ago as they said. This is a relatively new
2973 program. It was certainly a novel idea to consider the
2974 distributor as a choke point. I think that is kind of a
2975 pejorative term for what we are trying to do as a team as
2976 Attorney General Bondi said. We should be working in
2977 cooperation and collaboration with the DEA, and we shouldn't
2978 be in an adversarial posture, which these things, when you
2979 issue an ISO, that is where you end up as was stated earlier.

2980 So what happens then, and I have heard, I have talked to
2981 most of my members about this, and a common situation that
2982 will occur is that there will be a discussion, the
2983 distributor will sit down and say, we have reason to believe,
2984 we see some spikes, something is wrong with the ordering of
2985 this particular pharmacy. We think maybe they should be cut
2986 off. What do you think? And the common refrain, I have
2987 heard this more than once so there has got to be some element
2988 of truth to it, the common refrain is, that is a business
2989 decision for the distributor to make.

2990 Well, sure it is, but then that business decision can be
2991 used against you if you decide not to, and the questions that
2992 we submitted to the DEA last June 1 to Administrator Leonhart
2993 attempted to get to answer some of those specific questions
2994 within the confines of these meetings. A question the
2995 distributor would obviously have about a pharmacy practice,
2996 and this all stems to the data discussion earlier.

2997 They have data we cannot see. We cannot see that a
2998 pharmacy may be delivering, may be receiving deliveries from
2999 more than one wholesaler. All we see is our numbers, and it-
3000 -that has been a source of frustration. I am hoping today we
3001 can turn the dialogue into a constructive one. It is not us
3002 versus them, but how can we work together. I think we can
3003 make a lot of progress working together.

3004 Mr. {McKinley.} Let me stay on that question. If the--
3005 there are two other issues with it. First, are the
3006 pharmaceuticals that distributors, are they compensated for
3007 doing this police work for the DEA?

3008 Mr. {Gray.} Oh, no. This is all out of the
3009 distributor's pocketbook. We have--our companies have
3010 invested tens of millions of dollars in doing this.

3011 Mr. {McKinley.} Thank you. So a smaller distribution
3012 firm, how do they do that?

3013 Mr. {Gray.} Very expensive. If you want to talk to
3014 some of them, I can make that happen.

3015 Mr. {McKinley.} Well, I just wonder--

3016 Mr. {Gray.} Yeah.

3017 Mr. {McKinley.} --is the long and the short of this
3018 with the DEA trying to put the smaller distributors out of
3019 business?

3020 Mr. {Gray.} I wouldn't want to speculate on that. I
3021 can't imagine that that would be the case. I think the DEA
3022 is absolutely, you know, fervent and correctly so in
3023 attempting to stop this problem, but I think like any new
3024 initiative, we are in our dating period trying to figure out
3025 how to get along.

3026 Mr. {McKinley.} Is this an--is this one of those
3027 unfunded mandates that we are passing onto the companies to

3028 do, and we are not going to compensate them. Then we are
3029 going to turn around and criticize them for the cost of
3030 pharmaceuticals?

3031 Mr. {Gray.} Well, that is an interesting way to put it,
3032 but, well, I mean, as I say, the hardcore fact is when we put
3033 in these monitoring systems, it is at the company's expense
3034 to do so.

3035 Mr. {McKinley.} I want to see this in a most robust way
3036 to try to correct the problem, but I just have, I have this
3037 nagging feeling here that there are parts of the chain that
3038 are not being treated equally, and I hope that the DEA will
3039 revisit how they work with each--

3040 Mr. {Gray.} Well, we do, too, because we have a long
3041 history since I have been onboard in '04, we have worked more
3042 than--we were the first responders in Katrina, our companies
3043 are the ones that got in there and got--we were the only ones
3044 that got in and got medicines to the people stranded in New
3045 Orleans. We were the ones that set up the vaccine tracking
3046 system with the CDC in a cooperative effort. We worked
3047 cooperatively with the Secretary of HHS to develop the system
3048 for bird flu maintenance and stockpiling around the country.
3049 We have a long track record in the last 5 years of working
3050 hugely cooperatively with federal agencies and the
3051 government. I would love to see that same level of

3052 participation and cooperation with the DEA, because I believe
3053 they are correct. Together we can solve a lot of this
3054 problem. If they help us help them, we can make a lot of
3055 strides to solving this problem, but we are working in a
3056 vacuum.

3057 Mrs. {Bono Mack.} Thank you very much, and I would like
3058 to begin wrapping things up, and I thank all of our panelists
3059 very much for being here today, for your time, and for your
3060 commitment to this critically-important issue. If 30,000
3061 Americans died every year from food poisoning, Congress would
3062 take action. If 30,000 Americans died from pesticide
3063 exposure, Congress would take action. For that matter, if
3064 30,000 dolphins died and washed up on our beaches every year,
3065 Congress would take action.

3066 So why are the victims of prescription drug abuse
3067 treated any differently? But working together as we have all
3068 said I know that we can come up with some good answers, and
3069 we can save lives.

3070 So I again thank you all very much for being here and
3071 especially for weathering the delay that we had this morning.
3072 I would like to remind members they have 10 business days to
3073 submit questions for the record. I know we will have one
3074 specifically about undosed marking, and so we will submit
3075 questions to you, and I would ask the witnesses to please

3076 respond promptly to any questions you might receive.

3077 Again, thank you, and the hearing is now adjourned.

3078 [Whereupon, at 1:50 p.m., the Subcommittee was

3079 adjourned.]