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4 ``EXAMINING THE FEDERAL GOVERNMENT'S RESPONSE TO THE

5 PRESCRIPTION DRUG ABUSE CRISIS''

6 FRIDAY, JUNE 14, 2013

7 House of Representatives,

8 Subcommittee on Health,

9 Committee on Energy and Commerce,

10 Washington, D.C.

11 The Subcommittee met, pursuant to call, at 9:32 a.m., in

12 Room 2123 of the Rayburn House Office Building, Hon. Joe

13 Pitts [Chairman of the Subcommittee] presiding.

14 Members present: Representatives Pitts, Burgess,

15 Whitfield, Rogers, Murphy, Gingrey, Cassidy, Guthrie,

16 Griffith, Bilirakis, Ellmers, Capps, Schakowsky, Green,

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17 Butterfield, and Castor.

18 Staff present: Clay Alspach, Chief Counsel, Health; Gary
19 Andres, Staff Director; Sean Bonyun, Communications Director;
20 Matt Bravo, Professional Staff Member; Paul Edattel,
21 Professional Staff Member, Health; Brad Grantz, Policy
22 Coordinator, O&I; Sydne Harwick, Legislative Clerk; Carly
23 McWilliams, Professional Staff Member, Health; Katie Novaria,
24 Professional Staff Member, Health; Andrew Powaleny, Deputy
25 Press Secretary; Chris Sarley, Policy Coordinator,
26 Environment and the Economy; Heidi Stirrup, Health Policy
27 Coordinator; Alli Corr, Democratic Policy Analyst; Eric
28 Flamm, Democratic FDA Detailee; Elizabeth Letter, Democratic
29 Assistant Press Secretary; Karen Lightfoot, Democratic
30 Communications Director and Senior Policy Advisor; Anne
31 Morris Reid, Democratic Professional Staff Member; and Rachel
32 Sher, Democratic Senior Counsel.

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33 Mr. {Pitts.} The Subcommittee will come to order. The
34 chair will recognize himself for an opening statement.

35 Today's hearing is the first in a series of hearings
36 this subcommittee will hold on the subject of prescription
37 drug abuse, which has been described by the Centers for
38 Disease Control and Prevention as an epidemic in the United
39 States.

40 In 2010, 7 million individuals aged 12 or older--that is
41 2.7 percent of this population--were current nonmedical users
42 of prescription, or psychotherapeutic, drugs, and over one
43 million emergency department visits that year involved
44 nonmedical use of pharmaceuticals. Nearly all of these drugs
45 were originally prescribed by a physician.

46 According to the National Institute on Drug Abuse,
47 prescription drug abuse is most prominent among young adults
48 age 18 to 25. NIDA also reports that in 2010, almost 3,000
49 young adults died from prescription drug--mainly opioid--
50 overdoses, which is more than the total number of people that
51 died from overdoses of any other drug, including heroin and
52 cocaine combined.

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53 Opioid pain relievers, such as Vicodin and OxyContin,
54 are the largest class of abused prescription drugs, followed
55 by stimulants for treating attention deficit hyperactivity
56 disorder--ADHD--such as Adderall or Ritalin, and central
57 nervous system depressants for relieving anxiety, such as
58 Valium and Xanax.

59 According to the National Survey on Drug Use and Health,
60 published by the Substance Abuse and Mental Health Services
61 Administration (SAMHSA), of those individuals who used
62 prescription painkillers non-medically in 2010 and 2011,
63 nearly 3/4 received the drugs from a friend or relative,
64 either for free, that is 54.2 percent; through a purchase,
65 that is 12.2 percent; or by stealing the drugs, 4.4 percent.

66 Today's hearing focuses on the Federal Government's
67 response to the prescription drug abuse epidemic. It should
68 be noted that this committee has played a key role in
69 facilitating Prescription Drug Monitoring Programs by
70 authorizing the National All Schedules Prescription
71 Electronic Reporting Act (NASPER), co-sponsored by
72 Representative Whitfield and Ranking Member Pallone. NASPER,
73 which is housed at the Department of Health and Human

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74 Services, was signed into law on August 11, 2005, to assist
75 States in combating prescription drug abuse of controlled
76 substances through the PDMP.

77 It provides grants to set up or improve state systems
78 that meet basic standards of information collection and
79 privacy protections that will make it easier for States to
80 share information. PDMPs enable authorities to identify
81 prescription drug abusers, as well as the ``problem doctors''
82 who either overprescribe or incorrectly prescribe
83 prescription drugs.

84 While NASPER is an excellent step in the right
85 direction, the program has not been funded since fiscal year
86 2010, although HHS continues to fund state PDMPs through
87 grants to support interstate interoperability and integration
88 of PDMPs with electronic health records and to improve the
89 timeliness of access to PDMP data.

90 It is abundantly clear that the prescription drug abuse
91 epidemic is a crisis in the U.S. However, while we discuss
92 this complicated and dynamic issue we need to keep in mind
93 that many of these medications that so many are abusing are
94 critical for many patients living with chronic pain.

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95 The Institute of Medicine estimates that there are more
96 than 100 million adults in the U.S. living with chronic pain.
97 It is critical as we move forward that we remember that these
98 medications are vital for many Americans experiencing such
99 pain.

100 This hearing will help us better understand and define
101 the various components of the issues and the challenges we
102 face. In addition, this subcommittee will learn about the
103 programs we currently have in place and their level of
104 effectiveness.

105 Today's witnesses represent the Office of National Drug
106 Control Policy, the FDA, and the Substance Abuse and Mental
107 Health Services Administration. I look forward to hearing
108 their testimony. Thank you.

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

110 ***** COMMITTEE INSERT *****

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|
111 Mr. {Pitts.} And does anyone seek time? I guess I
112 don't have time. Thank you. I yield the balance of my time
113 and now recognize the gentlelady Ms. Schakowsky for 5 minutes
114 for an opening statement.

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

116 First, I would like to ask if I could put the opening
117 statement of Mr. Waxman into the record.

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

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

120 ***** COMMITTEE INSERT *****

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121 Ms. {Schakowsky.} Thank you.

122 I am happy that we are having this hearing on drug abuse
123 in the United States and I am glad that we can work together
124 in a bipartisan manner to tackle this problem. I want to
125 welcome all of our witnesses today.

126 This hearing provides an opportunity to raise awareness
127 and discuss action that we can take to end a crisis that is
128 truly destroying lives, hurting families and communities
129 across the country.

130 My constituent, Peter Jackson, tragically lost his 18-
131 year-old daughter Emily to this epidemic. While visiting
132 family, Emily's cousin offered her an OxyContin tablet that
133 had belonged to her uncle, who had recently died of cancer.
134 After taking the OxyContin tablet while drinking, Emily went
135 to sleep and never woke up. She died from respiratory
136 depression; she stopped breathing.

137 While Emily's story of dying after taking a single un-
138 prescribed OxyContin tablet may be extremely rare, death from
139 the abuse and misuse of prescription opioid drugs are not.
140 Prescription opioid drugs were involved in 16,650 overdose

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141 deaths in 2010, accounting for more deaths than from
142 overdoses of heroin and cocaine combined. This represents a
143 313 percent increase in deaths over the past decade.

144 In addition to those tragic deaths, there are other
145 negative health consequences that result from prescription
146 drug abuse. For every overdose death in 2010 there were an
147 additional 10 abuse treatment admissions, 26 emergency
148 department visits, 108 people with abuse or dependence, and
149 733 nonmedical users of those drugs.

150 In addition to the human toll, there are financial costs
151 associated with prescription drug abuse that our health care
152 system simply cannot afford. The direct health care cost of
153 prescription drug abuse exceeds \$70 billion each year.
154 Research has found that, on average, opioid abusers generate
155 direct costs 8.7 times higher than non-abusers each year. It
156 is a national imperative that we work to end this crisis.
157 Reducing the prevalence of prescription drug abuse will save
158 lives and save money.

159 There are actions underway that are helping to combat
160 this problem at the federal level. Last year, we passed
161 several provisions as part of the Food and Drug

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162 Administration's Safety and Innovation Act to combat
163 prescription drug abuse, including a requirement that the FDA
164 hold a public meeting on the scheduling of hydrocodone and
165 issue guidance on developing abuse-deterrent products.
166 Federal agencies are also operating programs to combat
167 prescription drug abuse, including developing and supporting
168 efforts to educate providers and populations at risk for
169 prescription drug abuse.

170 While federal efforts are critical, we must partner with
171 States if we are to be successful in ending prescription drug
172 abuse due to States' responsibility to license and train the
173 health care professionals that prescribe and dispense these
174 drugs. We must also build on current efforts by identifying
175 additional steps that we can take to tackle such abuse. We
176 must make drugs containing hydrocodone schedule II drugs.
177 While it will be important to take steps to ensure this
178 change does not limit access to patients with legitimate
179 medical needs, this change is needed to adequately reflect
180 the potential risk these drugs pose to public health.

181 We should also take steps necessary to restrict the use
182 of oxycodone pain relievers to severe pain, rather than

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183 moderate to severe pain, in order to prevent the
184 overprescribing of these powerful medications.

185 I look forward to hearing from our witnesses about the
186 Federal Government's efforts to combat prescription drug
187 abuse, to learn additional steps we can take to stop the
188 abuse and misuse of opioid drugs, and I would appreciate any
189 comment on the suggestions that I made in my testimony.

190 And I yield back.

191 [The prepared statement of Ms. Schakowsky follows:]

192 ***** COMMITTEE INSERT *****

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|
193 Mr. {Pitts.} The chair thanks the gentlelady and now
194 recognizes the vice chairman of the subcommittee, Dr.
195 Burgess, for 5 minutes for an opening statement.

196 Dr. {Burgess.} I thank the Chairman for the
197 recognition.

198 Now, the fact of the matter is that we lose more people
199 in this country to the drug overdoses than we do to
200 automobile accidents. And of those drug overdoses, 2/3 of
201 them are prescription drug overdoses. So we have got a
202 plenty big problem. The good news is there is plenty we can
203 do about it. But unfortunately, the agencies and lawmakers
204 have, so far, not taking anything other than a short-term
205 approach. We really need a broad-based, comprehensive
206 strategy that is focused on going after the bad actors.

207 So to start we could go after the pill mills. They may
208 be hard to find, but maybe not. They advertise, so we are
209 very fortunate. They tell us where they are, what their
210 hours are, they tell us their charges. So if I can find
211 them, how come the Board of Pharmacy can't? How come law
212 enforcement can't? And take a hard look at this.

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213 Look, I ran a medical practice for 25 years, never once
214 did I advertise a free initial visit, dispensing onsite,
215 discounts off meds, coupon included. This warrants a hard
216 look. It just doesn't fit a normal type of medical practice.

217 We should reauthorize and fight to fund NASPER. This
218 committee reauthorized it in the past. It is the only
219 authorizing legislation that encourages state Prescription
220 Drug Monitoring Programs. NASPER was a product of this
221 committee, bipartisan, drafted with medical providers, States
222 and patients in mind.

223 We should encourage qualitative drug screening and
224 reject contrary Medicare policies. We should encourage abuse
225 deterrent formulations and reward investment in these
226 technologies. We might also work with Canada to align our
227 policies in approving and reimbursing these technologies. We
228 should look at and examine the personal use exemption to see
229 if it encourages bringing controlled substances into the
230 country. We should do more to shutdown the rogue internet
231 pharmacies at home and abroad.

232 It boils down to this: right now, you can go to a
233 publication; you could go on the internet and buy a

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234 controlled substance by pointing and clicking at two things,
235 two statements you have to make: one, I need the drug; and
236 two, I ain't lying. Most people can meet that bar.

237 I am open to discussing provider education if it does
238 not subvert medical judgment. We have allowed a few bad
239 actors to jeopardize a doctor's ability to offer pain care
240 and care for the patients out of fear for patient abuse and
241 diversion. And this is an important point. Being someone
242 who has written prescriptions, I do have a perspective on
243 this that says we have got to stop the diversion but we also
244 need to be careful that our--whatever we do is not so
245 prescriptive that it prevents people who have a legitimate
246 need and use of this medication to not obtain it.

247 So pain costs are estimated at more than \$100 billion
248 yearly and they are the cause of 25 percent of sick days.
249 Prescription medications may be an important part of pain
250 therapy. If we don't stop the bad actors, we are going to
251 hurt the people who have legitimate uses for these
252 medications. The bad actors cannot be allowed to jeopardize
253 a doctor's ability to alleviate human suffering.

254 Again, there is much we should do. I understand why

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255 this may be a series of hearings and, Mr. Chairman, obviously
256 I look forward to working with you. We need to involve
257 doctors; we need to involve patients as witnesses.

258 Thank you, Mr. Chairman, for the consideration and I
259 will yield the balance of the time to Dr. Gingrey.

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

261 ***** COMMITTEE INSERT *****

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|
262 Dr. {Gingrey.} I appreciate my OB/GYN colleague from
263 Texas for yielding to me because I agree with so much of what
264 he said.

265 You know, the problem is a huge problem in not only the
266 cost of the legal dispensation or prescribing of these types
267 of medications, pain medications, anxiolytics,
268 antidepressants, whatever. But, just think about the cost of
269 decreasing productivity in individuals that maybe are a
270 little bit, just a little bit overmedicated. You know, this
271 might sound a little harsh, but honestly, I think maybe a
272 little pain or a little anxiety in our lives is a good thing.
273 It can be a productive thing and make you appreciate that you
274 have to work through that. And that if you try to completely
275 eliminate each of those things, then that is where you get to
276 the dependency, the addiction, the decreased productivity, or
277 the cost to society.

278 So I think physicians have a big role to play in this,
279 and even the ones that are prescribed legally. And I am not
280 talking here about the pill mills. The States doing, I
281 think, a good job of trying to crack down on that.

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282 But finally, we must take a close look at how we as a
283 society support treatment and recovery for patients
284 struggling to overcome addiction. We must look for new and
285 innovative treatment plans which treat this dependence and
286 leave the abuser without new addictions, where they are on
287 some other medication that is supposedly helping them and
288 they are almost just as addicted as they were before.

289 Mr. Chairman, I yield back and I thank you for the time.

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

291 ***** COMMITTEE INSERT *****

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292 |
 Mr. {Pitts.} The chair thanks the gentleman.

293 That concludes the opening statements. The Committee
294 has one panel before us today and I will introduce those
295 members at this time: Mr. Gil Kerlikowske, Director, Office
296 of National Drug Control Policy is with us; secondly, Dr.
297 Throckmorton, Deputy Director of Regulatory Programs, Center
298 for Drugs Evaluation and Research, U.S. Food and Drug
299 Administration; finally, Dr. Westley Clark, Director, Center
300 for Substance Abuse Treatment, Substance Abuse and Mental
301 Health Services Administration.

302 Thank you for coming. Your written testimony will be
303 made part of the record. You will be each given 5 minutes to
304 summarize your testimony.

305 Mr. Kerlikowske, you are recognized for 5 minutes for
306 your opening statement.

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|
307 ^STATEMENTS OF R. GIL KERLIKOWSKE, DIRECTOR, OFFICE OF
308 NATIONAL DRUG CONTROL POLICY, EXECUTIVE OFFICE OF THE
309 PRESIDENT; DR. DOUG THROCKMORTON, DEPUTY DIRECTOR FOR
310 REGULATORY PROGRAMS, CENTER FOR DRUG EVALUATION AND RESEARCH,
311 U.S. FOOD AND DRUG ADMINISTRATION; AND DR. H. WESTLEY CLARK,
312 DIRECTOR, CENTER FOR SUBSTANCE ABUSE TREATMENT, SUBSTANCE
313 ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

|
314 ^STATEMENT OF R. GIL KERLIKOWSKE

315 } Mr. {Kerlikowske.} Thank you, Chairman Pitts and
316 representative Schakowsky and members of the subcommittee,
317 and thank you for the opportunity to address the important
318 issue of prescription drug abuse in this country.

319 Preventing prescription drug abuse has been a major
320 focus of our office since my confirmation now 4 years ago.
321 We have worked very collaboratively with a number of federal
322 agencies throughout government to address what the CDC has
323 rightly termed an epidemic. My position allows me to raise
324 the public awareness and take action on drug issues that

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325 affect the Nation, and the Administration recognizes that
326 addiction is a disease, that prevention, treatment, and smart
327 law enforcement all have to play a part of a comprehensive
328 strategy to reduce drug use, to give help to those who need
329 it, and to ensure public health and safety.

330 And we are here today because the prescription drug
331 abuse as a devastating consequences for public health and
332 safety in the country. Increases in treatment admissions for
333 substance use disorders, emergency department visits, and,
334 sadly, the deaths that are attributable to prescription drug
335 overdoses place an enormous burden upon communities across
336 the country.

337 In 2010 alone, more than 38,000 Americans died from a
338 drug overdose; 22,000 of those overdose deaths were
339 attributable to prescription medications; and most of those
340 deaths, almost 17,000, were attributable to prescription
341 painkillers. And in response the Administration released a
342 comprehensive program called Prescription Drug Abuse
343 Prevention Plan.

344 The plan brings together a variety of federal, state,
345 local, and tribal partners to focus on the four major

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346 priority areas dealing with this: education, monitoring,
347 proper disposal, and enforcement, and the plan promotes
348 mandatory education and safe prescribing and addiction
349 practices for prescribers and dispensers.

350 Current training for health care providers on safe
351 opioid prescribing and addiction can be an adequate and
352 inconsistent. Medical school students receive an average of
353 only 11 hours of training on pain education. Most schools do
354 not offer specific training on opioids at all. Several
355 States including Iowa, Massachusetts, and Utah passed
356 mandatory prescriber education legislation. And we have come
357 a long way in educating the general public about prescription
358 drug abuse. We have worked with a wide array of state
359 government leaders, medical associations, public health and
360 safety organizations to prioritize prescription drug abuse
361 and overdose prevention.

362 The second pillar of the plan focuses on strengthening
363 the Prescription Drug Monitoring Programs. In 2006, only 20
364 States had PDMPs. Today, 49 States have authorized
365 legislation, 46 States have operational PDMPs. There are
366 currently 14 States that are able now to share data across

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367 state lines and we are supporting that expanded
368 interoperability.

369 The Administration has worked with Congress to allow the
370 Department of Veterans Affairs to share prescription drug
371 data with PDMPs and we are pleased to say that the VA's
372 rulemaking process is nearing completion, and VA has
373 authorized its health care providers to access those state
374 PDMPs when consistent with state laws.

375 And third, the Administration has continued to expand
376 safe and proper disposal of unused and expired medication.
377 Since 2010, the Drug Enforcement Administration has partnered
378 with thousands of local law enforcement agencies and our
379 Drug-Free Communities coalitions to hold six national take-
380 back days collectively, safely disposing of over 2.8 million
381 pounds of unused medication.

382 Lastly, the Administration plan focuses on improving law
383 enforcement capabilities to reduce diversion. The National
384 Methamphetamine and Pharmaceutical Initiative, funded through
385 our office of high intensity truck trafficking areas, has
386 trained more than 2,500 law enforcement and criminal justice
387 professionals on pharmaceutical crime investigations and

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388 prosecutions. The federal law enforcement continues to
389 partner with state and local agencies around the country to
390 reduce the pill mills and prosecute those that are
391 responsible for improper or illegal prescribing.

392 The Administration is working to expand access to
393 naloxone, an emergency overdose reversal medication for first
394 responders who may encounter overdose victims and can help
395 prevent a fatal opioid overdose. And we are also addressing
396 many of the other consequences of the epidemic, including the
397 emerging issues like neonatal abstinence syndrome and
398 indications of increased heroin use in other places
399 throughout the country.

400 In closing, let me recognize that none of these things
401 would be possible if my executive branch colleagues and I
402 want to accomplish for this Nation without the ongoing
403 support of Members of Congress. And thank you for the
404 opportunity to testify.

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

406 ***** INSERT A *****

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

408 Dr. Throckmorton, you are recognized for 5 minutes for

409 an opening statement.

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|
410 ^STATEMENT OF DR. DOUG THROCKMORTON

411 } Dr. {Throckmorton.} Mr. Chairman and members of the
412 subcommittee, I am Dr. Douglas Throckmorton, Deputy Director
413 for Regulatory Programs in the Center for Drug Evaluation and
414 Research at the FDA. Thank you for your opportunity to be
415 here today to discuss the misuse and abuse of prescription
416 drugs, especially prescription opioids.

417 The importance of this problem is hard to overstate.
418 Beyond the sobering statistics are individuals and their
419 families whose lives have been shattered by prescription
420 opioid misuse, abuse, and addiction. It is a crisis that
421 affects us all, and meaningful and enduring solutions will
422 require all of our collective efforts.

423 Balancing the needs of patients suffering from pain with
424 the need to combat opioid misuse, abuse, and addiction is a
425 priority for the FDA and for me personally. In seeking this
426 balance, FDA has pursued a targeted, science-based approach
427 aimed at critical points in the development and use of opioid
428 medications. While additional work remains to be done, I

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429 would like to mention some of the activities FDA is doing
430 now.

431 First, we are a science-based agency and are focusing on
432 improving the safe use of pain medicines. These activities
433 include recent work we have done to encourage the development
434 of abuse-deterrent drug formulations for opioids. The FDA
435 believes the development of these new formulations to
436 successfully deter abuse is an important part of our efforts
437 to improve their safe use.

438 For example, in January of this year, the FDA issued a
439 draft guidance document for industry outlining the
440 development of abuse-deterrent opioid drug products. And in
441 the fall, the FDA will participate in a public meeting to
442 discuss the issues addressed in that draft guidance, as well
443 as issues surrounding the development of abuse-deterrent
444 formulations for generic drug products.

445 In addition, the FDA has taken recent regulatory actions
446 concerning two opioid products, OxyContin and Opana ER, that
447 were reformulated with the intention of making the products
448 more difficult to manipulate and abuse. The data for these
449 two products were reviewed carefully and independently by FDA

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450 scientists and resulted in a change in the labeling for
451 OxyContin. Our decisions relied on the totality of the
452 evidence for the particular drug at hand, and given where we
453 are in the evolving science of abuse deterrence, were made on
454 a case-by-case basis.

455 A second critical area where we have devoted time and
456 resources is the development of effective patient and
457 prescriber education. The interaction between prescribers
458 and patients plays a critical role in improving the safe use
459 of these drugs and the FDA has taken a number of steps to
460 improve the educational materials that are available for
461 patients and prescribers.

462 For example, in July of 2012 we approved a risk
463 evaluation and mitigation strategy, known as REMS, for
464 manufacturers of over 20 extended-release and long-acting
465 opioids. Under this REMS, manufacturers are required to
466 support the development of effective prescriber training
467 programs offered by accredited continuing education providers
468 and to make them available at little or no cost to health
469 care professionals. The training is based on a syllabus
470 developed by the FDA with input from other stakeholders. We

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471 are currently posting those educational materials on our
472 website to make them easier for prescribers to find and make
473 use of.

474 A third critical area where we have devoted time and
475 resources is on ways to prevent the overdose deaths
476 associated with prescription opioids by improving the
477 treatment of overdose. Naloxone is an injectable medication
478 that is the standard treatment to rapidly reverse the
479 overdose of either prescription or illicit opioid. And when
480 given quickly, it can and does save lives.

481 At a public meeting the FDA convened last year with
482 several other parts of the Federal Government, stakeholders
483 encouraged the exploration of new ways to administer naloxone
484 that may be easier than currently available, such as auto-
485 injectors or via intranasal administration. In this area,
486 FDA is working to provide regulatory priority assistance to
487 manufacturers, who are working on assessing these new ways to
488 give naloxone.

489 To finish my remarks, our society faces two important
490 challenges. We must balance efforts to address the misuse,
491 abuse, and addiction that harms our families and communities

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492 and the need for appropriate access to pain medications for
493 patients that need them. There can be no doubt there is much
494 to be done and that we must act now. These are not simple
495 issues and there are no easy answers. Given the complexity
496 of the issues surrounding this problem, real and enduring
497 progress will require a multifaceted approach combined with
498 the dedication, persistence, and full engagement of all
499 parties.

500 FDA continues to prioritize our efforts in this area to
501 combat this significant public health crisis. We welcome the
502 opportunity to work with Congress, our federal partners, the
503 medical community, advocacy organizations, patients, and
504 families to turn the tide on this devastating epidemic.

505 Thank you for your continued interest in this important
506 topic and for the opportunity to testify regarding FDA's
507 contributions on this issue. I am happy to answer any
508 questions you have.

509 [The prepared statement of Dr. Throckmorton follows:]

510 ***** INSERT B *****

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|
511 Mr. {Pitts.} The chair thanks the gentleman and now
512 recognizes the gentleman, Dr. Clark, for 5 minutes for an
513 opening statement.

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|
514 ^STATEMENT OF H. WESTLEY CLARK

515 } Dr. {Clark.} Good morning, Chairman Pitts,
516 Congresswoman Schakowsky, and members of the subcommittee. I
517 am Dr. H. Westley Clark, and I am the director of the Center
518 for Substance Abuse Treatment within the Substance Abuse and
519 Mental Health Services Administration. Thank you for
520 inviting me to testify today regarding SAMHSA's role in
521 preventing non-medical use of prescription drugs and treating
522 individuals who abuse those drugs.

523 SAMHSA's mission is to reduce the impact of substance
524 abuse and mental illness on America's communities. We
525 envision a nation that acts on the knowledge that behavioral
526 health is essential for our health, prevention works,
527 treatment is effective, and people recover.

528 The challenge of prescription drug misuse and abuse is a
529 complex issue that requires epidemiological surveillance,
530 interventions, prescriber education, access to effective
531 treatment services, and continued research by the private and
532 public sectors. SAMHSA's strategy to reduce prescription

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533 drug misuse and abuse aligns with the four-part strategy of
534 ONDCP. We work across the U.S. Department of Health and
535 Human Services by participating in the Behavioral Health
536 Coordinating Committee's Prescription Drug Abuse
537 Subcommittee. We are in active partnerships with the CDC,
538 the FDA, the Office of the National Coordinator of Health
539 Information Technology (NIH), and others aimed at preventing
540 and treating prescription drug misuse and abuse.

541 According to our 2011 National Survey on Drug Use and
542 Health, nonmedical use of prescription drug ranks as the
543 second-most common illicit class of drugs in the United
544 States. You have mentioned these data and there is no need
545 for me to repeat it, but it is important to know that there
546 was a slight decline in nonmedical use between 2010 and 2011,
547 which suggests that the national, state, and local efforts to
548 reduce prescription drug misuse may be having an impact, but
549 there is still much work to be done.

550 State Prescription Drug Monitoring Programs, or PDMPs,
551 are an important component in government efforts to prevent
552 and reduce drug diversion and abuse. PDMPs monitor and
553 analyze scheduled prescription drugs with the goal of

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554 preventing prescription drug misuse and abuse, as well as
555 illegal diversion.

556 In 2005, the National All Schedules Prescription
557 Electronic Reporting Act, or NASPER, created a Department of
558 Health and Human Services grant program administered by
559 SAMHSA for States to implement or enhance PDMPs. NASPER
560 received funding from Congress in fiscal years 2009 and 2010,
561 which resulted in SAMHSA providing 26 grants to 14 States.
562 However, in fiscal years 2011 and '12, Congress did not
563 appropriate funding for the NASPER program.

564 In 2011, SAMHSA funded the enhanced access to PDMPs
565 through Health IT Project which was managed by ONC in
566 collaboration with SAMHSA's CDC and ONDCP. The project was
567 unlike the NASPER grants in that its purpose was to use
568 health IT to increase timely access to PDMP data.

569 In 2012, the PDMP Electronic Health Record Integration
570 and Interoperability Expansion program was funded by SAMHSA.
571 This program complements existing federal efforts by
572 improving real-time access to PDMP data through the
573 integration of PDMPs into existing technologies such as
574 electronic health records.

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575 SAMHSA has also engaged in the efforts to prevent and
576 treat prescription drug misuse and abuse through education
577 programs for prescribers and future prescribers, prevention
578 and early intervention programs, treatment of prescription
579 drug abuse, as well as through regulation. We support the
580 education of current prescribers through continuing medical
581 education courses and other less formal efforts such as
582 webinars.

583 The Screening, Brief Intervention, and Referral to
584 Treatment program is an important tool for the early
585 identification of persons who might be at risk for opioid
586 abuse and other substance use. SAMHSA provides grants to
587 States, territories, and tribal organizations to implement
588 SBIRT for adults in primary care. We have a residency grant
589 program through SBIRT to address future prescribers and
590 include screening for prescription drugs.

591 We support prevention and early intervention through
592 several other grant programs. Our block grant program is
593 targeted toward funding to States and territories for their
594 prevention and treatment and services efforts. The Strategic
595 Prevention Framework Partnerships for Success program is

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596 designed to address two of the Nation's top substance abuse
597 prevention priorities, including underage drinking and
598 prescription drug misuse and abuse among persons aged 12 to
599 25.

600 We work with ONDCP on our Drug-Free Communities efforts
601 in collaboration to make sure that communities can prioritize
602 prescription drug abuse. We are working with other federal
603 agencies to explore telemedicine to address the need for
604 increased access in rural settings. Our strategy to reduce
605 prescription drug misuse includes the expansion of improved
606 access to treatment, the Drug Addiction Treatment Act of 2000
607 permits qualified physicians to prescribe certain medications
608 for the treatment of opioid addiction in outpatient settings.

609 We also regulate opioid treatment programs that use
610 methadone and buprenorphine approved by FDA to treat patients
611 with opioid dependence. We are working in collaboration with
612 the DEA.

613 Through these and other efforts, SAMHSA is working daily
614 to address the issue in order to reduce the significant long-
615 term impacts of this serious public health problem. Thank
616 you for the opportunity to testify regarding SAMHSA's efforts

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617 in this area and I welcome any questions that you might have.

618 [The prepared statement of Dr. Clark follows:]

619 ***** INSERT C *****

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|
620 Mr. {Pitts.} The chair thanks the gentleman. The chair
621 apologizes; we are trying to get the jackhammer to stop, but
622 until that time, if you will please speak directly into the
623 mike, we would appreciate it.

624 Thank you for your testimony. I will begin the
625 questioning and recognize myself for 5 minutes for that
626 purpose.

627 Director Kerlikowske, the ONDCP oversees and coordinates
628 the many agencies involved in prescription drug abuse.
629 Please describe the advantages and challenges that come with
630 having so many agencies and departments involved in the fight
631 against prescription drug abuse.

632 Mr. {Kerlikowske.} Congress clearly recognized the need
633 for coordination, the fact that there are 15 primary federal
634 agencies that all have a role in the drug issue. I don't
635 think anything is more complex or challenging than the
636 prescription drugs. It is not like an issue where it is
637 coming across the border; it is coming right out of our own
638 medicine cabinets. The mere fact that it was not recognized
639 as a significant problem except by subject matter experts in

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640 the health field, people that ran treatment programs, but
641 generally, the public did not even begin to understand the
642 magnitude of the prescription drug problem.

643 We worked to bring everybody together to sit at the
644 table and to develop a plan knowing that any one component,
645 whether it was the law enforcement agencies, whether it was
646 the regulatory agencies, that any one component would not be
647 able to solve or at least significantly reduce this problem.

648 Our partners, two of which are here, but a number of
649 them are out as part of our program, all came together with
650 one goal, and that is to reduce this tragedy not only in the
651 loss of life but the expense, so we couldn't be more pleased
652 with 1) their cooperation, and 2) at least the inkling, as
653 Dr. Clark said, of some success in this area.

654 Mr. {Pitts.} Thank you. Dr. Throckmorton, generic
655 versions of long-acting opioids without abuse-deterrent
656 properties entered the market in January of this year. Does
657 the Agency intend to monitor real-time data in order to
658 evaluate whether such entry affects opioid abuse and how well
659 real-time data like this will be utilized by the Agency now
660 and in the future when the FDA is evaluating the science

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661 regarding claims of abuse deterrents?

662 Dr. {Throckmorton.} Mr. Chairman, the goal that our
663 agency has set is to incentivize the development of
664 successful abuse-deterrent formulations and find ways to move
665 them onto the market. Our intent is to set forth a roadmap
666 that makes that successful, makes that happen in good time.
667 Following up on that, we need to work to develop ways to move
668 generics that also have abuse-deterrent technologies, make
669 them possible to come onto the market as well.

670 You asked about monitoring of the response of the
671 marketplace to those sorts of decisions. We do watch that
672 information. We have an Office of Epidemiology that focuses
673 on marketing issues, as well as post-marketing safety issues.
674 We use that information as we look at individual decisions to
675 understand the impact that a decision that ours might have
676 with regard to the use of products in the market.

677 Mr. {Pitts.} And to follow up, the FDA has committed,
678 through the user fee process, to increase transparency and
679 predictability around the drug review and approval process.
680 Earlier this week, we wrote to DEA regarding delays in
681 reviewing FDA scheduling recommendations for new drug

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682 approvals containing controlled substances. Does the Agency
683 have recommendations on improving this process to address the
684 issue of DEA delays?

685 Dr. {Throckmorton.} It is an important question that we
686 make sure that we have timely access to new medicines that
687 are recommended for controlling, but we need to remember that
688 the final decision about the controlling is made by the Drug
689 Enforcement Administration under the Controlled Substances
690 Act. My focus in the Center for Drugs has been to make
691 certain that there is a timely scientific assessment from the
692 FDA that can in fact work to inform that decision by the Drug
693 Enforcement Administration. So what we have been doing is
694 looking back at our process to make sure that it is as
695 efficient and timely and scientific as possible so we get our
696 recommendations in good order to the Drug Enforcement
697 Administration through our Office of Assistant Secretary for
698 Health, which is at the Health and Human Services level.

699 Mr. {Pitts.} Thank you. Dr. Clark, can you discuss
700 your relationship with the 46 States that operate
701 Prescription Drug Monitoring Programs?

702 Dr. {Clark.} We are working in concert with the

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703 Department of Justice, the Harold Rogers program. We have,
704 through our special initiatives, reached out to as many
705 jurisdictions as possible so that we can link the PDMPs with
706 electronic health records.

707 As you know, as I mentioned, the NASPER program, which
708 was targeted toward grants to States, has not been funded, so
709 we have shifted our focus from that effort to looking at
710 other technologies so that we can address the public health
711 aspect of this by linking electronic health records to PDMPs
712 so that we can have real-time data so that the practitioner
713 in the clinic or in the emergency room has access to
714 information about the client sooner than some of the delays
715 associated with current State PDMP programs.

716 We can't wait 2 weeks to inform the clinician. We would
717 like to be able to get that clinician real-time access to
718 information so that they can make appropriate decisions about
719 the care. Sometimes, it is someone who is running a scam on
720 the doctor; sometimes, it is a patient who is having a
721 reaction to the medication. So it is really useful to have
722 real-time access to the clinical context of using
723 prescription drugs.

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724 Mr. {Pitts.} The chair thanks the gentleman. My time
725 is expired. And the chair recognizes the gentlelady from
726 California, Mrs. Capps, for 5 minutes for questions.

727 Mrs. {Capps.} Thank you, Mr. Chairman.

728 And I am so glad we are here today having a hearing on
729 an issue that really clearly cuts across party lines.

730 Prescription drug abuse is a real and pervasive problem,
731 and while it clearly impacts families and communities across
732 our Nation, it also affects our health care system. However,
733 I want to make sure that efforts to address this issue,
734 important as they are, do not cause other problems,
735 especially those regarding people with chronic pain. This is
736 a delicate balancing act in a way.

737 Americans' struggle with pain has been an important
738 issue for me for many years. In 2007, I introduced the
739 National Pain Care Policy Act and was pleased to see the part
740 of it was included with the Affordable Care Act. As a
741 result, the Institute of Medicine was directed to do a study
742 on pain, and what they found is that pain is the most common
743 reason people seek medical care. Over 160 million US adults
744 suffer from chronic pain. The severity, duration, and

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745 disabling consequences of pain vary from person to person, as
746 does the response to treatment. But pain accompanies a range
747 of other clinical conditions, as all of you know, including
748 cancer, diabetes, arthritis, and on and on. Access to
749 medications is critical for these patients and survivors in
750 order to complete other prescribed treatments and maintain
751 other activities of daily living. And many medications
752 prescribed to patients for acute pain, as well as chronic
753 pain contain hydrocodone. So Dr. Throckmorton, as FDA
754 reviews the potential rescheduling of hydrocodone-containing
755 medications, does sufficient data and analysis exist about
756 the potential impacts rescheduling could have on patient
757 access to hydrocodone-containing medications?

758 Dr. {Throckmorton.} Thank you, Congresswoman. First,
759 let me say I agree with you. Finding a balance between the
760 necessary access for pain medicines for patients that require
761 them and addressing this crisis of abuse is absolutely
762 essential, something that the FDA keeps in mind as we are
763 thinking about our regulatory activities. With regard to
764 assessing access to pain medicines, it is something we have
765 worked on internally; it is something I have discussed with

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766 outside groups extensively. I know there are a number of
767 people looking at better ways to measure that.

768 There is a part of our REMS implementation that we put
769 in place last year. For instance, we required to the
770 manufacturers to assess the impact of that REMS on access to
771 pain medications because we understand that it is an
772 important aspect of our regulatory activities and whatever we
773 end up deciding to do in the future.

774 With regards to hydrocodone, Congress, in the recent
775 Food and Drug Administration Safety and Innovation Act
776 directed us to hold public hearing on hydrocodone and up-
777 scheduling, and in that direction included language directing
778 us to talk to patients and groups that had experience on the
779 impact that this might have with regards to the up-scheduling
780 of hydrocodone. We held that meeting. We have over 700
781 comments to the docket about that meeting that we are
782 currently looking at. A large number of them comment on the
783 effects that different activities might have as regards to
784 access, something that we are reviewing as we think about
785 making our decisions.

786 Mrs. {Capps.} Thank you. And if there are access

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787 problems, could you elaborate--I know there is not much time
788 left--but on the process available to individuals who are
789 rightfully prescribed these medications but encounter
790 problems accessing them?

791 Dr. {Throckmorton.} The reason why they are having
792 trouble getting the medicine would be important to
793 understand. So if there is a drug shortage, for instance,
794 and their challenge is getting a drug that is not available
795 anywhere in their area, FDA has a drug shortage staff that I
796 supervise, and we would love to hear from you. We have a
797 website. We would want to work with you to find other ways
798 to make that pain medicine available to you.

799 If it is due to lack of availability at a pharmacy or
800 pharmacies near you, you know, because of concerns over
801 scheduling or something like that, those things I would have
802 a less clear answer on but I would suggest the Boards of
803 Pharmacy or other local area groups like that might be
804 somewhere to talk to.

805 Mrs. {Capps.} Thank you. And, Mr. Chairman, I am about
806 out of time and I didn't even get to ask the other 2 members
807 of the panel. This is such an important topic I think for us

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808 to be discussing, and I would certainly hope that this is
809 just one hearing, that we have many more because I wanted to
810 get into prevention, and that is a whole other topic and
811 involved may be some other people, too, but you certainly are
812 experts on this. We could certainly use some more hearings
813 on this topic in my opinion. So thank you very much for
814 scheduling this one.

815 Mr. {Pitts.} The chair thanks the gentlelady, and this
816 is just the first in a series of hearings we plan.

817 The chair now recognizes the vice chairman of the
818 Subcommittee, Dr. Burgess, for 5 minutes for questions.

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

820 And Mr. Kerlikowske, you sent a letter--you heard me
821 reference the alignment of our policies with those to our
822 neighbor to the north and you sent a letter about this. And
823 you got Dr. Throckmorton over there diligently working on
824 abuse deterrents and OxyContin, but how do we align our
825 policies with Canada to prevent the older generic form from
826 coming across the border? Because I, probably as we speak
827 about this, I can see someone developing a business plan that
828 would involve the importation of large amounts of generic

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829 OxyContin that didn't have an abuse deterrent.

830 Mr. {Kerlikowske.} It is an important issue because the
831 United States has done a lot to reduce the easy availability
832 and also the fact that the opioid prescription painkillers
833 here are not as easily manipulated, but the fact that Canada
834 has that was of great concern to us. So early on, before
835 they hit the market, we had written to the Health Minister.
836 The Health Minister from Canada replied that she actually
837 didn't have the authorities within Canadian law to limit
838 this, but she had not only heard from us; she had also heard
839 from the provinces who were also concerned that this would be
840 widely and easily available within the provinces.

841 So we notified Customs and Border Protection first to
842 identify and be aware of this in case they see these coming
843 through. So far in Milwaukee that is the only location that
844 we have received a report of seeing some of these, and it was
845 not a great number of them.

846 We have a meeting scheduled in July with our Canadian
847 counterparts who will be here in Washington, D.C., and I will
848 be traveling to Ottawa hopefully with a colleague from the
849 Food and Drug Administration to also work with them.

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850 Dr. {Burgess.} So you will be monitoring it?

851 Mr. {Kerlikowske.} Absolutely.

852 Dr. {Burgess.} And would you be averse to providing
853 periodic reports to the staff of this committee--

854 Mr. {Kerlikowske.} I would be happy to.

855 Dr. {Burgess.} --about that ongoing effort? You know,
856 let me just ask you on your four pillars in your testimony
857 you talked about, the last pillar was the enforcement piece.
858 And, you know, despite the salacious nature of the covers of
859 this magazine, I submit to you that I can help you locate the
860 bad actors. They advertise and it is not hard to pick them
861 out of a crowd. So I hope you are focusing some efforts on
862 disrupting the supply chain because, again, these people are
863 not shy about telling you who they are and where they are and
864 their hours of operation, their prices, and a discount
865 coupon.

866 Mr. {Kerlikowske.} You can see certainly Broward
867 County, Florida, was the kind of epicenter of this. They had
868 90 of the top 100 prescribing and dispensing--

869 Dr. {Burgess.} This magazine is from Broward County--

870 Mr. {Kerlikowske.} --opioids.

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871 Dr. {Burgess.} --so I wasn't going to identify the
872 location, but since you did--Dr. Throckmorton, let me just
873 ask you. Are there any efforts at the FDA to make naloxone
874 an over-the-counter preparation like an inhaler or an
875 autopen?

876 Dr. {Throckmorton.} We think it is important to first
877 understand how best to use the naloxone, so we are working as
878 a part of a much larger group of federal agencies to
879 understand the best uses of naloxone. As a regulator, my job
880 in that discussion is not to decide as a policy how naloxone
881 should be used, and instead, it is to lay out the regulatory
882 pathway should a firm be interested in developing one of
883 those products. So we have met regularly with the makers of
884 autoinjector products, makers of inhalational products to lay
885 out the pathways that are necessary for them to get approval
886 as prescription products.

887 At the meeting that we held last year, attended by NIDA,
888 attended by the Office of National Drug Control Policy and
889 SAMHSA, we heard loud and clear that there was a broad
890 interest in moving naloxone to over-the-counter status.

891 Dr. {Burgess.} Yes, let me just interrupt you. I am

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892 not sure I agree with that, but we live in a world where
893 levonorgestrel now is available over-the-counter with the
894 Tootsie Rolls and Snickers bars. If interdiction and
895 abstinence is not going to work in other areas, you know,
896 maybe this is something that needs to be looked at because
897 anyone who has ever seen the dramatic reversal of an amp of
898 NARCAN on an opiate overdose will understand that you go from
899 crisis to normal in the space of 26 seconds, and it is
900 dramatic.

901 Again, I am not saying that I advocate that, but I just
902 wonder in this brave new world that we have entered, is that
903 a consideration? So I hear that you are in fact entertaining
904 that.

905 Mr. Kerlikowske, I also have to mention about drug
906 diversion, and you mentioned the 11 hours in medical school.
907 You do learn a lot in your very first years in residency and
908 practice, and I just recall very vividly when I was a
909 resident at Parkland Hospital moonlighting at community
910 hospitals, and someone would come in with a textbook
911 description--in fact, they probably memorized the textbook--
912 but a textbook description of renal pain--renal colic pain

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913 and were savvy enough to bite their lip and spit in the cup
914 before they collected a specimen for you so they had blood in
915 their urine and fit the bill pretty quickly. And I know what
916 it is, Doctor; I have an appointment with my urologist. I
917 just need something to get me through the night. And about
918 the fourth time you hear that story, you think, there is
919 something fishy here.

920 Of course, doctor shopping is a big problem and the
921 doctors who are just leaving training and getting into
922 practice, this is where a lot of that educational activity
923 could do a lot to prevent diversion.

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

925 Mr. {Pitts.} The chair thanks the gentleman and now
926 recognizes the gentlelady from Florida, Ms. Castor, for 5
927 minutes for questions.

928 Ms. {Castor.} Thank you, Mr. Chairman.

929 And thank you, gentlemen, very much. I am especially
930 grateful to Director Kerlikowske because you have given us
931 such great guidance in the State of Florida where,
932 colleagues, it has been a horrendous problem in the State of
933 Florida. You would not believe, you could drive by some of

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934 these pain management clinics and see lines of people early
935 in the morning, and we would often hear from our colleagues
936 in Kentucky, in Virginia, in Tennessee about how folks would
937 just travel down to Florida, find a pain management clinic
938 that would prescribe, give them onsite hundreds of pills, go
939 back.

940 And this pipeline, fortunately, has been squeezed now.
941 Florida finally adopted a prescription drug database. We
942 have some stops and starts with that. I am concerned their
943 physicians and pharmacists are not using it; it is voluntary.
944 I am a little bit concerned the State hasn't provided a long-
945 term commitment to make it work, and I would like you all to
946 address that.

947 But local law enforcement, they are seeing some
948 improvements from where we would have at least one death per
949 day in our community from prescription drug abuse. They say
950 now with county ordinances on these pain management clinics
951 new requirements to go after the docs, arrests of doctors and
952 prosecutions. But I know local law enforcement can't do it
953 all.

954 Can you all tell how is the State of Florida doing

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955 because I know it has been, unfortunately, one of the worst
956 in the country? And then at the federal level what can we do
957 to provide greater tools to local law enforcement? And then
958 one of my local sheriffs says it is not up to local law
959 enforcement; this is an addiction and we have go to do more.

960 Director?

961 Mr. {Kerlikowske.} As a graduate of the University of
962 South Florida, I had a special affinity for the problems in
963 Florida in particular. But I can tell you that Florida is
964 doing markedly, remarkably better. The leadership of the
965 attorney general, Pam Bondi, on this issue has been very
966 good. We have worked hard with a number of groups there and
967 Florida has actually reduced the problem I think from seven
968 overdose deaths a day. They have been able to make progress.

969 I think from the Federal Government's standpoint what we
970 need to be able to do is to make sure that these prescription
971 drug monitoring plans are interoperable. Fourteen States now
972 can share data but we saw a moment of some of the physicians
973 that were suspect, as the vice chair mentioned, from Florida
974 to other States, and so that information needs to be done.
975 So that is one thing the Federal Government can continue to

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976 do.

977 Ms. {Castor.} You know, our database is voluntary and
978 it hasn't been up and running for very long, but still, there
979 is some frustration that you only have 10 percent of
980 pharmacists that are using it and not many doctors. So if we
981 have interoperability between States, that still doesn't get
982 to the problem of incentivizing pharmacists and doctors,
983 prescribers to use that. How do we better incentivize the
984 use of the database?

985 Mr. {Kerlikowske.} And we are actually seeing
986 significant improvements. One is that the electronic health
987 records system, which eventually will be compatible with
988 these kind of systems so that you don't have one PDMP
989 standalone system, and then you have got your other
990 electronic health records.

991 The other is the e-prescribing that has taken hold.
992 Physicians are not very happy about being able to prescribe
993 electronically a large number of different types of drugs,
994 but when it comes to controlled substances, they go back to
995 paper and pencil. All of these things are kind of underway,
996 but I think the amount of education and information that is

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997 being made to the physicians is a result of using a PDMP and
998 the stories that they have told and the fact that we are
999 strongly encouraging mandatory prescriber education will be
1000 helpful. Thank you.

1001 Ms. {Castor.} Okay. And, gentlemen, can you all tell
1002 me--I am a cosponsor of a bill, H.R. 1285 by Congressman
1003 Buchanan from the Sarasota area and Congressman Markey from
1004 the Energy and Commerce Committee. It would amend the
1005 Controlled Substances Act to make any substance containing
1006 hydrocodone a schedule II drug. Do you all support that?
1007 Could you just say yes or no because my time is limited?

1008 Mr. {Kerlikowske.} I don't believe the Administration
1009 has taken a position and we have strongly encouraged the
1010 science-based evaluation for the scheduling. So I wouldn't
1011 be able to tell you right now.

1012 Ms. {Castor.} Okay. Doctor?

1013 Dr. {Throckmorton.} He is speaking for the
1014 Administration.

1015 Ms. {Castor.} Okay. And same answer, Dr. Clark?

1016 Dr. {Clark.} Speaks for the Administration.

1017 Ms. {Castor.} Okay. Thank you all very much for your

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1018 efforts in this area.

1019 Mr. {Pitts.} The gentlelady's time is expired.

1020 At this time I request unanimous consent to include a
1021 statement from the National Association of Chain Drug Stores
1022 into the record.

1023 Without objection, so ordered.

1024 [The information follows:]

1025 ***** COMMITTEE INSERT *****

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1026 Mr. {Pitts.} The chair now recognizes the gentleman
1027 from Illinois, Mr. Shimkus, for 5 minutes for questions.

1028 Mr. {Shimkus.} Thank you, Mr. Chairman. And I just
1029 have two brief questions.

1030 One is I understand in Europe 85 percent of their
1031 prescription drugs is in blister packaging. Whether that is
1032 correct or not, that is what I have been informed. Do you
1033 think that would have any positive effect on some of these
1034 specific prescription type drugs, especially for those that
1035 might be going to, you know, families or families who are
1036 taking care of seniors and really the accountability and the
1037 inability to really just disburse that without breaking up
1038 the package?

1039 Dr. {Throckmorton.} I think it is a very good question,
1040 and the use of innovative packaging and storage techniques to
1041 make a difference in this particular crisis, one of the
1042 things that we have not had an opportunity to think through
1043 as fully as we would like to.

1044 I have formed a group within the FDA to start looking at
1045 these issues. I have a part of my center that focuses on

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1046 packaging and labeling and those things, and I have asked
1047 them to look at issues like this.

1048 One of the challenges about requiring blister packs for
1049 one kind of drug is that it spills over to requiring blister
1050 packs potentially for other kinds of drugs that have similar
1051 kinds of dangers, and there is a concern about access and
1052 impact in other ways on health care system. So we need to
1053 look broadly at how these packaging more creatively than we
1054 have, I believe.

1055 Mr. {Shimkus.} Anyone else want to add? No. We were
1056 talking about some of the--and I am not a medical doctor so I
1057 don't remember all the names and stuff of the various drugs
1058 or the drugs to remediate the drug effect, but I am curious
1059 as to how much coordination there is between each of you when
1060 there is a development of a promising treatment which could
1061 help address the national priority of abating the drug abuse
1062 crisis? And I do know the FDA really has the approval
1063 though, but are you all involved with them, especially in
1064 this case, Dr. Clark?

1065 Dr. {Clark.} Yes, not only the FDA has the leadership
1066 in that but we work in collaboration with ONDCP, NIH, and

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1067 others, as the literature, which as Dr. Throckmorton
1068 mentioned, that the science-based literature produces new
1069 ideas. We have this ongoing dialogue. We have working
1070 groups that are multiagency, multi-department to examine the
1071 implications. We also work with the organized medicine and
1072 the various medical societies to address these issues. We
1073 try to track these developments so that we can decide whether
1074 they can be moved into clinical practice.

1075 Mr. {Kerlikowske.} We spend more time with each other
1076 than our family.

1077 Mr. {Shimkus.} That is true up here, too, many times,
1078 unfortunately.

1079 So, Mr. Chairman, that is all I have. I yield back the
1080 balance of my time. Thank you.

1081 Mr. {Pitts.} The chair thanks the gentleman and now
1082 recognizes the gentlelady from Illinois, Ms. Schakowsky, for
1083 5 minutes for questions.

1084 Ms. {Schakowsky.} Thank you, Mr. Chairman. I wanted to
1085 also reinforce my view. I think I do have something as a
1086 comment that is already in the record, and when it comes to
1087 the changing the scheduling of hydrocodone from its current

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1088 schedule III to schedule II of the Controlled Substance Act,
1089 that was one of the suggestions that came from my constituent
1090 who lost his daughter.

1091 The other was he suggested--and I don't know if this is
1092 under consideration--take steps necessary to restrict the use
1093 of oxycodone pain relievers to severe pain rather than
1094 moderate to severe pain, so that would change the packaging
1095 in order to prevent the overprescribing of these powerful
1096 medications. I wonder if any--actually, whoever knows best.

1097 Dr. {Throckmorton.} Yes, that is something that I can
1098 comment on. There are citizens' petitions, there are
1099 requests for action before my agency about the changes in
1100 labeling that you are referring to, so I won't be able to
1101 talk in great specific about the changes in what is called
1102 the moderate-to-severe language that is in current opioid
1103 indications.

1104 I mean I will say, however, that the FDA has always had
1105 an interest in making sure that our labels are accurate and
1106 fair and include all of the information that we know to be
1107 scientific.

1108 I had a public meeting earlier in this year where I

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1109 posted a series of questions to academics, advocates, family
1110 members asking for their help in understanding how our
1111 current labeling for opioids might be improved, in general
1112 asking them for suggestions, and we got a number of comments
1113 and we are in the process of looking at those comments,
1114 looking at other ways to make sure those labels say what they
1115 need to. We believe educating prescribers begins with the
1116 approved labeling, which outlines how the products are best
1117 used based on our scientific judgment, and we need to make
1118 those as fully accurate as we can.

1119 Ms. {Schakowsky.} I wonder if part of the customer, the
1120 consumer education includes encouraging families with
1121 children between 12 and 18 to have a lockbox for certain
1122 drugs so that they keep them out of the hands of children,
1123 Dr. Clark?

1124 Dr. {Clark.} Yes, we do believe that prescription drugs
1125 should be treated very carefully. Lockboxes are good ideas.
1126 As Chairman Pitts pointed out, a lot of prescription drugs
1127 are shared between friends and family, so you have got this
1128 cultural dynamic that we also have to deal with. So
1129 consumers and family members need to be brought in.

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1130 And our prevention efforts include not only take-back
1131 programs that Mr. Kerlikowske mentioned but the idea of
1132 promoting of the appropriate management of description drugs
1133 in the home. So lockboxes is our one strategy; making sure
1134 we have an informed consumer, another strategy; making sure
1135 that the delivery system educates the consumer about the
1136 potential risk of misuse and diversion of the medications,
1137 yet another strategy.

1138 And, as was pointed out, we need to reach out to
1139 consumer groups and parent groups and consumer coalitions so
1140 that we can promote this cultural shift in attitudes about
1141 these medications.

1142 Ms. {Schakowsky.} Okay. I have one more question. It
1143 appears there is a new trend of manufacturers seeking
1144 approval of new abuse-deterrent formulations near the time of
1145 the expiration of their patents and marketing exclusivity, so
1146 they then withdraw the original formulation from the market
1147 claiming it is no longer safe in light of the availability of
1148 the abuse-deterrent formulations. And if the FDA agrees that
1149 the original formulation was removed for safety reasons, then
1150 the FDA is precluded from approving generic competitors

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1151 without comparable abuse-deterrent formulations. And in the
1152 absence of generic versions, then patients are forced to pay
1153 higher monopoly prices for extended time periods, which in
1154 turn has the potential to decrease patient access to these
1155 drugs. Have you heard about this?

1156 Dr. {Throckmorton.} Yes. And this is back to the
1157 discussion of the balances, you know, that need to be kept in
1158 mind as we think about addressing this abuse crisis. So in
1159 this case we have the necessary balance between incentivizing
1160 the development of abuse-deterrent formulations that work.
1161 We want to have opioids in formulations that deter abuse. I
1162 believe that is in everyone's best interest to find a way to
1163 incentivize that while at the same time recognizing the
1164 impact and importance of the generics in the U.S. market,
1165 currently well more than 75 percent of the total
1166 prescriptions, et cetera.

1167 Accomplishing that balance is something that the FDA is
1168 thinking and working very hard on. Our first action was
1169 earlier in the year when we put out the guidance laying out
1170 how we would try to incentivize the development of new
1171 formulations. Following up on that, we are now thinking

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1172 about ways to develop guidance on abuse deterrent
1173 formulations to generics to allow them to come on the market
1174 as well.

1175 In other places and in this place I would expect our
1176 focus would be on the performance of those generics and not
1177 on the technology that was used to make that generic. So we
1178 would require that the generics demonstrate they are abuse-
1179 deterrent, the thing that we would all want to have rather
1180 than that they used the same technology. We think that would
1181 incentivize the development of appropriate generics, generics
1182 that work, while recognizing the important role that the
1183 innovator plays here in terms of developing new innovative
1184 products.

1185 Mr. {Pitts.} The chair thanks the gentlelady and now
1186 recognizes the gentleman from Louisiana, Dr. Cassidy, for 5
1187 minutes for questions.

1188 Dr. {Cassidy.} Thank you, Mr. Chairman.

1189 Mr. Kerlikowske, what percent of docs write what percent
1190 of narcotics?

1191 Mr. {Kerlikowske.} Congressman, I actually don't know.
1192 I know that the information about the doctors said to

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1193 prescribe, for instance, oncologists write a large number of
1194 the--

1195 Dr. {Cassidy.} So oncologists, pain doctors?

1196 Mr. {Kerlikowske.} The pain doctors, et cetera. And I
1197 think Dr. Throckmorton probably can also help me. I just
1198 play a doctor on TV. I am with a real doctor.

1199 Dr. {Throckmorton.} And I won't be able to give you
1200 specific numbers; we can certainly get that. The majority of
1201 pain medications are actually written by primary care doctors
1202 and--

1203 Dr. {Cassidy.} No, that is the majority--

1204 Dr. {Throckmorton.} Yes.

1205 Dr. {Cassidy.} But if we look at those who write an
1206 extraordinary amount, you know, those that are two standard
1207 deviations out, by definition if you are two standard
1208 deviations out, you are 5 percent, right? So intuitively, if
1209 we are looking at the folks who we are concerned about, I am
1210 suspecting that it is going to be a small percent writing a
1211 lot of the inappropriate prescriptions. You are nodding your
1212 head. Do you think that intuition is correct?

1213 Dr. {Throckmorton.} It depends on where you cut that

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1214 line off is 5 percent or it is something like that. But
1215 there is clearly a minority of physicians that are writing
1216 for large amounts of these opioids. I agree with that.

1217 Dr. {Cassidy.} Now, I am not sure to whom this would
1218 go; I think one of the two of you because I am not sure this
1219 is SAMHSA's gig, but I know if you got 46 States that have a
1220 Prescription Drug Monitoring Program, I am a doc; I have a
1221 DEA number. Every time I write that number it a goes into a
1222 database and they know if I have written an Rx. I think,
1223 although I was not able to confirm, these databases and
1224 likewise have patient information. Now, I keep on wondering
1225 if our goal is to find that small percent of docs who are
1226 writing inappropriately and we have a unique identifier for
1227 whom that doc is and we can look up in the phone book and see
1228 where their practice is, why don't we just turn it over to
1229 Google and let them data mine and tell us who are the crooks?
1230 Do you follow what I am saying?

1231 Aside from being tongue-in-cheek, if we have all these
1232 unique identifiers and all these databases are real-time
1233 data, what is the challenge in figuring out which docs are
1234 the bad actors?

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1235 Mr. {Kerlikowske.} There are a couple challenges that
1236 really do come up. One is that things can change,
1237 particularly in rural areas, pretty dramatically if a
1238 physician leaves a practice and is gone and suddenly that
1239 physician taking his or her place has to write a lot more
1240 prescriptions because they have actually taken over.

1241 Dr. {Cassidy.} But as we look at the data, I mean
1242 knowing that the urban setting is where most of this is
1243 happening, but even if it is rural, what you describe is a
1244 little kind of codicil that is still broad sweep. It seems
1245 as if we have got a unique identifier, you have got a real-
1246 time database, and you have got 46 States with it; it doesn't
1247 seem like this should be such a challenge.

1248 Mr. {Kerlikowske.} You are right, but also the real
1249 devastation has been in the rural areas. Kentucky, southern
1250 Ohio--

1251 Dr. {Cassidy.} I will accept that as well, but again,
1252 you have got a unique identifier, you have got a real-time
1253 database; what is the great challenge?

1254 Mr. {Kerlikowske.} I think the other challenge is that
1255 because these are individual state programs, some are within

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1256 the law enforcement component, some are within the medical
1257 practice component, and each State uses those individually to
1258 determine--

1259 Dr. {Cassidy.} So does DOJ have access to these
1260 Prescription Drug Monitoring Programs?

1261 Mr. {Kerlikowske.} Those who have access?

1262 Dr. {Cassidy.} Department of Justice or do you or does
1263 the executive branch?

1264 Mr. {Kerlikowske.} No.

1265 Dr. {Cassidy.} So it is entirely state jurisdiction?

1266 Mr. {Kerlikowske.} Exactly.

1267 Dr. {Cassidy.} Now, we mentioned interstate compacts.

1268 I presume in these interstate compacts the States are
1269 communicating one to the other as to, listen, this fellow
1270 just dropped out; he moved to your State. He is someone you
1271 should watch for. Dr. Clark, do you have a thought?

1272 Dr. {Clark.} Well, we are moving toward that position.

1273 It is really important to recognize that the electronic
1274 health record integration and interoperability activity is
1275 moving toward that position. Some jurisdictions are in fact
1276 trying to come up with algorithms where you can identify the

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1277 outliers in terms of pain medication--

1278 Dr. {Cassidy.} Well, it just seems like a sort.

1279 Dr. {Clark.} It is a little more complicated than that,

1280 as Dr. Throckmorton pointed out, in part because you do in

1281 fact pull in the cancer doctors or the arthritis doctors--

1282 Dr. {Cassidy.} But I know that. But you know who the

1283 cancer doctors are. If there are 100,000 docs, there is

1284 going to be 5,000 who are cancer and 5,000 who are legitimate

1285 pain docs, and then there is going to be somebody who you

1286 know just moved to this state from that state to the state.

1287 Dr. {Clark.} Indeed. And that is what the electronic

1288 health records and interoperability--

1289 Dr. {Cassidy.} Now, see, it concerns me that your

1290 electronic medical record, because really I don't want the

1291 government snooping in my electronic medical record. On the

1292 other hand, if we have a real-time database your Prescription

1293 Drug Monitoring Program, that is the subset of folks who are

1294 writing Rx's and it is centered upon the physician, and you

1295 can look and see here is my top thousand writers, 500 are

1296 oncologists or pain docs or ortho, and here is--do you see

1297 what I am saying?

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1298 Dr. {Clark.} Yes, well, HHS has actually done a survey
1299 looking at part D programs and it discovered it was a little
1300 more complicated because indeed trying to pigeonhole a
1301 practice isn't as simple as all that. But you are right with
1302 the advent of increasing monitoring capability and big data,
1303 we will be able to make some kind of reasonable assessment of
1304 a practitioner and at least explore that practitioner, what
1305 he or she is doing.

1306 Dr. {Cassidy.} Okay. I yield back. Thank you.

1307 Mr. {Pitts.} I thank the gentleman and now recognize
1308 the gentleman from North Carolina, Mr. Butterfield, for 5
1309 minutes for questions.

1310 Mr. {Butterfield.} Thank you so very much, Mr.
1311 Chairman, and thank you for convening this hearing and thank
1312 the three witnesses for their testimony here today.

1313 Prescription drug abuse is certainly a serious problem
1314 that impacts an estimated 12-1/2 million Americans and now is
1315 considered a health epidemic by the Centers for Disease
1316 Control. And so it is a serious problem. This hearing today
1317 is very appropriate. This is a conversation that we must
1318 have and we must do something about it if we can.

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1319 In the last Congress I served as ranking member of the
1320 Commerce, Manufacturing, and Trade Subcommittee under the
1321 then-leadership of Chairwoman Mary Bono. The issue of
1322 prescription drug abuse is one that was and continues to be
1323 very important to her and to me. Our subcommittee held
1324 several hearings on prescription drug abuse last Congress,
1325 and so I have a somewhat keen understanding and interest in
1326 stemming the growing problem.

1327 The chair then and I shared a deep concern for
1328 individuals' well-being, especially young people who gain
1329 access to an abuse prescription drugs. The multiple hearings
1330 that we had on this issue during the last Congress made very
1331 clear to me that drug manufacturers and the drug supply chain
1332 are not the problem. With Purdue Pharma developing next-
1333 generation crush-resistant drugs, the industry is playing an
1334 increasing role in stopping illicit use. Nefarious black
1335 markets and drug diversion at the end-user stage are the
1336 problem.

1337 And so the question is how do we address this problem
1338 while avoiding burdensome regulations on your manufacturers
1339 and others along the supply chain?

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1340 And so I just want to follow up just a bit on Ms.
1341 Schakowsky's line of questioning a few moments ago. Abuse-
1342 deterrent drugs are a fairly new addition to the market, and
1343 so what impact have abuse-deterrent drugs had on the illegal
1344 and illicit use of prescription drugs? And so just thinking
1345 out loud, I would just imagine that if one drug is made
1346 abuse-deterrent, the person would just find another drug that
1347 is not abuse-deterrent that produces a similar result,
1348 shifting but not reducing the abuse.

1349 And I guess I can go to Dr. Throckmorton on this one.
1350 Should the FDA remove roadblocks to manufacturers who want to
1351 produce abuse-deterrent drugs so that they can speed the new
1352 formula to market to reduce overall abuse?

1353 Dr. {Throckmorton.} Yes, we should. And we are working
1354 to do exactly that. I view the development of abuse-
1355 deterrent technologies and encouraging their use in opioids
1356 as an incremental process. We are beginning now to walk a
1357 road where I had hoped to see a broad majority of opioids in
1358 abuse-deterrent formulations. That is going to help address
1359 your concern, the squeezing the balloon if you will, people
1360 moving from abuse-deterrent formulations to another

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1361 formulation that is easier to abuse.

1362 In the short-term here, I think we would be fooling
1363 ourselves if you imagine that wasn't going to happen, so my
1364 job--I think our agency's job is to incentivize the
1365 development of those new technologies broadly and to make
1366 certain that those technologies demonstrate that they work.
1367 So we should be developing abuse-deterrent formulations that
1368 successfully reduce abuse through reviewing of the data--I
1369 believe the FDA plays a critical role there--and then
1370 rewarding those new formulations in labeling, rewarding them
1371 in ways that will encourage their use by physicians and by
1372 patients with a long-term goal of having a broad range of
1373 opioids that are in abuse-deterrent formulations.

1374 Mr. {Butterfield.} Let me now go to Dr. Clark if I can.

1375 Dr. Clark, how can we educate health care providers to
1376 spot the warning signs of frequent flyers who might not have
1377 a legitimate need for powerful prescription drugs? Do you
1378 think the implementation of interoperable electronic medical
1379 records--you mentioned that earlier--would help to flag these
1380 individuals who are doctor-surfing only to get more and more
1381 prescriptions that they need to sell?

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1382 Dr. {Clark.} Indeed. We think that the
1383 interoperability between electronic health records and the
1384 prescribing is very important. We are working with the
1385 Office of the National Coordinator for Health Information
1386 Technology to achieve that. We think that educating
1387 practitioners is important. We work with the FDA and the
1388 National Institute of Drug Abuse. We both have training
1389 programs, NIDAMED for the National Institute of Drug Abuse
1390 and SAMHSA has a training program associated with Boston
1391 University. We have trained over 13,000 prescribers. We
1392 work with state medical societies. SAMHSA sponsors state
1393 medical society training, and we have, as a result of this
1394 broader effort that the Congress has mobilized, we are
1395 fighting.

1396 More and more practitioners are showing up at our
1397 conferences to listen and learn about prescription drug
1398 abuse, to listen and learn about adequate pain management
1399 strategies, to listen and learn how to monitor for deviant
1400 behaviors and also while maintaining a good balance of care
1401 because indeed pain is a problem. So we want to continue
1402 that effort here and we think that is a useful effort.

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1403 Mr. {Butterfield.} Thank you, Dr. Clark. My time is
1404 expired.

1405 I didn't get to Mr. Kerlikowske and I spent considerable
1406 time rehearsing your name and I won't be able to use it. But
1407 I yield back.

1408 Mr. {Pitts.} The chair thanks the gentleman and now
1409 recognizes the gentleman from Virginia, Mr. Griffith, for 5
1410 minutes for questions.

1411 Mr. {Griffith.} Thank you, Mr. Chairman. I appreciate
1412 it.

1413 Dr. Throckmorton, can you please update the Committee as
1414 to where the Agency stands related to requirements of the
1415 Food and Drug Administration's Safety and Innovation Act
1416 pertaining to public meetings surrounding the scheduling of
1417 combination hydrocodone products? Now, I know you mentioned
1418 in your testimony that a public meeting had been held and I
1419 think in one of the answers to the earlier questions you said
1420 you all were relying on science instead of going straight to
1421 rescheduling some of the drugs.

1422 But can you tell us, you know, what you hope for or we
1423 are hoping for an update on what you think is the process

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1424 going forward on this rescheduling?

1425 Dr. {Throckmorton.} Sure. I won't be able to talk in
1426 any detail because we have not yet formed a recommendation
1427 about what, you know, the matter. Our task was to respond
1428 both to the science, the request from the Drug Enforcement
1429 Administration to reconsider our recommendation from 2008, as
1430 well as respond to the language that Congress gave us in
1431 FDASIA directing us to hold the meeting that included
1432 membership to solicit input on things like the impact of up-
1433 scheduling. We are taking those two things very seriously.

1434 As I mentioned previously, that meeting elicited 760
1435 some comments, over 100 of them making specific
1436 recommendations for us to consider instead of up-scheduling,
1437 so making recommendations for other activities. We are
1438 trying to work through all of those to form the best science-
1439 based recommendations--

1440 Mr. {Griffith.} Any idea of a timeline on when you
1441 think something might come out?

1442 Dr. {Throckmorton.} I am afraid I can't give you a
1443 timeline. I can tell you that I understand your frustration.
1444 I understand that this is an important issue that we want to

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1445 move forward. My people are doing everything that we
1446 possibly can to do it right.

1447 Mr. {Griffith.} I appreciate that. Thank you.

1448 Now, it may come as a surprise to some of you all that
1449 Virginia actually has the oldest medicinal marijuana law on
1450 the books dating back to the 1979 act. That was, however,
1451 unlike some of those States that have said, you know, if it
1452 makes you feel good, do it. Virginia actually requires that
1453 there be a medical reason and there be a prescription, which
1454 is not currently allowed.

1455 Wouldn't you agree with me, Dr. Throckmorton, that we
1456 need to have a discussion about the legitimate uses of
1457 medicinal marijuana and freeing it up so that Virginia can
1458 exercise its will so that doctors can actually prescribe it
1459 in those areas that are authorized by the Virginia law?

1460 Dr. {Throckmorton.} My own personal views aside, the
1461 FDA would not have a clear role in responding to issues
1462 around medicinal marijuana. We do have a role in the
1463 scheduling of marijuana in a somewhat similar fashion that we
1464 have a role to play in hydrocodone. So there is a
1465 recommendation process that the DEA requests of us. That is

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1466 regarding the development of marijuana-related drugs.

1467 Mr. {Griffith.} But you would agree that we probably
1468 ought to be having a public discussion about legitimate
1469 medicinal marijuana usage?

1470 Dr. {Throckmorton.} I think I am not going to be able
1471 to comment on that, sir.

1472 Mr. {Griffith.} All right. I appreciate that.

1473 The Center for Substance Abuse Treatment recently
1474 released an RFA for Physician Clinical Support System,
1475 Medication-Assisted Treatment to support physician
1476 educational on the use of medications to treat opioid
1477 addiction. My understanding is that a number of treatments
1478 have been approved by the FDA to directly treat opioid abuse.
1479 One such drug that I am aware of is--and I am probably going
1480 to mispronounce it--Vivitrol. How does CSAT plan to expand
1481 its efforts to increase awareness and knowledge about these
1482 new medications, Doctor--or either one of you?

1483 Dr. {Clark.} One of the things that we are doing is
1484 working with medical societies, working with the treatment
1485 programs so that they are very much aware of the existence of
1486 medication. We have promulgated advisories so that people

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1487 can understand them and we are also meeting with the
1488 manufacturers so that we have a better understanding of what
1489 their strategies are. So we think this is an important
1490 issue.

1491 We work with the FDA and ONDCP so that we can promulgate
1492 increased access to treatment because that is one of our
1493 concerns, making sure that people have access to new
1494 treatments as they develop and the consumers have access to
1495 those.

1496 Mr. {Griffith.} I thank you.

1497 I would point out, Mr. Chairman, that I have heard a lot
1498 today about electronic medical records, and Dr. Cassidy
1499 issued a concern, a warning, a broad interpretation of the
1500 Smith v. Maryland case upon which the NSA relies on in its
1501 current standing would say that if you shared your medical
1502 records with a third party insurance company, you may also
1503 not require--I don't agree with that interpretation, but you
1504 may also not require a search warrant to get those records.
1505 I don't think that is right but that is another day.

1506 Thank you, Mr. Chairman. I yield back.

1507 Mr. {Pitts.} The chair thanks the gentleman and now

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1508 recognizes the gentleman from Pennsylvania, Dr. Murphy, for 5
1509 minutes for questions.

1510 Mr. {Murphy.} Thank you, Mr. Chairman. I appreciate
1511 the panel being here.

1512 I want to follow up on some of the questions here about
1513 drugs used to treat opioid addiction. The current published
1514 information published by the FDA--and I address this to Dr.
1515 Throckmorton and Clark--allows for the use of generic
1516 buprenorphine, which is Suboxone, in the context of the
1517 doctor-patient joint decision. However, there is a concern
1518 from psychiatrists who treat persons with addictions that the
1519 published indications are vague enough to allow for
1520 misinterpretation. Now, I have heard from doctors in my
1521 district that there is misinformation about when a doctor can
1522 prescribe generic buprenorphine versus the branded Suboxone
1523 strip. And so it is leading to access issues because
1524 pharmacists are concerned about prescribing the generic.

1525 Are any of you aware of a problem with this issue? And
1526 if not, is that something you can get back to me on or we can
1527 communicate on later? I am not trying to trip you up. I am
1528 just trying to see if we can start a dialogue on that.

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1529 Dr. {Throckmorton.} It would probably be better if we
1530 had a little bit more specifics about that one.

1531 Mr. {Murphy.} Thank you.

1532 Dr. {Throckmorton.} There were recent issues about
1533 generic and innovator Suboxone. There was a citizens'
1534 petition that was submitted to our agency that we responded
1535 to. I am not sure if that is exactly it but we would be
1536 happy to follow up and--

1537 Mr. {Murphy.} I would appreciate it if we can talk
1538 directly.

1539 Let me also ask about this. Now, we are aware of all
1540 the overdoses and how much they have killed with prescription
1541 painkillers. We know that States are collecting information
1542 on prescriptions but how this helps is still a concern. One
1543 person can go to 10 different pharmacies with 10 different
1544 prescriptions and collect those, and the States can sometimes
1545 then pick up if it is the same person. But, of course, John
1546 Doe can also say, oh, I am filling a prescription for my
1547 grandmother, my aunt, and other things, and the question is
1548 can we find that person in the current system who may be
1549 using legitimate prescriptions or the next step is false

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1550 names, et cetera?

1551 How does this collecting information by the States help
1552 us in finding such persons? Could some of you comment on
1553 that? Yes, sir.

1554 Mr. {Kerlikowske.} Congressman, the two important parts
1555 of these PDMPs, which are then run by the state Boards of
1556 Licensure, one is that a physician can have that instant
1557 access to, say, to a new patient or, you know, the number of
1558 doctors that that patient has also seen because these
1559 require, when they fill these prescriptions, identification.
1560 The other is that a Board of Licensure and the States
1561 regulate medicine, not the Federal Government, can use that
1562 to identify a prescriber who may be above and beyond and then
1563 take appropriate steps for inquiry.

1564 I think that people do look at innovative ways around
1565 this but the States--and I would recognize Kentucky as an
1566 example--that have the most knowledgeable people running
1567 their PDMPs have been pretty successful in bringing this
1568 down. And of course the other part of that goal then is to
1569 get somebody into treatment to reduce the problem.

1570 Mr. {Murphy.} Well, let me add another element to this.

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1571 A couple years ago Congress passed a law saying that people
1572 were picking up Sudafed had to show a photo ID, et cetera.

1573 Mr. {Kerlikowske.} Right.

1574 Mr. {Murphy.} And our concern is in terms of what you
1575 understand very well, for all of you, is that one person
1576 picking up multiple prescriptions for themselves we can
1577 pretty much identify that may be an abuse and that person can
1578 be picked up by the PDMPs, et cetera. One person who may be
1579 legitimately gathering prescriptions to pick them up for
1580 other family members we have to somehow identify who is a
1581 person with the problem, who is not. Can any of you comment
1582 on the concept of perhaps extending that, that requiring a
1583 photo ID so that person's name could also be checked if they
1584 are picking up more?

1585 Mr. {Kerlikowske.} I would certainly be happy to tell
1586 you what the state PDMPs are seeing as a result of that
1587 question. I would be glad to do that.

1588 Mr. {Murphy.} Any others have any comments on thoughts
1589 that agencies may have about extending that?

1590 Dr. {Throckmorton.} Well, one agency that is not here
1591 would be the Drug Enforcement Agency, and I think there are

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1592 limitations on how people can fill prescriptions that are not
1593 written directly to them. And it would be important just to
1594 look into that. And I don't know those details so wouldn't
1595 want to, you know, try to answer.

1596 Mr. {Murphy.} Dr. Clark, do you have any comments?

1597 Dr. {Clark.} And while we are thinking about this in a
1598 more formal way, I do know that many pharmacies, especially
1599 the chain pharmacies, are requiring photo ID on presentation
1600 even for the person for whom the prescription is written, and
1601 whoever picks up the drug, the photo ID is required. So I
1602 know that people are concerned about the issue.

1603 Mr. {Murphy.} And I understand the chain drugstores
1604 then, they will begin to raise questions themselves by
1605 contacting the doctor, and obviously, we want to stop the
1606 illegality of this and we want to help the people in need.
1607 So I hope that is an area where we can move toward some--this
1608 is a concrete action that Congress can take on this and I
1609 look forward to talking with you more about that.

1610 Thank you very much, Mr. Chairman. I yield back.

1611 Mr. {Pitts.} The chair thanks the gentleman and now
1612 recognizes the gentleman from Texas, Mr. Green, for 5 minutes

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1613 for questions.

1614 Mr. {Green.} Thank you, Mr. Chairman, and thank you for
1615 having the hearing today.

1616 Dr. Clark, you spoke about SAMHSA's effort to prevent
1617 prescription drug abuse in the first place and you have also
1618 described SAMHSA's treatment activities when addiction
1619 disorders rise. Treatment of addiction to prescription drugs
1620 is crucial in importance and, as we all know, promising
1621 behavioral and medical approaches exist to treat this form of
1622 addiction.

1623 The Affordable Care Act builds on bipartisan legislation
1624 cosponsored and supported by many members of this committee,
1625 the Mental Health Parity and Addiction Equity Act of 2008, to
1626 ensure that more individuals suffering from substance abuse
1627 use disorders receive the care they need.

1628 My first question is how do you anticipate the
1629 Affordable Care Act will impact access to services for people
1630 who are addicted to prescription drugs or have other
1631 substance use disorders?

1632 Dr. {Clark.} One of the things that is in the
1633 Affordable Care Act is in fact the provision of services for

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1634 mental health and substance use disorders, which means that
1635 individuals who have no coverage currently and that has been
1636 one of the barriers for people seeking treatment, that
1637 barrier would be removed. So the Affordable Care Act will
1638 allow health coverage for individuals who cannot afford the
1639 cost of care and therefore would be able to engage in care.

1640 It will also allow for a broader reach for using the
1641 structures like Accountable Care Organizations so that we can
1642 identify individuals early before they develop full-blown
1643 addiction issues, risky behavior if you will, so that we will
1644 be able to intervene at an earlier point in time.

1645 Mr. {Green.} So Medicaid and the marketplace exchanges,
1646 whether they are state or national exchanges, will expand the
1647 population for those who receive substance abuse treatment?

1648 Dr. {Clark.} Indeed.

1649 Mr. {Green.} Okay. It is clear from your comments the
1650 Affordable Care Act made it possible for many people with
1651 substance use disorders, whether it is addiction to
1652 prescription drugs or illicit drugs, to access treatment.

1653 Mr. Chairman, I know we have had differences over the
1654 Affordable Care Act but I hope we all share the goal of

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1655 providing more robust treatment to those who are working to
1656 overcome prescription drugs.

1657 Director Kerlikowske--close enough, I hope--with your
1658 name like Green it is not hard to pronounce--how do you track
1659 the progress in completing action items identified in the
1660 Administration's plan in meeting the goals you have set?

1661 Mr. {Kerlikowske.} When we put together the
1662 prescription drug plan, we brought everyone to the table for
1663 a number of months, and all of the agreements that are in
1664 there continue into an interagency work group. So we set
1665 some specific goals and then we bring that where those people
1666 that are closest to the problem and on the ground and had a
1667 responsibility for each of their agencies together on a
1668 quarterly basis to go over their progress.

1669 So we are starting to see--and I come from a profession
1670 that isn't known for its optimism in law enforcement, but I
1671 can tell you that seeing the changes that Dr. Clark and the
1672 chairman talked about from 2010 to 2011, I think we are
1673 starting to turn the corner on this prescription drug
1674 problem.

1675 Mr. {Green.} Good. Dr. Clark, I am interested in

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1676 hearing more about SAMHSA's coordination with the Centers for
1677 Disease Control and Prevention on surveillance activities.
1678 For example, you testified that SAMHSA funds the annual
1679 national survey on drug use and health which collects data on
1680 nonmedical use of prescription drugs, among other things.
1681 SAMHSA also oversees Drug Abuse Warning Network, or DAWN,
1682 surveillance activities of drug-related emergency department
1683 visits and drug deaths. Is that partnership going to
1684 continue and if you have any more to share with the Committee
1685 on that partnership because obviously we like agencies to
1686 work together?

1687 Dr. {Clark.} And indeed we are working together. I
1688 think the Assistant Secretary for Health Howard Koh and my
1689 immediate boss Pamela Hyde chairing the Behavioral Health
1690 Coordinated Committee, the objective is to make sure that we
1691 are working together, and Ms. Hyde works very closely with
1692 the director of the CDC to make sure that there is no
1693 duplication of effort but there is collaboration and
1694 coordination.

1695 And we have our data teams working together. The
1696 director of the Center for Behavioral Health Statistics and

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1697 Quality, Dr. Pete Delaney, is working with the National
1698 Center for Health Statistics to make sure that we get the
1699 best data possible dealing with the epidemiology of substance
1700 abuse.

1701 Mr. {Green.} Thank you. Thank you, Mr. Chairman. I
1702 yield back.

1703 Mr. {Pitts.} The chair thanks the gentleman and now
1704 recognizes the gentleman from Kentucky, Mr. Guthrie, for 5
1705 minutes for questions.

1706 Mr. {Guthrie.} Thank you, Mr. Chair. And I thank you
1707 all for coming.

1708 These first couple of questions are for Dr.
1709 Throckmorton. And I have been a strong proponent--I am from
1710 Kentucky and we have been real aggressive with trying to deal
1711 with the drug problem in our area, prescription drug problem.
1712 And the tamper-resistant technology has been important. In
1713 your written testimony you talked about there were two recent
1714 determinations from the FDA on different formulations for
1715 OxyContin and for Opana ER, and can you take a minute to
1716 explain why there were two different determinations of those
1717 two cases about the drug-resistant technology?

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1718 Dr. {Throckmorton.} Sure. I will speak in general
1719 terms. In both cases we looked at the available data on that
1720 product and specific the new formulation and then looked at
1721 it in comparison with the earlier formulation, the
1722 formulation that had been originally developed and asked
1723 questions about whether or not the new technology promised to
1724 reduce abuse. We think it is terribly important that this
1725 bar, this bar of concluding something is abuse-deterrent be
1726 high enough to be worth developing, make it an incentive,
1727 make it something that we can reward in labeling terms to
1728 make those products attractive for manufacturers to take the
1729 time and money to develop.

1730 In the case of OxyContin when we looked at the data,
1731 there were important aspects of the new formulation that
1732 really did predict it was going to be harder to abuse. One
1733 particular one is when people tried to make it ready to
1734 inject, it turns into a gel that is just physically
1735 impossible to inject into someone's arm. You know, some of
1736 that testing involved using people who are addicts trying to,
1737 you know, do things that, you know, that would allow this to
1738 be used and they were unable to do it.

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1739 Now, so those sorts of evidence strongly suggest that a
1740 product with those formulation characteristics is going to
1741 have reduced attractiveness to abusers in the real world. We
1742 are tracking that real-world experience now going forward.
1743 On the other hand, when we looked at the totality of the data
1744 around the Opana ER product, we didn't see data of that same
1745 kind, data that suggested that that product was really going
1746 to be meaningfully harder to abuse, meaningfully meaning we
1747 would see less abuse--

1748 Mr. {Guthrie.} I want to ask you another one and I got
1749 one more that I want to ask, but thank you for that. And on
1750 Capitol Hill there has been a lot of discussion about whether
1751 generic prescription opioids must have identical abuse-
1752 deterrent technology or whether it must simply be comparable
1753 or meet or exceed of the other drug. Can you discuss your
1754 perspective on this debate and what you are doing to ensure
1755 the process remains science-based and technology-neutral?

1756 Dr. {Throckmorton.} Absolutely. And I think it is a
1757 very important question. We are going to be talking about--
1758 we are working internally on and we are planning on talking
1759 about it at a public meeting at the end of September and

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1760 early October. What I anticipate is that we are going to
1761 rely on the generics demonstrating they are abuse-deterrent,
1762 not that they use the same technology. That would be the
1763 approach that we have used in other places.

1764 And so the testing that we will lay out, the testing
1765 that we will develop will be to decide whether or not the new
1766 formulation, however it is made, is abuse-deterrent to the
1767 level that it needs to be compared with the innovator, not
1768 that it used the same technology.

1769 Mr. {Guthrie.} Because I would like to ask Mr.
1770 Kerlikowske a question or just bring this up. A very good
1771 friend of mine--his name is Tommy Loving--he is head of our
1772 drug task force. Do you know Tommy? And very aggressive in
1773 this and we get together quite--I will see him in the morning
1774 actually for coffee probably.

1775 And he brought it to me a few months ago that heroin has
1776 really shown itself in an alarming statistic. And I said why
1777 is that kind of--you know, heroin, that seems like something
1778 that was 1970s, I guess? He said because our legislature has
1779 been so aggressive with the pharmacies, with the tamper-
1780 resistant, so now the prescription drugs are more difficult

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1781 to get than heroin.

1782 And I just want to see--I know you are aware of that,
1783 just the strategy with that. The prescription drug abusers
1784 are now finding an outlet easier to get heroin than
1785 prescription drugs because we have been so good in our State
1786 of trying to control it.

1787 Dr. {Throckmorton.} And that has been going on for a
1788 while. The anecdotal evidence across the country is that
1789 there is an increase in heroin and some of the survey
1790 instruments are also showing that we have a younger
1791 population.

1792 There is another component about this, too, and that is
1793 that young people are heroin-naïve. Older people really have
1794 an understanding of the dangers of heroin. Young people
1795 believe that it is not that powerful, that as long as they
1796 smoke it or snort it that they won't become an injecting drug
1797 user, and of course within a few weeks they do become an
1798 injecting drug user at the same time that prescription drugs
1799 are being made less available through all of the things that
1800 you have heard about today and the cost. And heroin is much
1801 less costly. So we have some real concerns about the heroin

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1802 issue, and I couldn't agree with the drug task force
1803 commander more.

1804 Mr. {Guthrie.} Thank you and I yield back.

1805 Mr. {Pitts.} The chair thanks the gentleman and now
1806 recognizes the gentleman from Kentucky, Mr. Whitfield, for 5
1807 minutes for questions.

1808 Mr. {Whitfield.} Thank you, Mr. Chairman. And thank
1809 you all for being with us today.

1810 I want to give a little bit of historical perspective on
1811 the Prescription Drug Monitoring Program, and since my facts
1812 are oftentimes wrong, if I am wrong, you all can correct me.
1813 And then I want to just ask a couple of questions.

1814 Kentucky, as my understanding in 1998, started a
1815 Prescription Drug Monitoring Program. In 2002, Hal Rogers
1816 started the Prescription Drug Monitoring National Training
1817 and Technical Assistance Program at the Department of
1818 Justice. Now, that was an unauthorized program because this
1819 committee has the jurisdiction.

1820 Since that time, it has received an average of 7 or \$8
1821 million a year, and we all acknowledge and say that it has
1822 been an effective program. I don't think anyone would

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1823 dispute that. But in 2005, this committee that does have
1824 jurisdiction recognizing the success of that program
1825 initiated NASPER. Now, the only difference is that the Hal
1826 Rogers program was centered at the Department of Justice and
1827 NASPER was over at HHS.

1828 NASPER received funding in 2011, and '12 I believe did
1829 not get funding. And, as a matter of fact, someone at the
1830 Appropriations Committee in the report language in the
1831 Omnibus Bill even specifically said no money will be spent on
1832 NASPER, which I thought was a little bit mean-spirited
1833 myself.

1834 But regardless of that, you three fellows are the
1835 experts in the area and I would ask you the question, do we
1836 need NASPER anymore? Maybe we should just eliminate NASPER
1837 and let's just focus on the Hal Rogers program. Or should we
1838 try to combine them? Or should we try to reauthorize NASPER?

1839 You know, I think a lot of the problems we have in the
1840 Federal Government on a lot of programs is that Congress does
1841 not have a coherent, organized approach to dealing with the
1842 problem. So would you all just give us--because I mean our
1843 committee does have jurisdiction. Maybe we should

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1844 reauthorize it and try to start over, but I would just ask
1845 for your guidance on this issue. And if each one of you
1846 would comment, I would appreciate it.

1847 Mr. {Kerlikowske.} I know that NASPER was designed to
1848 have a bit of a different take on the program versus the high
1849 technology of the Hal Rogers PDMPs. We are pleased that
1850 there is still money, as you said 7 to \$8 million each year
1851 that is made available to the States to start up these PDMPs.
1852 And I would be happy to sit down with not only
1853 representatives from Congress but also some of these inner-
1854 agency people and provide some level of our expertise and
1855 what we have seen as to NASPER. We would be glad to do that.

1856 Dr. {Clark.} I agree with Director Kerlikowske. There
1857 needs to be, shall we say, a convening of minds to look at
1858 what it is that we are trying to achieve and how best can we
1859 achieve it. The specific program may not be the issue; it is
1860 the technologies that exist and it is bridging some of the
1861 limitations. And it is also dealing with some of the
1862 conflicting imperatives associated with both programs.

1863 So our focus on linking Prescription Drug Monitoring
1864 Programs with electronic health records, working with the

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1865 Office of National Coordinated Health Information Technology
1866 and with the support of ONDCP in order to give practitioners
1867 real-time access, the amount of money and PDMPs just hasn't
1868 been a large amount of money in the first place, so the
1869 strategy might be how do we best use limited resources to
1870 enhance our efforts to deal with the prescription drug abuse
1871 problem without compromising the health of people who suffer
1872 from pain or other conditions requiring controlled
1873 substances.

1874 Mr. {Whitfield.} Yes. Now, Mr. Chairman, I might just
1875 suggest that--and maybe in a private setting--some of our
1876 staff could work with these three gentlemen and their staff
1877 to determine what can we do to make this program even more
1878 effective? I mean maybe all of the effort should be
1879 generated that the Hal Rogers program or maybe that there
1880 would be a combination or maybe there is something we can do.
1881 But since our program has expired, looking at
1882 reauthorization, I think it would be helpful to have these
1883 discussions. Thank you.

1884 Mr. {Pitts.} We will pursue that. Thank you.

1885 The chair now recognizes the gentlelady from North

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1886 Carolina, Mrs. Ellmers, for 5 minutes for questions.

1887 Mrs. {Ellmers.} Thank you, Mr. Chairman. And thank you
1888 for holding this subcommittee hearing. Thank you to our
1889 panel.

1890 I have a couple of questions in regard to patient safety
1891 for those who truly are in need of pain medication and how,
1892 as we are trying to make the system more effective for, you
1893 know, identifying abusers and how to use and work on that
1894 problem, how do we protect those patients as well?

1895 You know, the first thing that comes to my mind is the
1896 Sudafed issue and how an individual has to basically show
1897 their license, their identification, and I know why that has
1898 been put in place. I am curious as to why that approach was
1899 taken. Is it because it was an over-the-counter drug
1900 initially, and because it is used to formulate other drugs?
1901 Dr. Throckmorton, can you tell us a little bit about that
1902 approach? Because I am concerned that we might take an
1903 approach like that into the future with others.

1904 Dr. {Throckmorton.} I want to make sure that I
1905 understand the question you are asking. So with
1906 pseudoephedrine--Sudafed itself is not abused. It is--

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1907 Mrs. {Ellmers.} Correct.

1908 Dr. {Throckmorton.} --obviously, what it is being used
1909 to create--

1910 Mrs. {Ellmers.} Correct.

1911 Dr. {Throckmorton.} --highly dangerous, you know,
1912 methamphetamine. And, you are right, it was over-the-counter
1913 and, you know, Congress felt that there were additional
1914 restrictions that were necessary to ensure the safe use of
1915 that product.

1916 That is different than the conversation we are having
1917 around hydrocodone where--

1918 Mrs. {Ellmers.} Right.

1919 Dr. {Throckmorton.} --it in and of itself is a product
1920 that has the potential for abuse--

1921 Mrs. {Ellmers.} Addictive abuse.

1922 Dr. {Throckmorton.} --one that is already under some
1923 control for the Drug Enforcement Administration, the schedule
1924 III already has a--

1925 Mrs. {Ellmers.} So basically, the difference being that
1926 the Sudafed was an agent that was used to--

1927 Dr. {Throckmorton.} Create.

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1928 Mrs. {Ellmers.} --create another, and so therefore--

1929 Dr. {Throckmorton.} That is the--

1930 Mrs. {Ellmers.} --the idea was to find out who was--you

1931 know, make sure that those individuals who were actually

1932 purchasing it were identified.

1933 The other issue, I guess, then on that is what other

1934 protections is the FDA putting in place to ensure that

1935 patients who really are in need of those critical pain

1936 medications for, you know, whether it be chronic pain or

1937 acute pain, you know, what protections are in place so that

1938 again we might--you know, I hate when the pendulum swings one

1939 way when really what we need to do is kind of come up with a

1940 real balance.

1941 Dr. {Throckmorton.} Well, we think there are several

1942 things to do. So first and foremost, we have been listening

1943 carefully. So I have been now working on the opioids and,

1944 you know, for a substantial fraction of my time for the last

1945 several years. And I have had the opportunity to sit down

1946 with hospice care workers. I have sat down with cancer

1947 survivors. I have sat down with groups to see the need for

1948 access to pain medicines for patients that need them. I have

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1949 also sat down with groups, you know, that see the cost that
1950 prescription drug abuse is, you know, having in America. So
1951 to fully understand sort of the broad spectrum of views, we
1952 are trying to listen as carefully as we can.

1953 At the end of the day, one of the things that we
1954 concluded was the better educated people were about how best
1955 to use these medicines--and that means both the prescribers
1956 and the patients--the more comfortable we believed they would
1957 be in making the right choices. And the right choices here
1958 could be not prescribing an opioid to avoid abuse, avoid
1959 misuse, or it could be to make a choice to prescribe it
1960 because they are now educated well enough to know how to do
1961 it well, how to monitor that patient well, how to spot the
1962 signs of abuse--

1963 Mrs. {Ellmers.} Sure.

1964 Dr. {Throckmorton.} --and so they are not scared to use
1965 a word--

1966 Mrs. {Ellmers.} Okay.

1967 Dr. {Throckmorton.} --to use the opiates right.

1968 Mrs. {Ellmers.} And thank you because I think that is
1969 the best approach as well.

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1970 But if there is an individual right now--and I
1971 appreciate especially working with hospice and, you know,
1972 certainly that is an area where those medications are used
1973 and I can see that issue occurring--but if there is an
1974 individual who feels that their pain, for whatever purpose,
1975 whatever reason, has an issue with access and feels that they
1976 are having difficulty obtaining, is there a phone number? Is
1977 there a way--who does that individual reach out to? And any
1978 of you can comment on any of these things.

1979 Dr. {Throckmorton.} Partly, it will depend on what the
1980 source of not being able to get the medicine is. So if it is
1981 a drug shortage, for instance, that the drug is not available
1982 the way, you know, sometimes drugs have gone into shortage
1983 recently and we have shortages with fentanyl, for instance,
1984 periodically or whatever, that is absolutely something the
1985 FDA wants to hear about. I have a staff that work on that
1986 24/7 trying to understand, prevent, minimize those shortages.
1987 And we have a website at the FDA to allow people to report.

1988 If it is a pharmacy not carrying the drug, those are
1989 decisions that the FDA doesn't have a clear role in and I
1990 would suggest Boards of Pharmacy or some other local

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1991 authorities would be the place to talk to.

1992 Mrs. {Ellmers.} Thank you. Thank you. I apologize,

1993 Mr. Chairman. My time ran over. Thank you very much.

1994 Mr. {Pitts.} The chair thanks the gentlelady and now

1995 recognizes the gentleman from Florida, Mr. Bilirakis, for 5

1996 minutes for questions.

1997 Mr. {Bilirakis.} Thank you, Mr. Chairman. I appreciate

1998 it very much. And thank you for holding this hearing. And I

1999 thank the panel for their testimony.

2000 Along with many Floridians, I am concerned about the

2001 alarming increase in prescription drug abuse and illegal

2002 sales of prescription medications. I believe that issues

2003 concerning both overprescribing and the illegal use and sale

2004 of these drugs should be addressed. Prescription drug abuse

2005 is both a federal and state issue and I have worked with both

2006 local and federal officials to take on this issue.

2007 In my district, Pasco and Pinellas Counties have had

2008 some of the highest oxycodone causes of death with 197.

2009 Hillsborough County, this is the Tampa Bay area, was fourth

2010 in Florida with 128 deaths from oxycodone. Sadly, Pasco and

2011 Pinellas Counties also led the State in methadone deaths and

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2012 hydrocodone deaths. The number of ER-related visits from
2013 misuse or abuse of prescription drugs has nearly doubled in
2014 the past 5 years.

2015 Recently, there was a drug summit in Pasco County where
2016 both health officials discussed the growing problem of babies
2017 born addicted to prescription drugs. Pinellas County ranks
2018 first in this State for babies born addicted. Florida has
2019 taken some positive steps to fight prescription drug abuse
2020 such as legislation to eliminate pill mills in 2011.

2021 Florida currently runs four drug tracking programs in
2022 addition to the Controlled Substance Reporting System. The
2023 number of doctors on the DEA's list of top 100 purchasers of
2024 oxycodone declined by 97 percent in a single year and pain
2025 management clinic registration decreased by 36 percent. This
2026 is a good start but there is much more work to be done. I am
2027 sure you will agree. That is why I have instructed my office
2028 to look into issues of prescription drug abuse and
2029 developing, of course, future legislation. And again, Mr.
2030 Chairman, I really appreciate you holding this hearing.

2031 I have a couple questions. Mr. Kerlikowske, I talked a
2032 bit about this of course, the growing problem of babies born

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2033 addicted to prescription drugs such as the oxycodone. This
2034 is a serious problem in our communities. I would like to
2035 have you come down if you will to the Tampa Bay area and meet
2036 some of the local officials, the health officials and
2037 providers who are dealing with this growing problem.

2038 I want to ask you a question. Are there any funds or
2039 programs available for the local community to tap into to
2040 help with the problem either on the prevention or treatment
2041 side? And I also want to ask Dr. Clark, are there resources
2042 for my community, of course, from SAMHSA? So those are the
2043 questions.

2044 Mr. {Kerlikowske.} Congressman, we fund the Drug-Free
2045 Communities program, these grassroots communities programs
2046 that do prevention, and of course oftentimes that local voice
2047 is more powerful and more important to people about
2048 prevention. And we have worked with them to help them
2049 understand and become more knowledgeable.

2050 We fund almost 700 of them around the country to become
2051 more knowledgeable about this neonatal abstinence syndrome
2052 because we are seeing in a number of States, Florida, who is-
2053 -and I attended the first meeting of the advisory committee

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2054 that has worked so hard under the Attorney General to reduce
2055 that problem. It is a complex problem because there are
2056 women in pain that are also pregnant and are being treated.
2057 There are women in drug programs at the same time, and so
2058 there has to be a very careful balance.

2059 But I would also tell you I would be happy to visit the
2060 Tampa Bay area with you and examine this more closely.

2061 Mr. {Bilirakis.} Well, thank you very much. I
2062 appreciate that. I welcome that.

2063 Anyone else wish to comment on the panel?

2064 Dr. {Clark.} We have Targeted Capacity Expansion grants
2065 that are available to the States so the States can use their
2066 block grants to help promote education. We are developing an
2067 internal strategy to deal with NES. We recognize it is much
2068 broader than the prescription opioids. It involves heroin.
2069 But, as you know, that any time a woman has to take
2070 medication while she is pregnant, there is some associated
2071 risk for the neonate, and so what we will try to do is
2072 promote adequate education of consumers and practitioners so
2073 that we can address these issues.

2074 We have a Pregnant and Postpartum Women's program that

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2075 allows women who have addiction problems to get into
2076 treatment. During the time that they are pregnant and when
2077 they deliver, we can deal with both the mom and the child.
2078 And the data do show that the outcomes of the birth are much
2079 more positive when we have those kinds of programs.

2080 But the most important thing is having this concerted
2081 effort involving multiple layers at the State level, at the
2082 local level, community level involving practitioners as well
2083 as consumers.

2084 Mr. {Bilirakis.} Thank you. Thank you very much. I
2085 yield back, Mr. Chairman.

2086 Mr. {Pitts.} The chair thanks the gentleman.

2087 The House is voting on the Floor. There are less than
2088 10 minutes left to vote.

2089 That concludes the questions from the members. There
2090 might be other questions. We will submit those to you in
2091 writing if you would please respond promptly. And members
2092 should submit their questions by the close of business on
2093 Friday, June 28.

2094 So thank you very much to the witnesses, to the members
2095 for attending.

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2096 Without objection, the Subcommittee is adjourned.

2097 [Whereupon, at 11:23 a.m., the Subcommittee was

2098 adjourned.]