

This is a preliminary transcript of a Committee Hearing. It has not yet been subject to a review process to ensure that the statements within are appropriately attributed to the witness or member of Congress who made them, to determine whether there are any inconsistencies between the statements within and what was actually said at the proceeding, or to make any other corrections to ensure the accuracy of the record.

1 {York Stenographic Services, Inc.}  
2 HIF203.142  
3 LEGISLATIVE HEARING ON H.R. 5710, THE NATIONAL ALL SCHEDULES  
4 ELECTRONIC REPORTING REAUTHORIZATION ACT OF 2010; AND H.R.  
5 5809, THE SAFE DRUG DISPOSAL ACT  
6 THURSDAY, JULY 22, 2010  
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 10:04 a.m.,  
12 in Room 2322 of the Rayburn House Office Building, Hon. Frank  
13 Pallone, Jr. [Chairman of the Subcommittee] presiding.

14 Members present: Representatives Pallone, Green,  
15 Barrow, Inslee, Shimkus, Whitfield, Pitts and Gingrey.

16 Staff present: Karen Nelson, Deputy Committee Staff  
17 Director for Health; Ruth Katz, Chief Public Health Counsel;  
18 Naomi Seiler, Counsel; Rachel Sher, Counsel; Stephen Cha,

19 Professional Staff Member; Emily Gibbons, Professional Staff  
20 Member; Anne Morris, Professional Staff Member; Alvin Banks,  
21 Special Assistant; Ryan Long, Minority Professional Staff  
22 Member; and Clay Alspach, Minority Professional Staff Member.

|  
23 Mr. {Pallone.} I call the meeting to order.

24 Today we are having a hearing on NASPER and safe drug  
25 disposal, and I will recognize myself initially for an  
26 opening statement.

27 The two important pieces of legislation that we are  
28 addressing basically deal with the growing crisis of abuse of  
29 prescription medications. First is the reauthorization of  
30 the National All Schedules Prescription Electronic Reporting  
31 Act, or NASPERR. This is a bill that I believe the gentleman  
32 from Kentucky is the prime sponsor but myself and others on  
33 the subcommittee have been involved with it in the past. And  
34 secondly is the Safe Drug Disposal Act.

35 According to the 2010 National Drug Control Strategy put  
36 forth by the White House, prescription-drug abuse is the  
37 fastest-growing drug problem in the United States. Since  
38 1999, deaths from drug use have more than doubled, surpassing  
39 homicide, suicides and gunshot wounds as causes of death, and  
40 this increase in drug overdose death rates is largely because  
41 of prescription opioid painkillers. Deterrence of  
42 prescription-drug abuse is complicated by the fact that  
43 prescription drugs are often obtained with ease from those  
44 closest to the drug abuser. Studies show that upwards of 70  
45 percent of people who use prescription drugs for non-medical

46 purposes got them from a friend or relative for free, for  
47 money or by stealing them, sometimes unnoticed from the  
48 family's medicine cabinet, and many people, particularly  
49 teenagers, believe prescription drugs are safer than illicit  
50 drugs because they are prescribed by a health care  
51 professional.

52         The Office of National Drug Control Policy working with  
53 other federal, State and local community partners has taken a  
54 leadership role in promoting comprehensive strategies that  
55 ensure prescription drugs are only used for their intended  
56 purpose and that unused or expired medications are disposed  
57 of in a timely, safe and environmentally responsible manner.  
58 Ridding the family medicine cabinet of leftover prescription  
59 drugs is easier said than done for a variety of reasons.

60         I am therefore particularly proud of an initiative in my  
61 State, New Jersey, last year supported by the Administration  
62 called Operation Medicine Cabinet. This was the first in the  
63 United States where we had a statewide day of disposal of  
64 unused, unwanted and expired medicine. New Jersey residents  
65 in communities in all 21 countries participated in a public  
66 health initiative sponsored by the Drug Enforcement  
67 Administration, or DEA, in New Jersey. This was in the  
68 Office of the Attorney General and also in combination with  
69 the Partnership for a Drug-Free New Jersey.

70 I should note that the huge success of New Jersey's  
71 program led to the creation of the American Medicine Chest  
72 Challenge, which is a national day of prescription-drug  
73 disposal that will be held this November 13th.

74 Today we will hear from the Administration on their  
75 support for the Safe Drug Disposal Act, which will make  
76 necessary changes in the Controlled Substances Act to make it  
77 easier for people to return unwanted drugs through the drug  
78 take-back programs, and this bill is the product of the hard  
79 work of Representative Inslee and also Representative Bart  
80 Stupak.

81 Now, we are also going to hear from our distinguished  
82 panel today on their support to reauthorize the second bill,  
83 the NASPER bill. This law, which was originally enacted in  
84 2005, created an HHS grant program administered by SAMHSA for  
85 States to establish prescription-drug monitoring programs.  
86 PDMPs track drug prescriptions with the goal of preventing  
87 overuse and illegal diversion. Approximately 40 States  
88 maintain PDMPs or have laws their authorize their  
89 establishment. Starting in fiscal year 2009, Congress  
90 appropriated funding to support NASPER grants in 13 States  
91 and the bill before us will reauthorize the program until  
92 2013.

93 I mentioned that NASPER was an initiative that

94 Representative Whitfield, who is here now, worked on in 2005.  
95 You also, Mr. Shimkus, Bart Stupak, were involved in this. I  
96 think it is a good program. It certainly needs to be  
97 reauthorized.

98 [The prepared statement of Mr. Pallone follows:]

99 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
100 [The information follows:]

101 \*\*\*\*\* INSERTS 1, 2 \*\*\*\*\*

|  
102 Mr. {Pallone.} So now I would recognize Mr. Shimkus for  
103 his opening statement.

104 Mr. {Shimkus.} Thank you, Mr. Chairman.

105 I want to welcome our panel this morning. I think these  
106 bills are another good example of what we can do when we work  
107 together. These two pieces of legislation will both aid in  
108 tackling drug safety issues in the United States.

109 First, we will do so by reauthorizing the NASPER.  
110 NASPER addresses use and access problems. By reauthorizing  
111 this, we will ensure funds remain accessible to strengthen  
112 existing State programs while new ones get off the ground. I  
113 was an original cosponsor, as you mentioned, along with  
114 yourself and our colleague from Michigan, Mr. Stupak, and I  
115 want to really congratulate my colleague from Kentucky, Mr.  
116 Whitfield, who is the lead sponsor and the champion of the  
117 bill. His leadership has been very, very helpful and I am  
118 also glad he made it here on time for the hearing.

119 We also have the Safe Drug Disposal Act, which will ease  
120 the cumbersome process of disposal of unused controlled  
121 substance. There is a system in place for safe distribution  
122 of controlled substances. It only makes sense that we  
123 establish the same for the disposal of these drugs.  
124 Pharmacies and many others on the State and local level stand

125 ready to provide these services in their communities if given  
126 the ability.

127         The Safe Drug Disposal Act would create these avenues by  
128 working with existing framework of already up-and-running  
129 drug take-back programs. I support this legislation and  
130 thank the chairman for continuing to work with the minority  
131 to get language to a comfortable level for everyone. I also  
132 look forward to continuing to work together to help move both  
133 of these bills through the committee for consideration and by  
134 the House.

135         Finally, last week I mentioned the desire from our side  
136 to invite Dr. Berwick to testify before this committee.  
137 Obviously I haven't heard a response yet so we will be  
138 formalizing a letter to Chairman Waxman for a request to do  
139 that. We know that Dr. Berwick is now officially in his role  
140 as CMS director. He will serve in a key role. He had made  
141 some very interesting comments and we just need to have a  
142 chance to ask him about those comments or how he will operate  
143 in his new position or if there is some change as far as the  
144 rationing debate and how we will handle this new health care  
145 law. It is the biggest thing we have done since I have been  
146 here in Congress, and it is just time to start getting some  
147 questions answered on this.

148         I am not going to belabor the point, Mr. Chairman. You

149 have heard it before. And I will yield back my time.

150 [The prepared statement of Mr. Shimkus follows:]

151 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|

152 Mr. {Pallone.} Thank you.

153 The gentleman from Georgia, Mr. Barrow.

154 Mr. {Barrow.} Thank you. I will waive.

155 [The prepared statement of Mr. Barrow follows:]

156 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
157 Mr. {Pallone.} The gentleman waives.

158 Next we have the gentleman from Kentucky. I think I  
159 should mention that he--oh, Mr. Pitts. Oh, I am sorry. The  
160 gentleman from Pennsylvania, Mr. Pitts.

161 Mr. {Pitts.} Thank you, Mr. Chairman.

162 There is no doubt that prescription-drug abuse and  
163 particularly abuse of controlled substances is a serious  
164 problem in our country. The cost to society is high in lost  
165 productivity and wasted lives but also in direct costs to  
166 many government programs.

167 In September of last year, GAO released a study on  
168 Medicaid fraud and abuse related to controlled substances.  
169 In just this one federal program in just five States  
170 surveyed, GAO found the following: ``Tens of thousands of  
171 Medicaid beneficiaries and providers were involved in  
172 potential fraudulent purchases of controlled substances,  
173 abusive purchases of controlled substance or both through the  
174 Medicaid program in California, Illinois, New York, North  
175 Carolina and Texas. About 65,000 Medicaid beneficiaries in  
176 the five selected States acquired the same type of controlled  
177 substance from six or more different medical practitioners  
178 during fiscal years 2006 and 2007 with the majority of  
179 beneficiaries visiting from six to 10 medical

180 practitioners.''

181       These activities, known as doctor shopping, resulted in  
182 about \$63 million in Medicaid payments and do not include  
183 medical costs, that is, office visits, related to getting the  
184 prescriptions. GAO even found that according to Social  
185 Security Administration data, pharmacies filled controlled  
186 substance prescription of over 1,800 beneficiaries who were  
187 dead at that time.

188       These examples come from just one government program and  
189 they represent just one facet of the problem. But today we  
190 are addressing a tool that can be used to cut down on the  
191 fraud and abuse associated with controlled substance. The  
192 National All Schedules Prescription Electronic Reporting  
193 Reauthorization Act, or NASPERR, allows doctors to access the  
194 controlled substances prescription history of their patients  
195 in an effort to detect and deter abuse. I am pleased to be a  
196 cosponsor of this commonsense piece of legislation which had  
197 it been in place and funded during the time GAO was doing  
198 this study might have reduced the amount of doctor shopping  
199 that went on, may have prevented some of these fraudulent  
200 prescriptions for controlled substances from being written  
201 and may have saved taxpayers millions of dollars.

202       I look forward to hearing from our witnesses. Thank  
203 you, and I yield back.

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

205 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
206 Mr. {Pallone.} Thank you, Mr. Pitts.

207 Mr. Green, I know you just walked in. Would you to do  
208 an opening statement?

209 Mr. {Green.} What about my colleague?

210 Mr. {Pallone.} I already tried him. He waived.

211 Mr. {Green.} Well, then I will give mine.

212 Mr. {Pallone.} The gentleman from Texas is recognized.

213 Mr. {Green.} Thank you, Mr. Chairman, for holding the  
214 hearing today. We actually have subcommittees dealing with  
215 health care issues, one in our first-floor committee room,  
216 and I apologize for being late.

217 Thank you, Mr. Chairman, for holding this hearing on  
218 prescription-drug monitoring programs in the NASPER program,  
219 which Congress enacted in 2005. Our ranking member, Mr.  
220 Whitfield, was author of the National All Schedules  
221 Prescription Electronic Reporting Act, and I am proud to have  
222 been a cosponsor of this bill and supported it when it came  
223 through our committee in both the 108th and 109th and now  
224 again in the 111th.

225 The NASPER was clear to us then as it is now on both law  
226 enforcement level and drug safety level with safe  
227 prescription monitoring programs sporadic and not  
228 interoperable. It is relatively easy for individuals who

229 abuse prescription drugs to doctor-shop for controlled  
230 substances or obtain prescription drugs illegally with little  
231 detection from physicians or law enforcement.

232         The Texas prescription-drug monitoring program called  
233 the Texas Prescription Program was established more than 25  
234 years ago in 1981. Each year the Texas Prescription Program  
235 collects 3.3 million prescriptions and monitors schedule II  
236 prescription drugs. During the first year of the Texas  
237 Prescription Drug Program enactment, the number of schedule  
238 II prescriptions filled in the State fell by 52 percent. The  
239 program helped the State crack down on the pill mills and  
240 forged prescriptions but it is clearly a law enforcement  
241 program and housed at the Texas Department of Public Safety.

242         Without question, prescription-drug monitoring programs  
243 offer significant benefits for law enforcement but they  
244 should go hand in hand with drug safety and public health  
245 benefits. I am pleased that we are here to discuss  
246 reauthorizing the program and I fully support the legislation  
247 introduced by Mr. Whitfield, Mr. Stupak and Mr. Pallone.

248         Additionally, we discussed legislation introduced by Mr.  
249 Stupak and Mr. Inslee on drug take-back programs. I am an  
250 original cosponsor of Mr. Inslee's legislation, the Safe Drug  
251 Disposal Act, which amends the Controlled Substances Act to  
252 allow end users or caretakers of an end user to safely

253 dispose of unused prescription drugs and over-the-counter  
254 drugs through the Drug Enforcement Agency approved State-run  
255 drug take-back programs. Current law and DEA enforcement of  
256 the Controlled Substances Act can make it extremely difficult  
257 for end users to turn over unused meds for safe disposal.  
258 DEA rules are very strict and controlled substance can only  
259 be passed into the possession of law enforcement, which means  
260 they must be present at collection sites and drives. This  
261 requires coordination of law enforcement as part of this  
262 effort and it is impossible to have law enforcement at every  
263 collection site.

264       There is also a lack of public awareness of this rule  
265 and on what constitutes a controlled substance. This is a  
266 barrier in properly disposing of unused medications. Today  
267 unused meds are becoming a gateway to drug abuse, and  
268 flushing down the toilet can be harmful to our environment.  
269 We want to assist States and localities by facilitating the  
270 safe disposal of prescription medication, and I know Mr.  
271 Stupak and Mr. Inslee have been working to combine their  
272 legislation. I look forward to supporting their efforts.

273       And again, I thank our witnesses for being here, Mr.  
274 Chairman.

275       [The prepared statement of Mr. Green follows:]

276 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
277 Mr. {Pallone.} Thank you, Mr. Green.

278 And now Mr. Whitfield. I should tell you that Mr.  
279 Whitfield talks about NASPER all the time and has been  
280 constantly trying to improve and implement the program since  
281 he first got involved. I recognize the gentleman.

282 Mr. {Whitfield.} Well, thank you, Chairman Pallone and  
283 Ranking Member Shimkus. I would like to thank also Gene  
284 Green and Bart Stupak as well as Chairman Pallone and John  
285 Shimkus because it did take a real effort to get this  
286 legislation where it is today, and I might add that there was  
287 a program initiated in the Appropriations Committee a number  
288 of years ago around 2002 and they appropriated money that  
289 went to the Justice Department, and that prescription-drug  
290 monitoring program was primarily focused on law enforcement,  
291 which is vitally important, but the program had never really  
292 been authorized, and the Energy and Commerce Committee did  
293 have jurisdiction and we were able to introduce the  
294 legislation. It has been passed. There is now a monitoring  
295 program in 40 States, and we think it has potential to do a  
296 great deal of good for the American people to provide  
297 information for physicians as they treat patients that go  
298 across State lines and will dramatically improve the safety  
299 and effectiveness of our medical system.

300           So I look forward to the hearing today. I know the  
301 markup is going to be later this afternoon. But all of us  
302 know how complex health care is and how difficult the issues  
303 are, and frequently when I am at home, people ask me, well,  
304 you don't know anything about health care so how can you be  
305 up there doing what you are doing. Fortunately, we have Dr.  
306 Gingrey, who is a doctor, and I guess Dr. Burgess, but also  
307 some of us are fortunate to have some advisors that came up  
308 here as interns sometime, and we have one with us this  
309 morning that is working on our staff for a while, and it's  
310 Dr. Jason Pope, and he is right here. He is on the staff at  
311 Cleveland Clinic and he is an assistant professor of  
312 anesthesiology at Vanderbilt. So I do want you all to know  
313 that we feel like we have some good, competent advice on a  
314 lot of these issues and we are glad to have Dr. Pope with us  
315 for a while here in Washington, D.C.

316           And I yield back the balance of my time.

317           [The prepared statement of Mr. Whitfield follows:]

318 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
319 Mr. {Pallone.} Thank you.

320 I should mention there has been a change in plans. I  
321 think we have notified the staff that our intention is to  
322 have the markup 15 minutes after the hearing, so I don't know  
323 when that is exactly going to be but we are trying to move  
324 things as quickly as we can, so I thought I mention that.

325 The gentleman from Georgia, Mr. Gingrey.

326 Dr. {Gingrey.} Mr. Chairman, thank you. I thank Mr.  
327 Whitfield for his kind remarks about me and Dr. Burgess. I  
328 thank God for Dr. Pope because our information is a little  
329 dated, and I am sure that if Burgess was here, he would say  
330 well, Gingrey's is a lot more dated than mine.

331 In any regard, Mr. Chairman, thank you for holding the  
332 hearing today. Prescription-drug abuse is a major problem in  
333 this country. In my home State of Georgia, the fact that a  
334 number of pain clinics were charged with illegally  
335 prescribing strong narcotics to patients is but one reminder  
336 that our country is not doing enough to curb this startling  
337 trend.

338 Prescription drugs, when taken appropriately for a  
339 medical condition, can improve a patient's quality of life or  
340 help them cope with a debilitating illness. However, when  
341 they are improperly taken, they can lead to chemical

342 dependency, certainly from these pain clinics, and  
343 subsequently great hardship, loss of job, loss of marriage,  
344 loss of home. I could go on and on.

345         The two pieces of legislation that we are going to  
346 consider this morning have been drafted hopefully to address  
347 this problem, and I would like to thank the sponsors for  
348 their work in this area. Of particular note, I want to thank  
349 Congressman Whitfield for his continued efforts in electronic  
350 prescribing reporting through NASPER. It has been 5 years  
351 since Congressman Whitfield first championed the legislation  
352 into law and I am proud that I was asked to be a cosponsor of  
353 these efforts here today. I believe that the reauthorization  
354 of NASPER is a necessary step in the fight to addressing  
355 prescription-drug abuse and it will give States the support  
356 that they need to help prevent the overuse and illegal  
357 diversion of prescription drugs, particularly pain  
358 medication.

359         In addition, I would like to commend the sponsors of the  
360 various pieces of legislation that the subcommittee will be  
361 marking up this afternoon, both those that I serve with here  
362 on the committee and those off of the committee for their  
363 efforts. Given the nature of today's dual hearings, I would  
364 like to take a moment and single out a few sponsors  
365 personally for their efforts. First, Chairman Stupak's

366 legislation, H.R. 903, the Dental Emergency Responders Act of  
367 2009, is a commonsense solution to a problem that could  
368 benefit many during a national emergency. Therefore, I want  
369 to thank Chairman Stupak for sponsoring this legislation and  
370 I look forward to supporting it today.

371 Dr. Tim Murphy, my colleague on the committee and a  
372 fellow co-chair of the GOP Doctors Caucus, has advocated tort  
373 protection for volunteer providers, physicians from this  
374 committee for a few years now and I know our peers in the  
375 medical community appreciate his efforts. I look forward to  
376 supporting that bill, H.R. 1745, in committee today, and as a  
377 cosponsor going forward.

378 To all my colleagues, I understand that the process that  
379 led us here today has been a bipartisan one, thank goodness,  
380 for a change. And for that, I would like to commend Chairman  
381 Pallone and Ranking Member Shimkus for their efforts, and Mr.  
382 Chairman, I will yield back now.

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

384 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
385           Mr. {Pallone.} Thank you, Mr. Gingrey.

386           I think we are done with our opening statements. We  
387 will turn to our two witnesses. Let me introduce them at  
388 this time. First on my left is the Hon. Gil Kerlikowske, who  
389 is Director of the Office of National Drug Control Policy,  
390 and then we also have Joseph Rannazzisi, who is Deputy  
391 Assistant Administrator from the Office of Diversion Control  
392 for the U.S. Drug Enforcement Administration. I can't  
393 believe I got those two right. Your names are so long.

394           We ask you to try to keep 5 minutes, although you are  
395 the only two, so am not going to be strict, and then you can  
396 submit comments if you wish for the record, and after the  
397 hearing you may get additional written questions from us  
398 beyond what we question you today.

399           So we will start with Mr. Kerlikowske.

|  
400 ^STATEMENTS OF HON. R. GIL KERLIKOWSKE, M.A., DIRECTOR,  
401 OFFICE OF NATIONAL DRUG CONTROL POLICY; AND JOSEPH  
402 RANNAZZISI, J.D., DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF  
403 DIVERSION CONTROL, UNITED STATES DRUG ENFORCEMENT  
404 ADMINISTRATION

|  
405 ^STATEMENT OF R. GIL KERLIKOWSKE

406 } Mr. {Kerlikowske.} Thank you, Mr. Chairman and Ranking  
407 Member Shimkus and the distinguished members of the  
408 subcommittee. I think you have already made it very clear  
409 about the numbers, the information that has been provided as  
410 the CDC has said determined the epidemic and prescription-  
411 drug issues, so I will move past some of that.

412 But reducing prescription-drug diversion and abuse has  
413 been a major focus of the Office of National Drug Control  
414 Policy since my arrival a little over a year ago, and we have  
415 made it one of three signature initiatives within the office.  
416 The significant contributing factor to the diversion and  
417 abuse of prescription drugs is the widespread availability.  
418 Many people are not purchasing prescription drugs from a drug  
419 dealer on the street. In 2007 and 2008, among the persons  
420 aged 12 or older who used pain relievers non-medically in the

421 past 12 months, approximately 70 percent report having  
422 obtained the pain relievers from a friend or a relative. So  
423 this problem doesn't lend itself to traditional  
424 interventions. These drugs are originally dispensed, as Dr.  
425 Gingrey mentioned, for legitimate purposes and too often the  
426 public's perception is that they are safe for uses other than  
427 those for which they are prescribed, and we have to help  
428 change that public perception and the societal norm to one  
429 where unused or expired medications are disposed in a timely,  
430 safe and environmentally responsible manner.

431         One aspect of President Obama's National Drug Control  
432 Strategy relates directly to the disposal of unused or  
433 unwanted prescription drugs, and the family medicine cabinet  
434 is a significant source of diversion for those seeking to  
435 abuse prescription drugs. Yet the difficulty in disposing of  
436 such medications in a fashion that is simple, legal and  
437 environmentally responsible has been a challenge.

438         Currently, the federal government advises controlled-  
439 substance users to dispose of controlled substances in one of  
440 three ways: to throw them in the trash after taking proper  
441 precautions, to flush down the toilet in limited cases for  
442 the very dangerous drugs, or to participate in take-back  
443 programs, as had been mentioned earlier, oftentimes  
444 community-based with the approval of DEA and in conjunction

445 with law enforcement.

446         This legislation that the subcommittee is considering  
447 today will facilitate the establishment of pharmaceutical  
448 take-back programs around the country by making a statutory  
449 change to the Controlled Substances Act. This step is  
450 required before the Drug Enforcement Administration can fully  
451 implement the legitimate take-back of frequently abused  
452 prescription drug products containing controlled substances,  
453 and such a step will greatly improve the ability of consumers  
454 to legally, safely and securely dispose of drugs.

455         The strategy also calls for the expansion of  
456 prescription-drug monitoring programs. These statewide  
457 databases recording the controlled substances dispensed by  
458 doctors, nurse practitioners and prescribers is important,  
459 and reauthorization of H.R. 5710, the National All Schedules  
460 Prescription Electronic Reporting Reauthorization Act of  
461 2010, will be a great step in that direction. Information  
462 contained in a PDMP can be used by prescribers to guard  
463 against prescribing two or more drugs that might have  
464 negative interactions, can be used by pharmacists or  
465 prescribers to identify patients who may be shopping for  
466 prescriptions to sustain a prescription-drug addiction, and  
467 under specific circumstances by regulatory and law  
468 enforcement officials when pursuing cases involving rogue

469 prescribers or pill mills. Prescription-drug monitoring  
470 programs are authorized in 43 States but only 34 States  
471 programs are fully operational.

472         Each State's PDMP authorizing legislation determines  
473 where and how the PDMP in that State will function. We must  
474 ensure every State has a functional PDMP in place,  
475 prescribers and pharmacists regularly use these databases,  
476 and that PDMPs are developed with the capability to share  
477 information across State lines.

478         If these two measures are approved that are under  
479 consideration today, I believe it will be a tremendous step  
480 in the direction in limiting the harmful consequences of  
481 prescription-drug abuse in this country. I look forward to  
482 working with this subcommittee and I look forward to  
483 answering any of your questions. Thank you.

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

485 \*\*\*\*\* INSERT 3 \*\*\*\*\*

|

486 Mr. {Pallone.} Thank you.

487 Mr. Rannazzisi.

|  
488 ^STATEMENT OF JOSEPH RANNAZZISI

489 } Mr. {Rannazzisi.} Thank you, Chairman Pallone, Ranking  
490 Member Shimkus and distinguished members of the subcommittee.  
491 On behalf of Acting Administrator Michelle Leonhart and the  
492 nearly 10,000 members of the Drug Enforcement Administration,  
493 I am honored to appear before you today to provide testimony  
494 concerning two very important measures that will help stem  
495 the growing tide of pharmaceutical controlled substance  
496 diversion and abuse, the disposal of pharmaceutical  
497 controlled substances from our household medicine cabinets  
498 and the creation and utilization of prescription-drug  
499 monitoring programs. I would be remiss in not thanking  
500 Director Kerlikowske for his leadership in these initiatives  
501 and addressing the overall problem of drug abuse.

502 Addressing the diversion and abuse of pharmaceutical  
503 controlled substances continues to be one of the DEA's top  
504 priorities. One way to accomplish this goal is to help our  
505 communities dispose of unwanted, unused or expired controlled  
506 substances that remain in household medicine cabinets long  
507 after they are needed. The medicine cabinet provides easy  
508 and free access to controlled substances by drug seekers and  
509 non-medical users such as teenagers and increases the risk of

510 accidental ingestion and poisoning of children and the  
511 elderly. The Controlled Substances Act provides for a closed  
512 system of distribution with stringent procedures on  
513 procurement, distribution and possession of controlled  
514 substances. As part of this closed system, all persons who  
515 possess controlled substances must either be registered with  
516 the DEA or be exempt from registration. Under the Controlled  
517 Substances Act, ultimate users or patients are exempt from  
518 the requirement of registration when they possess this drug  
519 for a legitimate medical purpose. Although exempt, this  
520 exemption does not allow ultimate users to transfer  
521 controlled substances to any entity, even if the sole purpose  
522 of that transfer is for disposal. Therefore, the ultimate  
523 user or household member is left to personally dispose of the  
524 controlled substance. In many cases, the drugs remain in the  
525 household indefinitely or disposed of in an inappropriate  
526 manner, potentially impacting the water supply and  
527 environment.

528 States, countries and municipalities have tried to  
529 develop pharmaceutical collection and disposal programs to  
530 address the problems resulting from unwanted or unused  
531 medicines in household medicine cabinets. These programs are  
532 beneficial in many ways but the Controlled Substance Act  
533 provides for the collection and disposal of controlled

534 substances in very limited circumstances. DEA has provided  
535 technical guidance to various law enforcement agencies'  
536 efforts to conduct collection and disposal initiatives over  
537 the last several years but these operations were limited to  
538 specific cities or counties. As the chairman mentioned, in  
539 November 2009 DEA Newark in cooperation with the Partnership  
540 for Drug-Free New Jersey, State and local law enforcement  
541 partners and community coalitions initiated Operation  
542 Medicine Cabinet. In just 4 hours, over 9,000 pounds of  
543 unused, unwanted and expired meds were collected at law  
544 enforcement-run community collection sites throughout the  
545 State.

546 In order to stop the diversion of pharmaceutical  
547 controlled substances from the medicine cabinet, there must  
548 be a means by which ultimate users can transfer these  
549 substances to other entities for disposal. There are several  
550 bills pending to address this issue. In May 2009, the  
551 Department of Justice issued a views letter in support of  
552 H.R. 1359, the Secure and Responsible Drug Disposal Act of  
553 2009. This bill provides a means by which ultimate users may  
554 lawfully transfer controlled substances to other entities for  
555 disposal, affords the Attorney General discretion to  
556 promulgate regulations and provides the requisite flexibility  
557 to address collection and disposal in a comprehensive manner.

558 Without this legislation, DEA does not have authority to  
559 create a regulatory infrastructure to support the transfer of  
560 controlled substances from ultimate users to others for  
561 disposal.

562 Another initiative to address diversion and abuse of  
563 pharmaceutical controlled substances is the implementation  
564 and utilization of State prescription-drug monitoring  
565 programs. Although these programs vary from State to State,  
566 in general PDMPs reduce prescription fraud and doctor  
567 shopping by providing doctors and pharmacists with  
568 information concerning a patient's prescription history while  
569 ensuring patient access to needed treatment. Doctor shopping  
570 by drug seekers is one of the most common ways individuals  
571 unlawfully obtain pharmaceutical controlled substances. A  
572 doctor shopper may or may not have a legitimate medical  
573 condition. He or she visits several doctors that ultimately  
574 prescribe controlled substances for the same medical  
575 condition. The acquired drugs are then used to feed  
576 addiction or for illegal sale and distribution.

577 When authorized, PDMPs can assist law enforcement  
578 agencies and State regulatory bodies in the investigation of  
579 individuals involved in doctor shopping or medical  
580 professionals or individuals involved in the diversion and  
581 illegal distribution of controlled substances. Approximately

582 34 States currently have operational PDMPs and the DEA  
583 supports the establishment of these programs in every State  
584 and urges the States to work together to promote sharing of  
585 this information from State to State.

586 In conclusion, the collection, removal and safe disposal  
587 of unwanted or unused medications from households and the  
588 expansion of PDMPs will reduce or even eliminate some  
589 potential avenues of drug diversion and ultimately limit the  
590 availability of medications to drug seekers and abusers. We  
591 look forward to working with Congress to establish a solid  
592 foundation for take-back disposal programs and support any  
593 effort to expand the implementation and utilization of PDMPs  
594 to minimize avenues for diversion while protecting the public  
595 health and safety.

596 I thank the subcommittee for the opportunity to appear  
597 before you today and welcome any questions you may have.

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

599 \*\*\*\*\* INSERT 4 \*\*\*\*\*

|  
600 Mr. {Pallone.} Thank you.

601 We will take questions now from the panel, and I will  
602 start with myself, and I wanted to ask these questions of Mr.  
603 Kerlikowske. Basically I wanted to ask about the National  
604 Drug Control Strategy first and then about interoperability,  
605 and both relate to NASPER.

606 With regard to your office, you recently released a new  
607 National Drug Control Strategy, and I want to know how State  
608 prescription-drug monitoring programs fit into that broader  
609 strategy and if can you describe how the office will promote  
610 prescription-drug monitoring programs through that strategy.

611 Mr. {Kerlikowske.} We have been very supportive of  
612 PDMPs, particularly shortly after coming into office and  
613 having visited south Florida and looked at some of the  
614 problems that were occurring with so-called pill mills in  
615 that area, and then visiting with other States. The  
616 Department of Justice has been very good about holding the  
617 PDMP workshops, bringing people together, and of course in  
618 this legislation, it would require that the director of ONDCP  
619 be involved in the advertising to people about how PDMPs can  
620 be helpful and can be useful, and so we are supportive of  
621 them. We have seen them work. We have worked with our  
622 partners at the Drug Enforcement Administration and could not

623 think more highly of them.

624           Mr. {Pallone.} Okay. You know, Mr. Whitfield reminded  
625 me of the difficulties we have had over the years that he  
626 struggled with, you know how we had these sort of two  
627 different programs, and so my second question is if you agree  
628 that prescription-drug abuse needs to be considered a public  
629 health problem and not just a law enforcement problem, and  
630 what else is the office doing to reduce prescription-drug  
631 abuse?

632           Mr. {Kerlikowske.} We made it a signature effort in  
633 several ways. The first was that it actually until--and many  
634 members of this subcommittee have been involved in this but  
635 it really hasn't been recognized for the dangerousness. When  
636 I was--and I will just give you a great example of my own  
637 lack of knowledge. I had been a police chief for a long  
638 time, and I actually think I keep up with the literature and  
639 really know this stuff inside out. When I was told at  
640 confirmation that more people are dying from drug overdoses  
641 than from gunshot wounds and that that was being driven by  
642 prescription drugs, I said well, you know, I really didn't  
643 know that. I tested a number of my colleagues, none of whom  
644 I will name, to ask them if they also recognize the  
645 dangerousness of prescription drugs that were out there.  
646 Quite frankly, they did not either. And when I talked to

647 judges and when I talked to prosecutors, they didn't either.  
648 So first, getting this front and center with the American  
649 public about the dangers.

650 The second thing is, is working with the hospitals, the  
651 Joint Commission on Accreditation, to help them develop  
652 protocols. We also have visited a number of medical schools.  
653 Quite often we don't see an awful lot in the curricula for  
654 doctors throughout their training in recognizing dependence,  
655 in recognizing addiction and in understanding some of those  
656 problems. So those are just a few of the ways, and there are  
657 others that are highlighted in the drug control strategy.

658 Mr. {Pallone.} Okay. And then on the interoperability  
659 issue, the bill sets a new requirement that States specify a  
660 timeline for achieving interoperability of their programs  
661 with bordering States that participate in the NASPER program  
662 and it also directs the Secretary to monitor States' efforts  
663 to achieve interoperability. I know that that is important.  
664 I know it also began because of some of the concerns, you  
665 know, what they had in Kentucky where people were just going  
666 to other States. So my understanding is that the office is  
667 not trying to encourage all States to have identical  
668 prescription-drug monitoring programs. Is that accurate?  
669 Well, let me say this. Why is interoperability so important?  
670 Is it true that the office is not trying to encourage all

671 States to have identical programs but then can different  
672 States' programs achieve some level of interoperability even  
673 if they are not identical?

674         Mr. {Kerlikowske.} Mr. Chairman, I think that Kentucky  
675 led the way in working with the State of Ohio to absolutely  
676 address that. These statewide databases are important, and  
677 the fact that so much of the regulatory work is done by the  
678 Boards of Pharmacy and the medical boards and having a one-  
679 size-fits-all is not something that we would recommend. That  
680 being said, the NASPER legislation is particularly helpful  
681 because it lays down essentially basic guidelines for what  
682 should be included. And so that exchange of information  
683 among the States would be the things that would be most  
684 useful according to the practitioners that use these in  
685 identifying this.

686         And lastly, I would tell you that again in our visit to  
687 the pill mills in south Florida, a number of arrests that  
688 occurred through the HIDTAs, which are part of ONDCP also,  
689 back in Kentucky, Tennessee and West Virginia, were people  
690 that were traveling from those three States to south Florida  
691 in order to obtain such things as OxyContin.

692         Mr. {Pallone.} So, but, I mean, again, you don't see a  
693 problem in the fact that the programs aren't identical in  
694 order to achieve the interoperability?

695           Mr. {Kerlikowske.} I don't, as long as there is some  
696 basic information that can be exchanged electronically so  
697 that those boards and those States that need that basic level  
698 of information can use them and utilize them to begin to slow  
699 down or even reverse this terrible problem that you have  
700 identified.

701           Mr. {Pallone.} Okay. Thank you.

702           Mr. Shimkus.

703           Mr. {Shimkus.} Thank you, Mr. Chairman.

704           Mr. Director, a lot of my questions are similar to what  
705 the chairman mentioned, so obviously you feel that the  
706 prescription-drug monitoring program is an important aspect  
707 of this fight. That is question one. And we are talking  
708 about prescription drugs. A lot of the problems, even  
709 connecting--I border Mr. Whitfield's district and I also  
710 border southeastern Indiana. What about the whole meth issue  
711 and ingredients that are not prescription-drug issues? You  
712 have the same issue as States themselves are trying to limit  
713 and have lists to prohibit the pseudoephedrine purchase  
714 across State lines. Can you speak to that?

715           Mr. {Kerlikowske.} I can. As you know, Mr. Shimkus,  
716 the Office of National Drug Control Policy was not as  
717 particularly attentive to methamphetamine in its early years  
718 as I believe it should have been, and having spent 9 years in

719 the West I clearly recognized the issue of methamphetamine.  
720 I don't intend for ONDCP to allow that to happen again, and  
721 we want to make sure that we are on top of it. So  
722 methamphetamine in the grand scheme of our national drug  
723 issues is not as high as some other issues. On the other  
724 hand, when your small areas in southern Illinois or places  
725 just outside Seattle were being devastated by  
726 methamphetamine, we should have been on top of it and moved  
727 more quickly. Congress did that through the Combat Meth Act.

728         Unfortunately, what we are seeing is that now the people  
729 who are so good at purchasing over-the-counter or behind-the-  
730 counter drugs through false IDs, et cetera, are circumventing  
731 the Combat Meth Act. We have seen two measures of success so  
732 far. One is in the State of Oregon, which has made  
733 pseudoephedrine a prescription only, and their numbers of  
734 methamphetamine problems are in single digits as far as  
735 laboratories. And then recently Governor Haley Barbour just  
736 signed into law in Mississippi similar legislation to make  
737 pseudoephedrine a prescription only. There is no definitive  
738 evaluation but certainly what we have seen in Oregon bears  
739 worth watching.

740         Mr. {Shimkus.} Thank you. I appreciate the focus and  
741 your expertise in having to deal with this.

742         Let me ask Mr. Rannazzisi, do you think the drug take-

743 back bill allows DEA to mandate that registered entities  
744 implement or establish a drug take-back program, current  
745 registered entities? Your evaluation, what do you think this  
746 legislation does to them?

747 Mr. {Rannazzisi.} I think the legislation provides us  
748 with the opportunity to create a framework for drug disposal.  
749 When we create regulations for something like drug disposal,  
750 we don't try and specify who, what or where. What we try and  
751 do is create a framework and allow people to fit within that  
752 framework.

753 Mr. {Shimkus.} And just to follow up, the concern would  
754 be through regulations, mandates being placed on entities  
755 that currently don't have mandates and then they will have  
756 the funds to be able to implement that, so that is the focus  
757 of this question and that is why I asked that.

758 Mr. {Rannazzisi.} I don't think I could comment on how  
759 the regulatory process is going to proceed until we actually  
760 have a piece of legislation, and even then because of the APA  
761 rules, Administrative Procedure Act rules, I don't believe I  
762 could comment on them.

763 Mr. {Shimkus.} Well, and I agree, but part of this  
764 process is a two-way process.

765 Mr. {Rannazzisi.} Yes.

766 Mr. {Shimkus.} So hopefully people are listening to

767 comments here to realize that we want to make sure that an  
768 unfunded mandate may not fall upon someone who is not  
769 expecting it.

770 Mr. {Rannazzisi.} I could assure you that during  
771 rulemaking we go through notice and comment and we take all  
772 of those comments were very seriously.

773 Mr. {Shimkus.} Yes, I am not asking you to commit  
774 yourself. I am just using the bully pulpit to just make a  
775 point.

776 On these programs, who do you envision would run these  
777 programs? I mean, you have done some war gaming.

778 Mr. {Rannazzisi.} Absolutely. The problem is that the  
779 programs are such a hodgepodge of different organizations and  
780 groups all surrounding law enforcement. At this point in  
781 time, you know, while we have not decided who would run the  
782 programs, we look to the States and the State regulatory  
783 boards to assist us with the program and kind of guide us  
784 along about what they would look at towards a program. So at  
785 this point in time, we always look to the States, you know,  
786 and take their recommendations to heart. So at this point in  
787 time we would probably look to the States.

788 Mr. {Shimkus.} Mr. Chairman, that is all I have and I  
789 yield back.

790 Mr. {Pallone.} Thank you, Mr. Chairman.

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

792 Mr. Kerlikowske, PDMPs track prescriptions for drugs  
793 that might be subject to diversion or abuse. However, it is  
794 important to monitor the tracking programs to find out what  
795 is working and what is not. Is SAMHSA collecting information  
796 to help evaluate the NASPER program?

797 Mr. {Kerlikowske.} Mr. Green, I actually don't know  
798 what information SAMHSA is collecting but I can tell you  
799 there are two things going on with evaluations of  
800 prescription PDMPs. One is, and it is a bit dated now, the  
801 2006 study that was done that showed some benefits of the  
802 PDMPs. The second thing is that the CDC will be releasing, I  
803 believe by the end of summer, some research and evaluation on  
804 PDMPs. I would tell you that they are not perfect and that  
805 we need to make sure that more prescribers are using the  
806 PDMPs. That will be a key aspect and I think it is perhaps  
807 one of the weaknesses. But it is part of the responsibility  
808 for all of us, I believe, to get that word out to the  
809 prescribers that this is an effective, useful database, and  
810 if they do engage in it, it will help them a great deal.

811 Mr. {Green.} Are there any federal efforts to evaluate  
812 the State prescription-drug monitoring programs?

813 Mr. {Kerlikowske.} There are. The CDC effort is an  
814 evaluation, and I don't know how many States, but it is an

815 evaluation of different efforts in some of the different  
816 States.

817         Mr. {Green.} I have one more question, Mr. Chairman.  
818 Let me find it.

819         Mr. Rannazzisi, as we have heard, the Controlled  
820 Substances Act should not create a pathway for patients and  
821 others with leftover controlled substance to return them to  
822 pharmacies or take-back programs for proper disposal. To  
823 address the resulting problem, you stated the DEA has  
824 utilized existing regulations to assist law enforcement  
825 agencies to conduct community take-back programs. My  
826 question is, can you explain to us the logical issues and  
827 resource implications for the DEA in assisting these programs  
828 and can you describe how these programs ideally would operate  
829 if we amended the Controlled Substances Act so the DEA could  
830 issue regulations to enable drug take-back programs to accept  
831 these controlled substances?

832         Mr. {Rannazzisi.} First of all, I noticed somebody on  
833 the panel mentioned that it was DEA regulations, a problem  
834 with DEA regulations. It is not a regulation problem, it is  
835 a statutory problem. The statute prohibits anyone, except  
836 for registrants, from transferring controlled substances.  
837 When an ultimate user obtains a controlled substance, he is  
838 exempted from the registration requirement of the Controlled

839 Substances Act. Because law enforcement has an exemption  
840 also, they could obtain or take in controlled substances.  
841 Currently, that is the only way we could do this, DEA or law  
842 enforcement working with communities, but the law enforcement  
843 office or the law enforcement agency has to be present, has  
844 to take that drug. It can't be done by any other person but  
845 the law enforcement agency.

846 I can't tell you exactly how the--since we don't have  
847 the bill yet, I can't tell you exactly how we would create an  
848 infrastructure. What I can tell you is law enforcement will  
849 still probably be involved, not so much on every take-back  
850 program but they will still have the exemption and they will  
851 still want to be involved. I know that our law enforcement  
852 partners on all of these initiatives have been very  
853 straightforward with us. They want to be involved because  
854 this is so important to them. As the director said,  
855 prescription-drug abuse is a nationwide problem and law  
856 enforcement is very aware of that problem and they will do  
857 everything in their power to remove those drugs from the  
858 illicit market.

859 Mr. {Green.} Well, it would seem like we need,  
860 particularly our committee and our jurisdiction, to provide  
861 assistance for folks so they can dispose of their  
862 prescription drugs including controlled substances in some

863 way instead of just flushing them down into the water supply,  
864 and the studies we have seen and I think a lot of people have  
865 of the amount of prescription medication that is now in some  
866 of the water that ultimately we will be drinking is one way,  
867 if we can make it easier for people to legally and safely  
868 return unused prescriptions. So I appreciate what you are  
869 doing.

870 Thank you, Mr. Chairman.

871 Mr. {Pallone.} Thank you, Mr. Green.

872 Next is the gentleman from Pennsylvania, Mr. Pitts.

873 Mr. {Pitts.} Thank you, Mr. Chairman.

874 Mr. Rannazzisi, expand a little bit on how individuals  
875 currently dispose of their prescription drugs. With respect  
876 to controlled substances, how are individuals allowed to  
877 dispose of prescription drugs? I mean, do you allow  
878 pharmacies to accept those drugs?

879 Mr. {Rannazzisi.} Pharmacies are not able currently to  
880 accept controlled substances back from their patients. That  
881 is just a requirement under the Act. The Act, again, allows  
882 for transfer of controlled substances from registrant to  
883 registrant. Since an ultimate user is not a registrant, a  
884 pharmacy cannot accept that back from them.

885 Mr. {Pitts.} So how do individuals currently dispose of  
886 prescription drugs?

887           Mr. {Rannazzisi.} As the director said, there's three  
888 ways. Currently, ONDCP and HHS on their website, or ONDCP on  
889 its website has a model for drug destruction. It involves  
890 taking the drugs, deactivating them in something like wet  
891 coffee grounds, wrapping up and then throwing them in the  
892 trash. There's also on both ONDCP and HHS websites a list of  
893 narcotics and other controlled substances that may be  
894 flushed, or there are ongoing law enforcement take-back  
895 programs in certain communities where they could drop their  
896 medicines off.

897           Mr. {Pitts.} Mr. Kerlikowske, NASPER sets standards for  
898 protecting patient privacy in the controlled-substance  
899 monitoring program including restricting who may have access  
900 to prescribing information. Can you speak to this issue? Do  
901 you think it's important to have minimum criteria among these  
902 programs with regard to patient information?

903           Mr. {Kerlikowske.} It is. It is one of the things that  
904 I think makes NASPER such an attractive law, and that is that  
905 it is driven by the States but clearly the States have taken  
906 on different issues regarding the blend between a law  
907 enforcement issue and a medical practice issue. There are  
908 State medical boards that work very hard to make sure that  
909 the physicians or all the prescribers are following those  
910 rules and regulations. There are certain protocols then for

911 turning over the information at the particular appropriate  
912 time to law enforcement, and at the same time the States have  
913 made great strides forward under NASPER to make sure that  
914 patients and professionals in the medical practice, that the  
915 privacy issues are protected, and so I think that that is a  
916 wonderful part of the legislation.

917       Mr. {Pitts.} Now, NASPER requires that dispensers like  
918 pharmacies report each dispensing of a controlled substance  
919 no later than one week after the date the drug was dispensed.  
920 Do any States have real-time reporting in the controlled-  
921 substance monitoring programs and can you discuss the  
922 advantages or disadvantages of having a uniform real-time  
923 reporting requirement?

924       Mr. {Rannazzisi.} I am not familiar with any of the  
925 real-time reporting requirements that the States have had. I  
926 think that one of the reasons for the one-week position is  
927 that quite often, particularly if it is--and this could apply  
928 more in rural areas--that the ability to have information  
929 stack up or pile up and not get entered into the database in  
930 a fairly timely manner could cause some difficulties both for  
931 a prescriber who wants to find out if in fact this patient  
932 was going to multiple other places in a short period of time  
933 and that would be helpful. I think many times the goal would  
934 be, if it was online and real time, would be helpful.

935 Mr. {Pitts.} Thank you, Mr. Chairman.

936 Mr. {Pallone.} Thank you.

937 Mr. Whitfield.

938 Mr. {Whitfield.} Thank you all very much for your time  
939 today and testifying on this legislation.

940 Mr. Rannazzisi, early on there was some policy  
941 discussions and really some disagreements about whether this  
942 program should be at HHS or Department of Justice. As  
943 someone involved in law enforcement, do you feel that there  
944 are adequate safeguards in this legislation that you can have  
945 access to fulfill your needs and objectives?

946 Mr. {Rannazzisi.} And I am no expert on NASPER  
947 legislation, but from what I understand, currently there are  
948 adequate safeguards for us, for law enforcement.

949 Mr. {Whitfield.} Because we do think that that is  
950 important, and of course, I think the main thrust has been  
951 the safety of the use of prescription drugs, but we know it  
952 is a serious problem, drug abuse, and I had a lot of law  
953 enforcement people in my district, and I have actually been a  
954 little bit surprised that have actually formed taskforces now  
955 to deal with the abuse of prescription drugs, and I really  
956 was not aware that it was such a major problem nationally,  
957 but from hearing your testimony, it is one of the most  
958 serious problems. Is that correct?

959           Mr. {Kerlikowske.} Mr. Whitfield, you are absolutely  
960 correct. I don't think that the recognition has been there,  
961 and I think that spans across an awful lot of the populace  
962 about the dangerous of prescription drugs and also about the  
963 problems that we are seeing from the abuse of prescription  
964 drugs. I think the most recent arrests in Kentucky,  
965 Tennessee and West Virginia from south Florida, almost 500  
966 arrests, really helped to highlight that, but, you know,  
967 during the National Governors Conference, I had a chance to  
968 visit with Governor Manchin, and he said I cannot go anywhere  
969 in West Virginia to a public meeting in which someone is not  
970 telling me about a prescription-drug problem.

971           So I think all of the time and the attention that all of  
972 the federal agencies, ONDCP, DEA, EPA, et cetera have given  
973 to it, to work with this subcommittee and the subcommittee  
974 staff on this legislation, both in PDMPs and also in take-  
975 backs, is a good example of getting the information out  
976 there, and it is a good example of really government being so  
977 responsive and listening to essentially the cries of the  
978 public about this problem that will make us all safer, and I  
979 comment the subcommittee for their work.

980           Mr. {Whitfield.} Do either of your agencies or  
981 departments have any ongoing programs that are active in  
982 working with local law enforcement to give them suggestions

983 on how to be more effective in this area of prescription-drug  
984 abuse?

985       Mr. {Rannazzisi.} To start off, we reorganized the  
986 Office of Diversion Control and the field elements of the  
987 Office of Diversion Control and created tactical diversion  
988 squads, which are State and local taskforce. We have 34 in  
989 operation right now. We hope to have within the next year  
990 and a half 65 throughout the United States, and all they will  
991 concentrate on is prescription-drug diversion and chemical  
992 diversion. That's a State and local cooperative. And  
993 Kentucky State Policy is a perfect example. KSP has been on  
994 the leading edge of going after and tracking down people who  
995 are diverting controlled substances and we work very closely  
996 with Kentucky State Police and the State of Kentucky.

997       It is so important to address this problem as a State  
998 and local cooperative effort because of funding issues and  
999 because of fact that, you know, this is one issue that we are  
1000 not going to be able to do it alone.

1001       Mr. {Kerlikowske.} And Congress has recognized the  
1002 value of high-intensity drug trafficking areas, the 28 HIDTAs  
1003 that are funded, and all of the HIDTAs which are comprised of  
1004 State, local and federal law enforcement but also include  
1005 some aspects of prevention and treatment. All of the HIDTAs  
1006 are very much aware of the prescription-drug problem, and in

1007 many of these areas have shown real leadership and innovation  
1008 in attempting to both work on take-backs to support PDMPs but  
1009 also to do the necessary investigation and enforcement when  
1010 we have either doctor shopping or physicians in fact, or  
1011 prescribers, I should say, that may be abusing the law.

1012 Mr. {Whitfield.} Thank you, Mr. Chairman.

1013 Mr. {Pallone.} Thank you, Mr. Whitfield.

1014 Mr. Gingrey.

1015 Dr. {Gingrey.} Mr. Chairman, thank you, and I am going  
1016 to ask a series of questions of both Mr. R and Mr. K, and you  
1017 can call me Mr. G.

1018 First of all, the obvious, but what kind of prescription  
1019 drugs are the most likely to be abused?

1020 Mr. {Kerlikowske.} The opioid painkillers.

1021 Mr. {Rannazzisi.} Yes, I have to agree with that.

1022 Dr. {Gingrey.} And the reason I ask that, I expected  
1023 that response, I have noticed that a lot of the even  
1024 legitimate doctors who are involved in pain management, a lot  
1025 of these physicians start out their professional career as  
1026 anesthesiologists, but not always, and you see so many of  
1027 these pain clinics that are popping up, as both of you know,  
1028 and opioids, but recently it was brought to my attention that  
1029 a lot of these doctors prescribe methadone now for pain, and  
1030 as I said in my opening statement, I am a little bit dated.

1031 I haven't practiced for 10 years. But I was always thinking  
1032 of methadone as what you gave people at these drugs clinics  
1033 where the hopeless addicts that could not ever get off  
1034 opioids and you would give them a prescription for methadone.  
1035 Tell me a little bit about that, what your knowledge of that  
1036 is, and your concerns, if any.

1037 Mr. {Kerlikowske.} Methadone was originally created as  
1038 a painkiller in the early 1900s. It became the gold standard  
1039 for narcotic addiction treatment in the 1970s, and it is now  
1040 reemerging as a very, very fine painkiller, especially in  
1041 certain areas where the drug is used in combination with  
1042 other drugs. The problem with methadone is the kinetics of  
1043 the drug. The drug accumulates, and there are a lot of  
1044 overdoses because of that.

1045 Dr. {Gingrey.} It accumulates?

1046 Mr. {Kerlikowske.} Yes, it accumulates in the body. It  
1047 stays in the body for a very long period of time. If a  
1048 person is not following the doctor's instructions on how to  
1049 take the drug, there could be overdoses. If the person is  
1050 taking other substances with the drug, it affects the  
1051 clearance of the drug, the patient could overdose. If it is  
1052 an opioid-naïve patient who has never taken an opioid before,  
1053 the person could overdose. The drug is a very cheap, good  
1054 painkiller, but it does have its issues if it is taken

1055 appropriately without a doctor's supervision.

1056 Dr. {Gingrey.} A two-edged sword, if you will.

1057 Mr. {Kerlikowske.} Yes.

1058 Dr. {Gingrey.} Maybe Mr. Whitfield just asked this  
1059 question about NASPER, and of course Chairman Pallone and  
1060 Ranking Member Shimkus along with Mr. Whitfield have done the  
1061 major work on NASPER and leading up this reauthorization, but  
1062 do you feel that this will help in regard to all these  
1063 concerns with abuse of prescription drugs, particularly the  
1064 pain medication like methadone and other opioids?

1065 Mr. {Kerlikowske.} It is not the silver bullet but we  
1066 have seen success in these programs. We think it has to be  
1067 done in conjunction with a lot of the other things that were  
1068 mentioned, the education of the public, both NASPER but also  
1069 the take-back I think is a wonderful combination for Congress  
1070 to take on and to move forward. I think we can actually--we  
1071 took a hard look at the 10 months before I was in office, the  
1072 10 months after I came to office about the number of mentions  
1073 in the press about prescription drugs, and it was a  
1074 significant increase, so I think the more--and as Mr. Shimkus  
1075 said, using the bully pulpit that you all have to bring this  
1076 to the attention of the public and Dr. Gingrey, you in  
1077 particular having the medical background, you serve as  
1078 wonderful spokespersons to alert people to dangers that

1079 perhaps they just really have not recognized.

1080 Dr. {Gingrey.} Well, I thank you for that, those kind  
1081 words, and in fact, I have got a chemical background, a  
1082 bachelor of science in chemistry, and a medical background.  
1083 I had no idea that you could wrap up that medication with  
1084 coffee grounds and throw it away. Can you tell me a little  
1085 bit more about how that works, and if that information is on  
1086 your website, how many people are going to go look and find  
1087 that out and then all of a sudden rummaging through the  
1088 trashcans looking for coffee grounds?

1089 Mr. {Kerlikowske.} Well, I think that is the real  
1090 benefit of this hearing today and the real benefit of also  
1091 the work that, as you said, Chairman Stupak did and  
1092 Congressman has done on working on a clear, simpler, more  
1093 easily understood take-back program. I think that is  
1094 tremendously helpful. There are some drugs that are so  
1095 potent and can be absorbed in the skin that EPA, FDA and  
1096 ONDCP have recommended that they be disposed of by flushing  
1097 down the toilet. There are others that need to be, as you  
1098 said, made in combination with other things that are in the  
1099 garbage that would make them particularly unattractive to be  
1100 able to use. But having the take-back programs that are  
1101 widely known and thought of I think will be a big help.

1102 Dr. {Gingrey.} Well, I appreciate that.

1103 I know my time is expired, Mr. Chairman, but I don't  
1104 want to see people rooting through the trashcan or the toilet  
1105 bowl, for that matter, so I like the take-back program. I  
1106 yield back.

1107 Mr. {Pallone.} Thank you.

1108 Let me ask unanimous consent to include in the record  
1109 the annual report of the Operation Medicine Cabinet New  
1110 Jersey. This is the Partnership for a Drug-Free New Jersey  
1111 program that I mentioned before.

1112 Without objection, so ordered.

1113 [The information follows:]

1114 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1115           Mr. {Pallone.} And now we have joining us with the  
1116 subcommittee today Mr. Inslee, who is the prime sponsor of  
1117 the Safe Drug Disposal Act legislation that we are  
1118 considering. Mr. Inslee.

1119           Mr. {Inslee.} Thank you. Thank you for letting me join  
1120 you. Before I ask a couple questions of a couple great  
1121 witnesses, I just wanted to thank some people involved. This  
1122 has been a great team effort, bipartisan. Particularly I  
1123 want to note Bart Stupak, who has been working for a long  
1124 time on this issue. Bart now at the end of his Congressional  
1125 career will be known throughout history not only as making  
1126 the greatest catch ever in Congressional history in the  
1127 Republican dugout but also championing this issue, and I  
1128 really want to thank Bart's leadership on this.

1129           Also, Representatives Stupak, Waxman, Moran, Baldwin and  
1130 Pallone, it has just been a great effort, and I think we have  
1131 got a good product here, and I appreciate the two witnesses,  
1132 so I will ask a couple softball questions, if I can.

1133           First, Mr. Kerlikowske, we are having a heck of a time  
1134 filling your shoes back in Seattle. We are trying. It is  
1135 really tough. We might have to hire three people actually to  
1136 fill your shoes, and I appreciate your work on this. I just  
1137 wonder if you might comment on the importance of making sure

1138 that the programs we do design are accessible and are easily  
1139 accessed by communities and giving communities flexibility  
1140 and how they are going to design these programs. I just  
1141 wonder if you might want to comment on that.

1142         Mr. {Kerlikowske.} I do. Your work and initiative on  
1143 this along with Congressman Stupak's work has been  
1144 particularly helpful to us. I am really so impressed with  
1145 the Safe Drug Disposal Act that is being considered because  
1146 it really is kind of a whole-of-government approach, and we  
1147 often sometimes hear that government doesn't listen or pay  
1148 attention. This is a model bill. One of the things that I  
1149 think will be particularly important is that we work very  
1150 closely to make sure with the Department of Justice and the  
1151 Attorney General's Office that the programs that are put into  
1152 effect make sense, are easily understood, and more  
1153 importantly, are evaluated and used, for helping to rid the  
1154 medicine cabinets of some of these dangerous drugs and rid  
1155 them in a way that, as you have remarked to me on a number of  
1156 occasions, gotten rid of in a way that is very  
1157 environmentally sensitive and make sure that we are  
1158 protecting the environment. This is a wonderful opportunity  
1159 for us to do a better job of protecting the public and to  
1160 bringing to their recognition some of these dangers, and with  
1161 the passage of this, as the process moves forward, we will be

1162 particularly attentive to the concerns that you have raised  
1163 throughout the formulation of this legislation.

1164 Mr. {Inslee.} Thank you. I appreciate it.

1165 Mr. Rannazzisi, I wonder if you would like to comment on  
1166 the number of options that will be available, the number of  
1167 locations where these take-back programs maybe appropriate.  
1168 Do you just want to give us thoughts on that?

1169 Mr. {Rannazzisi.} Again, it would be premature without  
1170 the legislation, the actual statute to comment on it.  
1171 However, I could tell you that we have said all along what we  
1172 would like to do is create a regulatory infrastructure that  
1173 is not specific to one or two or three different programs but  
1174 allows the States and entities within the State to create a  
1175 program within those guidelines to fit the needs of their  
1176 citizens, and I believe we could do that if given the  
1177 opportunity by regulation, that flexibility to do that.

1178 Mr. {Inslee.} We will look forward to that. Again,  
1179 thank you for your work. This is a big deal on a bipartisan  
1180 basis. Actually, I think last week I saw a headline in  
1181 Seattle that prescription-drug abuse became number one as far  
1182 as abuse, I think in the State. So know this is happening  
1183 nationwide, and we appreciate your work and thanks for all  
1184 the bipartisan work, our teammates. Thank you.

1185 Mr. {Pallone.} Thank you, Mr. Inslee.

1186 Mr. {Whitfield.} Chairman Pallone.

1187 Mr. {Pallone.} Sure. You want to--

1188 Mr. {Whitfield.} No, I would just ask unanimous consent  
1189 that each member have five legislative days to submit  
1190 additional letters of support.

1191 Mr. {Pallone.} Absolutely, and also I would remind our  
1192 witnesses that you may get additional questions from members.  
1193 I asked the members to submit those additional written  
1194 questions within 10 days or so, so you may get those  
1195 additional questions from us.

1196 Mr. {Shimkus.} Mr. Chairman.

1197 Mr. {Pallone.} Yes.

1198 Mr. {Shimkus.} And I would ask just for a second,  
1199 because Oregon was mentioned and it is prescribing  
1200 pseudoephedrine, and that is an issue that we have talked  
1201 before, and we will have debate, especially in the health  
1202 care arena and access to family, cost of drugs, but I think  
1203 it is also important to note that there has been an increase  
1204 in Mexican drug meth cartel in Oregon at the same time. So  
1205 there may be some benefits in home cooking. There may be an  
1206 uptick in Mexican drug cartel, and it is important to keep  
1207 that in the record.

1208 Mr. {Pallone.} Sure. Thank you.

1209 So anyway, thank you very much for your input. We are

1210 actually going to go to markup pretty soon on the  
1211 legislation. So this was very helpful to us. I appreciate  
1212 it.

1213 Let me mention to the members, we are supposed to have a  
1214 vote, I don't know, any minute, I guess, within the next--two  
1215 votes within the next few minutes on the Floor. So what I  
1216 would ask is that we come back here about 15 minutes after  
1217 the Floor votes and then we will begin the markup at that  
1218 time, which is not only on these bills but some other bills  
1219 as well that had previous hearings.

1220 So without further ado, thank you all, and this  
1221 subcommittee hearing is adjourned.

1222 [Whereupon, at 11:12 a.m., the subcommittee was  
1223 adjourned.]