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EXAMINING LEGISLATIVE PROPOSALS

TO COMBAT OUR NATION'S DRUG ABUSE CRISIS

THURSDAY, OCTOBER 8, 2015

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:15 a.m., in Room 2322 Rayburn House Office Building, Hon. Joe Pitts [chairman of the subcommittee] presiding.

Members present: Representatives Pitts, Guthrie, Shimkus, Murphy, Lance, Bilirakis, Bucshon, Brooks, Green, Engel, Butterfield, Sarbanes, Matsui, Lujan, Kennedy, and Tonko.

Staff present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Karen Christian, General Counsel; Noelle

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Clemente, Press Secretary; Carly McWilliams, Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Graham Pittman, Legislative Clerk; Chris Sarley, Policy Coordinator, Environment and Economy; Adrianna Simonelli, Legislative Associate, Health; Sam Spector, Counsel, Oversight and Investigations; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Health; Eric Flamm, FDA Detailee; Waverly Gordon, Professional Staff Member; Tiffany Guarascio, Deputy Staff Director and Chief Health Advisor; Una Lee, Chief Oversight Counsel; Samantha Satchell, Policy Analyst; and Kimberlee Trzeciak, Health Policy Advisor.

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1 Mr. Pitts. The subcommittee will come to order. I believe
2 the clock is a little slow, so we will get started.
3 And I want to start by mentioning we have a couple of
4 distinguished alumni in the audience of this committee. Phil
5 Gingrey, who was a member of our subcommittee, welcome. A very
6 distinguished member, Mary Bono Mack, is here. Where is Mary?
7 She often raised this issue with me. So welcome. We appreciate
8 all of your interest and input as well.
9 The chair will recognize himself for an opening statement.
10 Today's hearing will consider a number of proposals intended to
11 address various aspects of our nation's drug abuse crisis. The
12 Oversight and Investigations Subcommittee has held five hearings
13 examining this public health epidemic and current efforts
14 underway to combat prescription drug abuse. It is clear that,
15 despite these efforts, the epidemic has continued to grow
16 exponentially.
17 Today is a good opportunity to better understand what
18 Congress can do to help. I appreciate the administration
19 witnesses being here and working with us on these complicated
20 issues. I also look forward to the testimony of outside experts
21 on these various bills in the near future. Prescription drug abuse
22 does not discriminate: it is not limited by geography, income,
23 or age. According to the National Institute on Drug Abuse, one

24 in five Americans has used prescription drugs for nonmedical
25 reasons.
26 In 2011, the Substance Abuse and Mental Health Services
27 Administration published a National Survey on Drug Use and Health
28 and found that 1.7 million 12 to 25 year olds abused prescription
29 drugs for the first time, which amounts to more than 4,500 new
30 initiates per day. These startling statistics should concern all
31 of us. Unfortunately, only about 10 percent of people with
32 substance abuse disorders will get any form of medical care.
33 There are many of our constituents and their families that still
34 need help, and I applaud my colleagues for working on legislation
35 with that goal in mind.
36 I now yield to the distinguished gentleman from Indiana, Dr.
37 Bucshon.
38 Mr. Bucshon. Thank you, Mr. Chairman. Congressman Womack
39 and I introduced H.R. 2872 as a starting point that will eventually
40 result in legislation that helps reverse the heroin and opioid
41 epidemic. Over 100 years ago, Congress first began legislating
42 opioid addiction treatment policies, and since that time,
43 Congress has had to come together and pass such legislation time
44 and time again. Given the worsening epidemic, it is time for
45 Congress to act once more.
46 H.R. 2872 is not a final product. To that end, Congressman

47 Womack, Congressman Tonko, and I held the first Opioid Addiction
48 Treatment Workgroup composed of the leading opioid addiction
49 professional associations and other stakeholders to discuss our
50 legislation. Our objective is to refine this legislation to
51 become a bill that all the key stakeholders support.
52 We can only reverse the opioid epidemic by effectively
53 treating the underlying cause, and part of that underlying cause
54 is our Federal Government's public health response to addiction.
55 Clearly, what we are currently doing is not working well enough,
56 and change is needed. We will need to treat addiction as the
57 medical disease that it is, and confront the very real issues that
58 prevent a person from receiving individualized care specific to
59 his or her circumstances.
60 We need to understand what the data is telling us, and we
61 shouldn't allow the status quo to prevent a legitimate
62 deliberation over what is the best path forward for addressing
63 a crisis that is touching all of our communities. These are the
64 challenges that we must overcome.
65 [The Bill H.R. 2872 follows:]
66
67 ********** INSERT 1 **********

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68 Mr. Bucshon. At this point, I also ask unanimous consent
69 to submit for the record a statement from the American Association
70 for the Treatment of Opioid Dependence.
71 Mr. Pitts. Without objection, so ordered.
72 [The information follows:]
73
74 ********** COMMITTEE INSERT 2 **********

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75 Mr. Bucshon. Thank you, Mr. Chairman. I yield back.

76 Mr. Pitts. And I would like to ask unanimous consent to

77 submit the following document for the record: a letter from the

78 American Medical Association. Without objection, so ordered.

79 [The information follows:]

80

81 ********** COMMITTEE INSERT 3 **********

82 Mr. Pitts. The chair now recognizes the ranking member, Mr.
83 Green, 5 minutes for an opening statement.
84 Mr. Green. Good morning, and thank each of you for being
85 here today. As we know, the Centers for Disease Control and
86 Prevention declared our nation's prescription drug abuse crisis
87 an epidemic. In 2013, drug overdose was the leading cause of
88 injury death in the United States. This is a battle we have waged
89 for more than 100 years. When Congress first passed laws to
90 confront the problems of heroin and opioid addiction, we once
91 again face the challenges of controlling and combating this menace
92 that is ravaging communities across the country.
93 In the past few years, overdose deaths involving opioids
94 increased fourfold and the number of heroin use has almost
95 doubled. Cases of HIV and hepatitis C are on the rise. Despite
96 universal recognition of the problem, our current efforts are not
97 enough to meet the challenges of the crisis. The drivers of the
98 problem are complex and there is no single silver-bullet solution.
99 It is critical that we approach this challenge through a public
100 health lens.
101 Experts have documented serious impediments to widespread
102 access to treatment, including a shortage of substance abuse
103 providers, social and cultural stigmas, and lack of health
104 coverage for such services. Current research suggests that a

105 combination of medication-assisted treatment and behavioral
106 treatment such as counseling and support services are the most
107 effective way to treat opioid addiction.
108 In 2013, medication-assisted treatments were available in
109 only 9 percent of substance abuse treatment facilities. For
110 example, in 2012, 96 percent of States and the District of Columbia
111 had opioid abuse dependence rates higher than their buprenorphine
112 treatment capacity rates. Thirty-eight States reported that at
113 least 75 percent of the opioid treatment programs, also known as
114 methadone clinics, were operating at a greater-than-80-percent
115 capacity.
116 Today, we are here to examine seven legislative proposals
117 aimed at combating our nation's drug abuse epidemic. They build
118 upon the hearings this committee has held and represent various
119 approaches to improving prevention and treatment. Each is a
120 product of thoughtful consideration and dedication from their
121 sponsors, and I thank my colleagues for their efforts and the
122 chairman for having this hearing. It is critical that we give
123 law enforcement, health providers, and communities enhanced tools
124 to address this epidemic. We need more resources and a
125 coordinated effort to ensure the evidence-based treatment is
126 available and diversion is stymied. The statistics are
127 staggering. The need for action is clear. Again, thank you for

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128 being here.

129 And I would like to yield 1 minute to Congressman Lujan.

130 Mr. Lujan. Thank you, Mr. Chairman and Ranking Member, for
131 scheduling this incredibly important hearing on a crisis that is
132 plaguing our nation. This crisis touches everyone, from dense
133 urban cities to rural states like New Mexico, for getting access
134 to health services can often be a challenge. Most recent data
135 from New Mexico's health department puts the accidental drug
136 overdose rate at 24.3 per 100,000. That is more than double the
137 national average. In two of the counties in my district, the
138 overdose rate is more than five times the national average.

139 Too many people are being forgotten and too many people are
140 suffering. That is why I have introduced the Improving Treatment
141 for Pregnant and Postpartum Women Act to strengthen efforts to
142 ensure that some of our most vulnerable get the care they need.
143 I want to thank my colleagues, Representative Matsui, Tonko,
144 Clark, and Cardenas, for joining me in introducing this bill, and
145 I look forward to today's discussion and getting this done. Mr.
146 Chairman, the thoughtfulness behind all of this legislation is
147 so important, and I just hope that we can get this done. Thank
148 you, Mr. Chairman. I yield back.

149 [The Bill introduced by Mr. Lujan follows:]

150

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151 ********** INSERT 4 **********

152 Mr. Green. Mr. Chairman, I yield another minute to
153 Congresswoman Matsui.
154 Ms. Matsui.. Thank you very much. Thank you, Mr. Chairman,
155 for holding this hearing today on such an important topic. There
156 is a growing prescription drug epidemic plaguing this country that
157 we can no longer ignore. Prescription drugs are the second-most
158 abused category of drugs among young people, and sadly, these
159 painkillers often serve as a gateway to cheaper street drugs like
160 heroin.
161 The abuse of both prescription painkillers and heroin is
162 devastating families and undermining public health and safety in
163 our communities. In order to address this epidemic, we need to
164 engage the full range of players, including patients, providers,
165 parents, and manufacturers, as they all can and should play a
166 critical role in curbing the abuse of prescription drugs.
167 Addressing this crisis should be a priority, and I am pleased
168 that this committee is holding a hearing on this important issue.
169 I look forward to hearing from other witnesses as we consider
170 strategies for addressing this epidemic. Thank you, and I yield
171 back.
172 Mr. Green. Mr. Chairman, I yield the remainder of my time
173 to Congressman Sarbanes, if he would like to make a very brief
174 statement.

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175 Mr. Sarbanes. It will be brief indeed. Thank you for
176 yielding. One of the bills we are going to be talking about or
177 I will be referring to is the Co-Prescribing to Reduce Overdoses
178 Act. This would allow for co-prescribing of naloxone when
179 physicians are prescribing opioids in cases where the patient is
180 at high risk for overdose, and it would allow for a demonstration
181 project to support certain facilities in exploring this
182 opportunity, training physicians on it, who in turn can train
183 patients on how to self-administer this lifesaving drug. We have
184 an epidemic across the country. Certainly, Baltimore, Maryland,
185 is experiencing this, and we look forward to testimony today on
186 topics of this kind. And I yield back. Thank you.
187 [The Bill introduced by Mr. Sarbanes follows:]
188
189 ********** COMMITTEE INSERT 5 **********

190 Mr. Green. Mr. Chairman, I would also like ask to place into
191 the record a statement by the Drug Policy Alliance.
192 Mr. Pitts. Without objection, so ordered.
193 [The information follows:]
194
195 ********** COMMITTEE INSERT 6 **********

196 Mr. Pitts. The gentleman yields back. And now the chair
197 recognizes the gentlelady from Indiana, Mrs. Brooks, who is
198 filling in for the chair of the committee.
199 Mrs. Brooks. Thank you, Mr. Chairman. I would like to
200 thank the committee for bringing attention once again to this
201 important topic. Sadly, Indiana is leading the country but not
202 in a way we would like. Unfortunately, according to our State
203 Public Health Commissioner, Dr. Adams, Indiana is one of 13 States
204 where the prescribers write enough prescriptions that every
205 citizen in our State has a paying prescription.
206 Unsuspecting addicts get hooked on opioids, but oftentimes,
207 they switch to heroin, not only for the high but because now it
208 is less expensive, and it is actually easier to get. And heroin
209 on our streets is cheaper, stronger, and thanks to the synthetic
210 add-ins, more unpredictable in its results than in the past. From
211 '99 to 2009 Indiana health officials have seen a 500-percent
212 increase in the rate of drug overdose death, and in fact, overdose
213 deaths now surpassed motor vehicle-related deaths in our State.
214 And it is not just the overdoses, but in this past year, as
215 this committee has already heard, Indiana has seen a drastic spike
216 in hepatitis C and HIV due to opioid and heroin infusions, with
217 the most recent figure at 183 confirmed cases of HIV in one small
218 rural county alone.

219 Now, we have held lots of roundtable discussions with
220 providers and with prescribers and with law enforcement, but
221 tragically, it is the families of the addicts and of those who
222 have died who have become the real experts in this field. The
223 consistent thread in the debate is that 80 percent of heroin use
224 starts with prescription for pain meds, and many prescribers are
225 unaware they may be a major part of the problem.
226 So there is no silver bullet to fix it, but that is why I
227 am very pleased that Congressman Kennedy and I have introduced
228 H.R. 2805, the Heroin and Prescription Opioid Abuse Prevention,
229 Education, and Enforcement Act of 2015. Yes, it is a
230 comprehensive approach to solving the problem. It incorporates
231 law enforcement, medical providers, educators, and first
232 responders.
233 I am thankful to my colleagues for participating in today's
234 hearing and I look over to working with them in the coming weeks
235 to advocate not only for passage of this bill, but the many
236 thoughtful solutions being proposed by this committee. I yield
237 back.
238 [The Bill H.R. 2805 follows:]
239
240 ********** INSERT 7 **********

241 Mr. Pitts. The chair thanks the gentlelady. And now the
242 chair recognizes the gentleman from Massachusetts, Mr. Kennedy,
243 filling in for the ranking member of the full committee.
244 Mr. Kennedy. Thank you, Mr. Chairman. I appreciate the
245 opportunity. And I want to thank the witnesses for coming to
246 testify today, and for your extraordinary dedication to these
247 issues and your service to our country.
248 The other day, I asked some of my constituents to tell me
249 about their experience with opiate abuse and drug addiction,
250 whether it was their own personal struggle or the battle of a loved
251 one. Their responses were heartbreaking: a grandmother who
252 lost her 25-year-old grandson over the summer, a father whose
253 56-year-old son battled mental illness late in life and eventually
254 fell victim to cocaine addiction, a young woman who just lost her
255 cousin to an overdose 2 weeks ago, a mother whose son was denied
256 entrance into a treatment program last month because he was
257 already in detox after overdosing. So she gave him the money he
258 needed to buy drugs and test positive. The themes of each story
259 were unique, but every constituent ended their message the same
260 way, by calling on Congress to act.
261 Many of the bills we are considering today will help us began
262 to answer those calls, including one I was proud to introduce with
263 my colleague, Congresswoman Brooks, earlier this year. Chairman

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264 Pitts and Ranking Member Green, thank you for your continued
265 commitment to this issue. I look forward to listening to the
266 conversation today and discussing some bipartisan solutions.
267 I would like to yield the balance of my time to Representative
268 Tonko.
269 Mr. Tonko. And I thank the gentleman for yielding. I am
270 pleased that we are holding this legislative hearing today on
271 bills that aim to ease the burden of our nation's growing opioid
272 epidemic. I am here today in support of the Recovery Enhancement
273 for Addiction Treatment Act, also known as the TREAT Act, on which
274 I joined with my fellow upstate New Yorkers, Representatives
275 Higgins, Katko, and Hanna, to introduce.
276 This legislation would lift the current caps in place on the
277 number of patients that doctors can serve while prescribing
278 buprenorphine, a medication-assisted treatment for opioid
279 addiction. Under current laws, if every opioid treatment program
280 and DATA 2000-waivered physician treated the maximum number of
281 patients, that would still be roughly 1 million opioid-addicted
282 individuals unable to secure treatment.
283 The hope with this bill is that we can lessen this gap between
284 individuals seeking treatment and our inadequate treatment
285 capacity. While this legislation is not a cure-all and we still
286 need to examine measures to ensure the highest quality care, I

287 believe the TREAT Act will go far in helping to alleviate our acute
288 treatment capacity issues and put more people on the path to
289 recovery. I urge our committee to take swift action on this bill
290 so that we can turn the tide on this epidemic. And with that, I
291 thank you and yield back to Representative Kennedy.
292 Mr. Kennedy. Unless there is another member of the minority
293 that wants time, I yield back.
294 Mr. Pitts. The chair thanks the gentleman. That concludes
295 the opening statements. As usual, all written opening statements
296 of the members will be made a part of the record as well. We have
297 two panels for this hearing. We are going to take one today; the
298 second, the week of October 20 when we come back from break. But
299 I would like to thank our first panel here today, and I will
300 introduce them in the order of their testimony.
301 First, we have Mr. Michael Botticelli, Director of the
302 National Drug Control Policy, Executive Office of the President;
303 secondly, Dr. Richard Frank, Assistant Secretary for Planning and
304 Evaluation, Health and Human Services; and finally, Mr. Jack
305 Riley, Deputy Administrator, Drug Enforcement Administration.
306 Thank you very much for coming today. Your written
307 testimony will be made part of the record. You will be each given
308 5 minutes to summarize. We have a series of three little lights.
309 Green will be on for 4 minutes, yellow a minute, and at minute

310 number 5 the red will come on. We ask you to wrap it up if you
311 could, and then we will go to questions and answers. So thank you
312 very much for coming. And, Mr. Botticelli, you are recognized for
313 5 minutes for your summary.

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314 STATEMENTS OF MICHAEL BOTTICELLI, DIRECTOR, NATIONAL DRUG CONTROL
315 POLICY, EXECUTIVE OFFICE OF THE PRESIDENT; RICHARD FRANK,
316 ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, HEALTH AND HUMAN
317 SERVICES; AND JACK RILEY, DEPUTY ADMINISTRATOR, DRUG ENFORCEMENT
318 ADMINISTRATION
319
320 STATEMENT OF MICHAEL BOTTICELLI
321 Mr. Botticelli. Thank you, Chairman Pitts, Ranking Member
322 Green, and members of the subcommittee, for the opportunity to
323 appear here today to discuss the Administration's response to the
324 epidemic of opioid abuse, particularly the rise in nonmedical
325 prescription opioid and heroin use, overdose deaths, and the use
326 of new psychoactive substances.
327 The Office of National Drug Control Policy produces the
328 National Drug Control Strategy, which is the Administration's
329 primary blueprint for drug policy. This strategy treats our
330 nation's substance use problems as a public health issue, not just
331 a criminal justice issue.
332 Using ONDCP role as the coordinator of Federal drug control
333 agencies, in 2011 our Administration released a plan to address
334 the sharp rise in prescription drug misuse. This plan contains
335 items categorized in four areas: education of prescriber and
336 patients, increased prescription drug monitoring programs,

337 proper medication disposal, and law enforcement efforts.

338 The Administration has also convened at Congress's urgence
339 an interagency Heroin Task Force co-chaired by ONDCP and the
340 Department of Justice to more closely examine our strategies as
341 it relates to heroin use in the United States. The task force
342 will release its strategic plan later this year.

343 There has been a stark increase in the number of people using
344 heroin over recent years and the number of overdose deaths
345 involving heroin. As communities and law enforcement struggle
346 with an increasing number of overdose deaths, heroin use, and
347 increased heroin trafficking, it is important to note that
348 plentiful access to opioid drugs via medical prescribing and easy
349 access to diverted opioids for nonmedical use is feeding our
350 opioid drug use epidemic.

351 Even though data indicate that over 95 percent of
352 prescription opioid users do not initiate heroin use, four out
353 of five new heroin users have experience as nonmedical
354 prescription drug users. Given this interrelationship, the
355 public health response to heroin use must be part of the response
356 to nonmedical prescription opioid use.

357 A further complicating factor in addressing this epidemic
358 is law enforcement reporting of heroin that is laced with
359 fentanyl, an opioid drug that is estimated to be 100 times more

360 potent than heroin. This increased potency has resulted in more
361 overdose deaths in many parts of the country.
362 We have seen overdose deaths from prescription opioid level
363 off, but unfortunately, this is coupled with a dramatic 39 percent
364 increase in heroin-involved overdose deaths in one year, from 2012
365 to 2013. To address the overdose death issue, we are working to
366 increase access to naloxone for first responders and individuals
367 close to those with an opioid drug use disorder, and to promote
368 Good Samaritan laws so witnesses to an overdose will take steps
369 to help save lives.
370 First responders nationwide are rising to this challenge of
371 addressing the increase in opioid use in overdose deaths, but the
372 medical establishment also needs to increase access to treatment
373 for individuals with opioid use disorders before they become
374 chronic or result in other public health consequences such as
375 infectious diseases or neonatal abstinence syndrome.
376 Given that little to no time in graduate medical education
377 programs is devoted to the identification or treatment of
378 substance use disorders and given that very few physicians have
379 availed themselves of voluntary training options, our
380 Administration continues to press for mandatory prescriber
381 education tied to controlled substance licensure. Evidence
382 shows that medication-assisted treatment with FDA-approved

383 medications, when combined with behavioral therapies and other
384 recovery supports, has shown to be the most effective treatment
385 for opioid use disorders. Our Administration continues to pursue
386 a wide variety of ways to increase access to these lifesaving
387 medications. But since some of these products are subject to
388 diversion, it is essential that this expansion be done in a way
389 that promotes high-quality care and minimizes the opportunity for
390 diversion.
391 It is also important to continue our efforts to educate the
392 public about the risks and consequences of nonmedical
393 prescription opioid and heroin use and the availability of options
394 for treatment for opioid use disorders to help improve and save
395 lives. To help with all of these efforts, the Administration's
396 fiscal year 2016 budget proposal includes $133 million in new
397 funding to reduce opioid misuse, abuse, and overdose deaths.
398 Lastly, a few comments about the use of new psychoactive
399 substances, or NPS. The Administration's activities to reduce
400 the use, availability of NPS include data collection, research,
401 prevention, treatment, domestic and foreign law enforcement
402 actions, and international cooperation to reduce the manufacture
403 and distribution of these serious life-endangering substances.
404 The health risks of NPS can be significant, including serious
405 injury and even death. The contents and effects of synthetic

406 cannabinoids and synthetic cathinones are unpredictable due to
407 a costly changing variety of chemical compounds used in
408 manufacturing processes that are devoid of quality control and
409 regulatory oversight. These substances also contain toxic
410 impurity byproducts, and the potency can vary significantly from
411 batch to batch.
412 In conclusion, this Administration will continue our work
413 with Congress and our Federal, State, and local partners on public
414 health and public safety issues resulting from the epidemic of
415 the nonmedical prescription opioid and heroin use, as well as new
416 psychoactive substances.
417 Thank you.
418 [The prepared statement of Mr. Botticelli follows:]
419
420 ********** INSERT 8 **********

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421 Mr. Pitts. The chair thanks the gentleman and now

422 recognizes Dr. Frank, 5 minutes for your summary.

423 STATEMENT OF RICHARD FRANK

424

425 Mr. Frank. Thank you, Chairman Pitts.

426 Mr. Pitts. Make sure the button is pressed. Yes.

427 Mr. Frank. Thank you, Chairman Pitts, Ranking Member Green,

428 and members of the subcommittee. I appreciate the opportunity

429 to speak with you about addressing the misuse and abuse of opioids.

430 We at HHS share your sense of urgency to take action to end

431 this epidemic. Secretary Burwell has made halting the opiate

432 epidemic a top priority.

433 The numbers on the epidemic are stark. In 2014, more than

434 10 million people reported nonmedical use of prescription

435 opioids, and nearly a million reported use of heroin. Moreover,

436 it is estimated that more than 2 million people have an opioid

437 use disorder. These disorders tear apart families, increase

438 crime, and kill too many of our neighbors.

439 When Secretary Burwell arrived at HHS a little over a year

440 ago, she directed our senior leadership to develop and implement

441 an initiative to address the opioid problem. She insisted that

442 it be department-wide, focused, and evidence-based so as to

443 produce maximum impact. That effort resulted in the strategy

444 that consists of three elements: first, improving prescribing

445 practices for opioid pain medications; second, expanding the use

446 of medication-assisted treatment for opioid use disorder; and
447 third, expanding the use and distribution of naloxone to reverse
448 overdoses.

449 In the time I have with you today, I want to focus on our
450 efforts to expand the use of medication-assisted treatment, or
451 MAT. MAT is a treatment that combines medication, behavioral
452 interventions, recovery support services, and careful patient
453 monitoring. There are three FDA-approved medications used in
454 MAT: methadone, buprenorphine, and naltrexone. MAT, using each
455 one of these, has been shown to be effective in clinical trials
456 and in public health interventions. It is in fact the most
457 effective approach to treating opioid use disorders. Yet MAT is
458 woefully underused. Provision of MAT faces unique barriers in
459 part because methadone and buprenorphine are controlled
460 substances.

461 In addition, stringent medical management techniques are
462 used to control utilization, and in the case of buprenorphine,
463 the number of opioid use disorder patients a certified physician
464 can treat is limited to 100 at any one time.

465 Our approach to expanding the use of MAT is guided by, first
466 of all, the recognized need to expand the use of MAT; two, the
467 fact that effective use of MAT means delivering the full package
468 of services: pharmaceuticals, counseling, recovery supports,

469 and monitoring for a patient's adherence; and third, that the
470 capacity be expanded in a way that minimizes the risk of drug
471 diversion. This approach is supported by the American Society
472 of Addiction Medicine's recent guidelines on appropriate use of
473 MAT.

474 Given these guardrails, I want to share with you the steps
475 we are taking to expand MAT that we believe have much in common
476 with proposed legislation that has already been mentioned today
477 such as the TREAT Act.

478 Following Secretary Burwell's recent announcement, we are
479 engaging in rulemaking related to expanding access to
480 buprenorphine-based MAT. Our Health Resources and Services
481 Administration, or HRSA, recently announced a competition for
482 $100 million to expand the use of MAT in community health centers.
483 SAMHSA recently awarded $11 million per year for 3 years to 11
484 States across the Nation to increase MAT, and is proposing an
485 additional 25.1 million for this purpose to go to 22 States for
486 fiscal year 2016.

487 CMS recently issued a letter to State Medicaid Directors
488 describing opportunities and authorities that States can use to
489 provide a continuum of care to beneficiaries suffering from
490 substance use disorder, including opioid use disorder.

491 We are also exploring ways to expand education and training

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492 for providers in the treatment of opioid use disorders. We are

493 committed to tracking and evaluating our efforts, that we make

494 the best use of public resources, and in the end, we will measure

495 our success by the impact we have on families, people, and

496 communities touched by the opioid crisis.

497 Thank you.

498 [The prepared statement of Mr. Frank follows:]

499

500 ********** INSERT 9 **********

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501 Mr. Pitts. The chair thanks the gentleman and now

502 recognizes Mr. Riley, 5 minutes, for your opening statement.

503 STATEMENT OF JACK RILEY

504

505 Mr. Riley. Chairman Upton, Chairman Pitts, Ranking Member
506 Pallone, Ranking Member Green, and members of the subcommittee,
507 I want to thank you for this opportunity to testify this morning
508 about our nation's most pervasive drug issues: the continuing
509 opioid epidemic and the rise of synthetic drugs.
510 DEA's single mission is enforcing the Controlled Substances
511 Act, and we are honored to work closely with our counterparts,
512 including those in education, enforcement, research, recovery
513 field, as well as partners in the supply chain.
514 Sadly, today, 120 Americans will die as a result of drug
515 overdose. Heroin and prescription drugs cause over half of those
516 fatalities. Accordingly, DEA views the opioid addiction
517 epidemic as the number one drug threat to our country.
518 I spent my entire career in law enforcement. Having been
519 an agent with the DEA for over 30 years, I have to tell you I have
520 never seen it this bad. Prescription drug abuse has increased
521 tremendously in the last 15 years. The abuse of prescription
522 drugs and resulting addiction has fueled a spike in the use of
523 heroin. In fact, four out of five new heroin users have misused
524 prescription painkillers.
525 Increases in heroin purity, its low cost on the streets, the

526 expanding role of violent Mexican organized crime groups, and the
527 toxic business relationship with violent urban street gangs has
528 also played a significant role in the resurgence of heroin. DEA
529 is addressing this evolving threat by targeting the highest-level
530 traffickers and the vicious organizations they run.

531 I have personally spent the bulk of my career chasing the
532 man I consider to be the most dangerous heroin dealer in the world,
533 El Chapo Guzman. He and his Sinaloa Cartel clearly dominate the
534 U.S. heroin market, as the map I have brought with me today
535 depicts.

536 Just as we cannot separate violence from drugs, we cannot
537 separate controlled prescription drug abuse from heroin. As a
538 result, DEA established highly effective tactical diversion
539 squads, 66 in total, to target the critical nexus between the
540 diversion of prescription drugs and heroin. DEA has also
541 addressed the threat posed by the drugs that are in our medicine
542 cabinets through our National Take-Back, the latest one being just
543 2 weeks ago. We have removed over 5-1/2 million pounds of unused
544 and unwanted drugs. However, DEA drug disposal is still a problem
545 to us and we can't solve it on our own.

546 DEA promulgated a regulation last year to allow the drug
547 supply chain to become authorized collectors. At present, we
548 have 500 registrants. It is simply not enough. This is one

549 important way in which we can step up as partners in our effort
550 to curb prescription drug abuse.
551 Lastly, I want to address the growing synthetic issue that
552 we are facing. Some of these designer drugs are referred to as
553 synthetic THC and marketed with similar effects. Nothing could
554 be further from the truth. Last year, there was a 229-percent
555 spike in calls to Poison Control Centers for synthetics. The
556 physical reaction to even one use of a synthetic drug varies
557 widely, and in some cases, has resulted in death.
558 DEA has identified literally hundreds of synthetic drugs
559 that have been encountered during Federal, State, and local law
560 enforcement operations. Manufactured in overseas laboratories,
561 these drugs are unregulated, have no medical use, and are not
562 tested for safety. This means that those who misuse these
563 products -- most likely teens and adolescents -- are really
564 unwittingly allowing themselves to become guinea pigs.
565 Law enforcement has been encountering these substances more
566 and more. According to the National Forensic Laboratory
567 Information System, substances identified as synthetic
568 cannabinoids by Federal, State, and local forensic laboratories
569 have increased from 52 reports in 2009 to over 49,000 reports just
570 last year.
571 DEA has made several enforcement operations targeting this

572 problem, including Operation Log Jam, Project Synergy I and II,
573 which have collectively resulted in 377 arrests and over $80
574 million in cash seized, and literally tons of synthetic drugs
575 taken off our streets. These operations demonstrate the scope
576 of the problem, but I believe they are really just the tip of the
577 iceberg.

578 I want to thank you for your partnership. DEA and I look
579 forward to continuing to work with this subcommittee and Congress
580 on these important issues.

581 [The prepared statement of Mr. Riley follows:]

582

583 ********** INSERT 10 **********

584 Mr. Pitts. The chair thanks the gentleman. That concludes
585 the opening statements of the witnesses. We will now begin
586 questioning. I will recognize myself for 5 minutes for that
587 purpose. Dr. Frank, and then Mr. Botticelli, in your view, what
588 are the most significant obstacles at the present time preventing
589 more individuals with opioid use disorders from receiving the most
590 effective treatments?
591 Mr. Frank. I think there are several factors. I think
592 supply of treatment is certainly one important factor. The
593 second one is stigma and the shame that comes from seeking
594 treatment, the attitude of friend to neighbors. And then third,
595 I think we are still working on our payment and coverage
596 arrangements as we implement our parity legislation, and as we
597 move towards expanding our parity regulations.
598 Mr. Pitts. Mr. Botticelli?
599 Mr. Botticelli. As you indicated, only about 20 percent of
600 people who have substance use disorder get care and treatment,
601 and the factors that are often cited in those surveys, as Dr. Frank
602 alluded to, is, one, insurance status. And we know that either
603 not having insurance, or not having insurance that appropriately
604 covers a spectrum of substance use disorder services is
605 particularly challenging.
606 As he also talked about, stigma plays a role. We know that

607 in national data, and I hear it time and time again reflected in
608 people's stories, that it keeps them from asking for help, or
609 delaying their care.
610 And the third aspect, particularly as it relates to opioid
611 use disorders, as we have been discussing here, is the really
612 dramatic underutilization of medication-assisted therapies not
613 only in our treatment programs but in our correctional facilities.
614 We know we have many parts of the country that don't have a
615 dedicated treatment program, and looking at, and I think
616 particularly, the Secretary's initiative, focusing on increasing
617 access to community health centers -- becomes particularly
618 important. So we know that not having dedicated treatment in a
619 local community is really, really important.
620 Mr. Pitts. Would the two of you expand on that, on the role
621 that you think medication-assisted therapy should play?
622 Mr. Botticelli. I will start and --
623 Mr. Pitts. Yeah, go ahead.
624 Mr. Botticelli. -- have Doctor -- again, I think there
625 is common agreement and that all of the studies are really very
626 crystal clear that, by far, people with opioid use disorders do
627 better on medication-assisted treatment when done in a
628 high-quality way that includes other behavioral therapies and
629 supports, bar none. So we know that not only do people do better,

630 they don't die, they don't get infectious disease as it relates
631 to it. And part of our efforts on the Administration level, both
632 at ONDCP in conjunction with HHS, is to ensure that people have
633 adequate access.
634 In addition to grants and other activities, we have also been
635 strengthening our Federal contracting language to ensure that
636 those programs that get Federal dollars that support treatment
637 include the entire spectrum of FDA-approved medications for
638 opioid use disorders.
639 Mr. Pitts. Dr. Frank, do you want to add to that?
640 Mr. Frank. The one point I would add to that is that it is
641 not only important that we have people out there able to conduct
642 medication-assisted treatment, but they have to do it in a way
643 that is evidence-based, that is, having all of the components in
644 place, the counseling, the recovery supports, the patient
645 monitoring. You need the whole package for it to work. But
646 clearly, when you have that, it is the most effective treatment
647 out there.
648 Mr. Pitts. Thank you. Mr. Riley, I appreciate DEA's
649 willingness to work with the committee to ensure that
650 veterinarians can travel with and administer pain medication to
651 their animal patients. Athletic team physicians also have an
652 inherently mobile practice, yet as was the case with the vets,

653 the statute prohibits them from administering appropriate
654 medication to their patients outside of their physical office.
655 Will you commit to working with the committee and Chairman
656 Sessions on a responsible solution to this important issue?
657 Mr. Riley. Well, yes, sir, we will and we are. This is a
658 difficult balancing act, in terms of making sure that the supply
659 is there to legitimate patients given by legitimate caregivers,
660 but we also want to make sure that the ability of diversion in
661 these situations are as limited as much. So I look forward to
662 working with the committee, and I know we already are.
663 Mr. Pitts. Thank you. I also appreciate DEA's efforts to
664 combat the recent influx of incredibly dangerous synthetic drugs
665 hitting communities across the country, yet I understand that due
666 to no fault of your own, the criminals are a step or two ahead
667 of you. Can you explain how Congressman Dent's bill would help
668 in this regard?
669 Mr. Riley. Well, first of all, I want to say thank you to
670 the leadership in this issue because it really is an issue for
671 us. As I look across the country today, what keeps me up at night
672 is clearly the heroin issue, the opioid addiction issue, various
673 organized crime groups. But second that is the growth of
674 synthetic drugs primarily targeting our young people. I
675 personally witnessed this where people have lost their lives. So

676 from a cop's point of view, sir, and that is what I am, anything
677 that could help us as a tool to make sure we can move quicker,
678 we would welcome. And again, we are going to work with the
679 committee to get it done.
680 Mr. Pitts. The chair thanks the gentleman and now
681 recognizes the ranking member, Mr. Green, 5 minutes for questions.
682 Mr. Green. Thank you, Mr. Chairman. Current research
683 suggests that the most effective treatment to combat opioid
684 addiction is a combination of medication and counseling.
685 Methadone, which was approved nearly 50 years ago, is a synthetic
686 opioid. Methadone is also a DEA Schedule II drug. Director
687 Botticelli, could you talk a little bit about the evidence base
688 regarding methadone and how it impacts patients' retention and
689 treatment, transmission of infectious disease, and other health
690 outcomes?
691 Mr. Botticelli. So methadone is one of the most highly
692 evaluated treatments for opioid use disorders. It has been
693 around for over 50 years. And so not only have we seen kind of
694 remarkable results in terms of treatment engagement and
695 retention, and reduction in infectious disease but also reduction
696 in criminal behavior, increase in full-time employment. It is
697 one of the highly effective medications that we have as it relates
698 to opioid use disorders.

699 I think the bright spot that we do have with the opioid use
700 epidemic is a growing armamentarium of highly effective
701 medications, and when done in a quality way, methadone treatment
702 programs wrap not only medication but look at addressing other
703 medical conditions but also ensure that people have access to
704 behavioral therapies and other recovery supports.
705 Mr. Green. Okay. Dr. Frank, what are the advantages and
706 disadvantages of using methadone to treat opioid addiction?
707 Mr. Frank. Thank you for the question. As Director
708 Botticelli said, first and foremost, it is extraordinarily
709 effective, and that is a huge advantage. It is administered in
710 a highly structured environment that provides testing, support,
711 and therefore has a very low probability of diversion. Now, this
712 structured setting is there because of the way methadone is
713 metabolized, and careful attention to dosing is necessary early
714 in the treatment because of the increased risk of mortality. And
715 a disadvantage is that methadone is particularly prone to stigma.
716 Mr. Green. Okay. Another drug used for opioid addiction
717 is buprenorphine. This drug is a synthetic opioid and a DEA
718 Schedule III drug. Buprenorphine can be prescribed by physicians
719 who receive a DATA waiver. They are only permitted to treat a
720 maximum of 100 patients at a given time. Dr. Frank, can you talk
721 about the evidence base for buprenorphine and its impact on

722 overdoses and other health outcomes?

723 Mr. Frank. Yes, thank you. There have been 16 clinical

724 trials on buprenorphine. It is impossible to pronounce, isn't

725 it?

726 Mr. Green. Oh, it is very, although we are learning.

727 Mr. Frank. Buprenorphine -- -

728 Mr. Green. People who think Members of Congress can't learn

729 are so off.

730 Mr. Frank. So there have been 16 trials of

731 buprenorphine-based medication-assisted treatment. They

732 consistently show strong effectiveness in treatment retention and

733 reduced illicit opioid use. They also show improved maternal and

734 fetal outcomes in pregnancy, relative to placebo trials, and they

735 also have some mortality benefits. So they also have been highly

736 effective.

737 Mr. Green. I understand that an injectable drug called

738 Vivitrol also has been approved by FDA to treat opioid addiction.

739 Vivitrol is an opioid antagonist, meaning it blocks opioid

740 receptors. It is neither a narcotic nor a DEA-scheduled drug.

741 Director Botticelli or Dr. Frank, can you comment on the evidence

742 base regarding the use of Vivitrol in the treatment of opioid

743 addiction?

744 Mr. Botticelli. Once again, there is significant study to

745 show that injectable naltrexone is highly effective in terms of
746 dealing with opioid addiction. I think the premise here is we
747 have three really highly effective medications that are
748 underutilized. But it is also, I think, important to understand
749 that, as in any disease, you want as many highly effective
750 medications as possible, to make sure that we are matching the
751 right treatment with the right person, and that if one fails, you
752 have another option to be able to use for people. So, you know,
753 again, I think our approach is to ensure that people have access
754 to all of the three FDA medications that we have.
755 Mr. Green. Is there a problem with diversion of either of
756 those drugs? Because I know you said earlier in the testimony
757 that methadone wasn't a diversion on these two drugs?
758 Mr. Botticelli. You know, clearly, and I think it would be
759 disingenuous to say that there is not a diversion issue,
760 particularly with buprenorphine. However, what we see when it
761 is done in a high-quality way, when it is done with sufficient
762 patient monitoring, that it is particularly effective in terms
763 of the work that we see.
764 Mr. Green. Okay. Mr. Chairman, finally, buprenorphine, I
765 think I can get that done.
766 Mr. Pitts. The chair thanks the gentleman and now
767 recognizes the gentleman from Indiana, Dr. Bucshon, 5 minutes for

768 questions.

769 Mr. Bucshon. Thanks, Mr. Chairman. As background, I was a

770 practicing cardiovascular surgeon for 15 years, and my wife is

771 an anesthesiologist so I have a little bit of experience

772 prescribing and seeing patients on these medications. And now

773 I kind of get my medical knowledge through my wife, and as an

774 anesthesiologist, when patients come to surgery these days, it

775 is amazing the number of people who are already on prescription

776 narcotics for a variety of reasons, it is just striking, as well

777 as others like benzodiazepines. But we are addressing the

778 opioids today.

779 The other thing is this does go across socioeconomic class;

780 it goes across ages. For example, the number one prescribed

781 medication under Medicare Part D is a prescription opioid pain

782 medicine. That is seniors. So this is really a problem we need

783 to address, and it really is something that I am really happy that

784 we have chosen to have this hearing, amongst many others today

785 and in the past and future.

786 But enhanced provider education is another priority for

787 reversing the current epidemic -- as a provider, I can say that

788 that is true -- by really reducing inappropriate prescriptions

789 of opioids. So what steps should be taken to strengthen

790 prescriber training and primary care, outpatient opioid

791 treatment, and methadone clinics for the use of non-opioid methods
792 of managing pain, and also non-opioid things like Vivitrol and
793 other medicines in the recovery of opioid addiction? Mr.
794 Botticelli, you can start that.
795 Mr. Botticelli. Maybe I will start, and I will let Dr. Frank
796 talk about HHS efforts in this domain. As the Congresswoman from
797 Indiana pointed out, a 2012 study by the CDC showed that we are
798 prescribing enough pain medication in the United States, not just
799 in Indiana, to give every adult American 75 pain pills. And while
800 we clearly want to make sure that pain is treated in the United
801 States, when you look back over the past 10 years, all of the
802 morbidity and mortality is directly correlated to the increase
803 in prescribing. So we know that giving people good education is
804 important. That is why we continue to pursue mandatory
805 prescriber education. And I will yield to Dr. Frank to talk about
806 HHS efforts in those domains.
807 Mr. Frank. Let me mention four things that we think are
808 important. First is continue bringing prescription drug
809 monitoring programs into the clinical world so that we can track
810 prescribing patterns as part of routine medical practice and can
811 do so across states and across settings. That is one thing.
812 Second thing is we are in the process of developing
813 guidelines for prescribing, particularly for non-cancer pain.

814 And we have accelerated that effort and should be putting those
815 guidelines out early next year. We have just had a set of public
816 meetings where we have rolled out some initial ideas and gotten
817 public feedback on it.

818 Third is we are engaging with a variety of medical societies
819 and specialty groups to find ways and to partner with them to up
820 the amount of training that is done within each of their
821 organizations. And then finally, for the second year in a row,
822 we have brought together the 50 States to compare best practices
823 for helping to improve prescribing and monitoring of
824 prescriptions.

825 Mr. Bucshon. And I think that is really important. I can
826 tell you in my own medical training in medical school and honestly
827 7 years of residency, I never had a specific month or week even
828 directed at how to manage pain, and that is a person who is a
829 surgeon. So we really learn how to manage pain almost on the go,
830 so to speak, and I think addressing that issue probably with
831 accrediting agencies that accredit medical school training or
832 residency training is another avenue.

833 But I can tell you, as a physician, it takes months or maybe
834 even years to understand how to manage pain, whether that is
835 nonsurgical, whether that is related to injury, and top that off
836 with managing people that already have significant issues with

837 using prescription medication and trying to manage their pain,
838 that we clearly need to address training, probably all the way
839 back to medical school moving forward, and that may take us a
840 generation to fix. So I yield back. Thank you.

841 Mr. Pitts. The chair thanks the gentleman and now the chair
842 recognizes the gentleman from North Carolina, Judge Butterfield,
843 5 minutes for questions.

844 Mr. Butterfield. Thank you very much, Chairman Pitts, and
845 thank the witnesses for your testimony today. Let's see. Where
846 do I start? All of you are right. All of my colleagues are right.
847 All of the witnesses are right. We have a crisis in this country,
848 and it is preventable, in my opinion. And so it is therefore
849 incumbent upon all of us to address the opiate epidemic that has
850 claimed too many, too many victims in my district and in your
851 districts and all across the country.

852 Opiate addiction doesn't discriminate. It does not
853 discriminate. Black, white, rich, or poor, anyone can succumb
854 to opiate addiction. And that presents a very difficult
855 challenge to finding ways to curb the epidemic. My home State of
856 North Carolina has seen a 300-percent death increase due to opiate
857 poisoning since 1999. Our emergency officials where I live in
858 Wilson, North Carolina, respond to overdose calls every other day
859 on average. In March, police in the city of Greenville, North

860 Carolina, responded to six heroin overdoses in a single day.

861 This is real. It is a real problem which reaches each and
862 every community in our country from the most urban to the most
863 rural and across every demographic. There is much that we can
864 and should do in response to this significant problem. Recently,
865 I received a letter from our attorney general, Mr. Roy Cooper,
866 and 37 other state Attorneys General urging Members to support
867 legislation to assist with recovery from opiate addiction. One
868 of the provisions important to my State included in that
869 legislation is funding to increase access to naloxone for first
870 responders. This drug is a lifesaving treatment which can
871 counteract some of the damages of narcotic overdoses.

872 And so I appreciate the convening of this hearing to consider
873 some of the policy options to combat this dangerous national
874 epidemic. While some of these pieces of legislation are steps
875 in the right direction, we must consider increasing access to
876 naloxone -- and I may be pronouncing that wrong -- for law
877 enforcement.

878 It is also clear that we cannot do this alone. The private
879 sector is a key stakeholder and is stepping up to the plate. From
880 abuse-deterrent formulations to injectable and implantable
881 treatments, the future of medicine can help reduce prescription
882 drug abuse and diversion.

883 But let me underscore the urgency of doing it now. From 2001
884 to 2013 there was a threefold increase in deaths from opiates,
885 and the doctors in the room, I appreciate you helping to put a
886 spotlight on this problem. There has been a threefold increase
887 in deaths from opiates. These are our nation's mothers and
888 fathers and sisters and brothers. This is a crisis. To Director
889 Botticelli, thank you for your testimony. Are abuse-deterrent
890 formulations having an impact here in the United States?
891 Mr. Botticelli. One of the areas that we continue to
892 evaluate is how abuse-deterrent formulations will diminish
893 people's use. I think we are continuing to work with FDA to look
894 at the evaluation strategies. But clearly, we know that this is
895 a prime strategy that we have been putting forth in our
896 Prescription Drug Abuse Plan to really look at the impact that
897 abuse-deterrent formulations will continue to play in reducing
898 prescription drug use issues.
899 I think as you discussed that abuse-deterrent formulations
900 are one part of a larger strategy that we have to employ in terms
901 of dealing with this issue. Clearly, we don't want people just
902 switching from one drug to another. We want to use that as an
903 opportunity to get people into care and treatment. So this is
904 obviously a prime part of our strategy, an important part of our
905 strategy, but it has to be linked to other things to ensure that

906 people get interventions and get good, high-quality care.

907 Mr. Butterfield. While I have your attention, let me talk
908 about manufacturers just for a moment. Can you describe whether
909 we should be doing more to encourage opiate manufacturers to
910 convert their medicines to abuse-deterrent formulations?

911 Mr. Botticelli. And I probably can't speak as eloquently
912 as the FDA can on this issue, but clearly, they have signaled their
913 strong preference for approving abuse-deterrent formulations as
914 part of their overall goal and work that they are doing. And
915 again, it has been clearly part of our overall prescription drug
916 abuse strategy to continue to promote abuse-deterrent
917 formulations.

918 Mr. Butterfield. Thank you. Now, I will go to my far right.
919 And we don't use that word, do we? All right. Go to the right.
920 All right. Deputy Administrator Riley, as a representative from
921 an area which has withstood some of the strongest storms in our
922 nation's history, I am concerned. I am interested in the Medical
923 Controlled Substances Transportation Act of 2015. I know you
924 recognize that. Can you describe whether this legislation would
925 increase access of potentially lifesaving treatments to those in
926 need in federally declared disaster areas?

927 Mr. Riley. Well, clearly, in situations unfortunately the
928 Carolinas are going through now --

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

929 Mr. Butterfield. Yes.

930 Mr. Riley. -- it is an important aspect. While I don't
931 know the specifics of the bill, I can tell you that we are working
932 with the committee on this. We recognize this is an issue that
933 really needs attention, and I give you my word we are going to
934 come to some agreement here. We can work it out.

935 Mr. Butterfield. Mr. Chairman, you have been very patient
936 with me. Thank you. I yield back.

937 Mr. Pitts. The chair thanks the gentleman and now
938 recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes
939 for questions.

940 Mr. Bilirakis. Thank you so much. I appreciate it.
941 Thanks for your testimony, panel. I have a question for Mr. Riley.
942 Recently, as many of you discussed in your testimonies, heroin
943 deaths have been increasing across the country at an alarming
944 rate, unfortunately. Both Pinellas and Hillsborough Counties in
945 Florida, which I represent -- I represent a portion of both of
946 those counties -- they have seen heroin deaths rise in some cases
947 by more than 700 percent over the course of a year. Unbelievable.
948 Mr. Riley, what can we do to best address not only how to control
949 the supply side of prescription drug abuse, but also address the
950 demand issue so that this population doesn't turn to illicit
951 drugs?

952 Mr. Riley. Thank you for the question, sir. Well, I think
953 you hit it on the head. While I have been in law enforcement for
954 30 years, I do recognize we cannot arrest our way out of this.
955 This is an issue that can be found in every corner of this country
956 in cities large and small, rural and urban. And we have got to
957 get everybody's help, from law enforcement to policymakers, to
958 educators, faith-based organizations, clearly treatment, and the
959 registrants that handle prescription drugs. So it is an
960 educational fight as much as it is I think a law enforcement fight.
961 Now, on the law enforcement side, I also have to tell you
962 we have never seen organized crime -- and I will use the Sinaloa
963 Cartel. We have never seen in my 30 years a criminal entity so
964 well financed, vicious, and willing to do anything to make a buck.
965 What keeps me up at night, sir, is the growing relationship between
966 American street gangs, urban street gangs, and the toxic business
967 relationship that they have formed with Mexican organized crime.
968 That in itself I think has fostered the spread of heroin across
969 the country.
970 Today's heroin is not what it was 5 years ago. It is cheaper,
971 it is more pure, it can be smoked and snorted. So it has really
972 attracted a completely different user base. So everybody in this
973 room plays a role in our success, and that is why I applaud this
974 committee for even bringing this up.

975 But I can tell you DEA around the world, working with our
976 partners, it is the number one priority. One of the things that
977 we are doing better, sir, that we haven't done before, is we are
978 communicating. The bad guys for years have counted on the cops
979 not sharing information, not sharing intelligence information.
980 We are doing that better now than we have ever done it, even with
981 our foreign counterparts.
982 I have spent quite a bit of time on the border and also in
983 Mexico. I have to tell you we have never seen the exchange of
984 information with the Mexican law enforcement authorities as good
985 as it is. Our ability to share information and for them to share
986 information back for domestic cases is at an all-time high. So
987 I am optimistic on the law enforcement front that we are moving
988 forward. But clearly, everybody has a piece of this.
989 Mr. Bilirakis. Thank you. That is good to know. Mr.
990 Botticelli, you mentioned a steep rise in the number of babies
991 born with neonatal abstinence syndrome. Counties within my
992 district were found to be suffering from some of the highest number
993 of babies born addicted to opiates in the country. What do you
994 see as the greatest obstacle to ensuring access to services, and
995 how can these challenges be addressed?
996 Mr. Botticelli. So, again, this is, I think, an opportunity
997 for us to work with Congress on additional issues, particularly

998 the Protecting Our Infants Act that was passed in the House, and
999 I think it is a really great opportunity to expand our efforts.
1000 So clearly we, you know, as you have indicated, have seen
1001 a dramatic increase in the rise of pregnant women and neonatal
1002 abstinence among babies who are born here in the United States.
1003 You know, obviously, our overall efforts to focus on reducing
1004 prescription drug misuse and heroin use play a big role, but also
1005 making sure that pregnant women have good access to care and
1006 treatment, we have effective medications, again, for the use in
1007 this and that moms have particularly good access to a wide variety
1008 of treatment services. So this becomes really important for us
1009 to look at this.
1010 We also want to ensure that we are not putting additional
1011 stigma on pregnant women in terms of their ability to seek care,
1012 and we hear that time and again. Dr. Frank talked about the role
1013 that stigma plays, but that is particularly true with pregnant
1014 women, and we don't want to do anything to further enhance that,
1015 particularly among pregnant women in terms of their ability to
1016 seek care.
1017 Mr. Bilirakis. Thank you, sir. Would you be willing to
1018 come to my district and participate in a roundtable on this
1019 particular issue?
1020 Mr. Botticelli. Absolutely. I --

1021 Mr. Bilirakis. I am in the Tampa Bay area.

1022 Mr. Botticelli. Great. I would be happy to do that. I

1023 have had the opportunity, as I have traveled, to talk and visit

1024 many neonatal intensive care units, had the opportunity to talk

1025 to practitioners. I think we have further work to do, and this

1026 is where we are looking forward to working with Congress on making

1027 sure that we have good standardized protocols for the treatment

1028 of pregnant women, that we have good surveillance. And so again,

1029 I think this is another area where administration priorities and

1030 congressional priorities are aligned.

1031 Mr. Bilirakis. Absolutely. Thank you very much. I yield

1032 back, Mr. Chairman.

1033 Mr. Pitts. The chair thanks the gentleman and now

1034 recognizes the gentleman from New Mexico, Mr. Lujan, 5 minutes

1035 for questions.

1036 Mr. Lujan. Thank you very much, Mr. Chairman. I appreciate

1037 this important hearing today. And, Mr. Chairman, my questions

1038 began with Dr. Frank. Looking specifically at the legislation that

1039 I have introduced, Assistant Secretary Frank, to see what we can

1040 do in, especially rural States like New Mexico, where it is hard

1041 to get to some of these areas and families are being separated

1042 because of the challenges of substance abuse, which is compounded

1043 by these distances and healthcare shortages, what are we doing

1044 to ensure that those in need of help are getting it? How do we
1045 make sure people don't have to wait 3 months to be able to get
1046 access to this care? And how do we make sure that rural
1047 communities are not left behind?
1048 Mr. Frank. Thank you for that question. As you probably
1049 know, Secretary Burwell, being from a rural area herself in West
1050 Virginia, where the opioid abuse and mortality rates are very
1051 high, is extraordinarily sensitive to these issues. And one of
1052 the things that is behind our new grant program putting $100
1053 million into community health centers to increase access to
1054 buprenorphine is to actually get more services, more people
1055 trained into the areas of high need and low availability. And
1056 so that is a major thrust of what we are doing there.
1057 The other is to sort of revisit our rulemaking on access to
1058 buprenorphine and other medication-assisted treatments so that
1059 we can increase the number of doctors, potentially increase the
1060 physician capacity to treat opioid use disorder.
1061 Mr. Lujan. And, Dr. Frank, can you quickly touch on the
1062 importance of how we should consider giving states flexibility
1063 when it comes to treatment programs? There is a program in a
1064 little community in my district in Espanola called Inside Out that
1065 talks about the length of time that it takes to get treatment.
1066 And many judges in New Mexico are requiring 6-month treatment

1067 programs. There aren't very many 6-month treatment programs, and
1068 the only ones available are if you get incarcerated. So we are
1069 spending money to put someone in jail and not putting that money
1070 into treatment for these individuals that are addicts.

1071 Mr. Frank. Yes, thank you for that question. Actually, I
1072 have been there, and I think that it is important. And in fact,
1073 the reason that we are using grant mechanisms is in part to allow
1074 us to kind of match the interventions and match the strategies
1075 to the local needs, and in particular, making sure that the patient
1076 is at the center of what we do, and their circumstances kind of
1077 dictate the way we put the treatment in place.

1078 Mr. Lujan. Inside Out also makes the important point, as
1079 we have talked about, naloxone or Narcan, that -- what can we
1080 do to make sure that that is readily available? It is about the
1081 safest substance, as we talk about these treatments, that someone
1082 can take. Is there a push or can Congress do something to make
1083 that available over-the-counter, as opposed to not being a
1084 prescription mechanism? Because of some of these addicts, you
1085 know, when there is an emergency or an issue, you have to go try
1086 to get a prescription. They need it then and now to save their
1087 lives. What are your thoughts, sir?

1088 Mr. Botticelli. As you indicated, increasing access to
1089 naloxone by anyone who is in a position to reverse an overdose

1090 has been a particularly important priority for us. We have been
1091 working with law enforcement across the country, have really been
1092 heartened to do that. We have been significantly heartened by
1093 the number of states, including New Mexico, that have passed
1094 naloxone distribution efforts.
1095 We are continuing to support, and will in the President's
1096 fiscal year 2016 budget, a naloxone purchase. SAMHSA sent out
1097 a letter to States saying that some of the existing grant
1098 structures can be used to support naloxone purchase. So that will
1099 continue to be a priority for us to look at how we increase the
1100 capacity for naloxone and look at supporting grant programs to
1101 look at increased naloxone purchase.
1102 Mr. Lujan. And, Mr. Riley, I am trying to do the math here.
1103 Everything that I read suggest that 90 percent of the poppies in
1104 the world are grown in Afghanistan, or the opioids are produced
1105 in Afghanistan. So that leaves 10 percent for the rest of the
1106 world, and it is grown in lots of places. Ninety percent of the
1107 heroin coming to the United States is attributed to Colombia and
1108 Mexico, with 50 percent going to one cartel. So am I to understand
1109 that with less than 10 percent production, or a fraction of that
1110 production, Mexico and Colombia are growing their own poppies that
1111 lead to 90 percent of heroin that is coming to the United States?
1112 Or is there opium coming from Afghanistan to Mexico and to Colombia

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1113 that is making its way to the United States? And if that is the
1114 case, how do we stop it?
1115 Mr. Riley. Well, I can tell you that the majority of the
1116 opium and heroin produced in the Afghanistan theater is destined
1117 for China, Russia, and Europe. We see as little as 5 percent in
1118 the United States. But clearly, between the Colombians' criminal
1119 organizations and the Mexican criminal organizations, they
1120 control virtually all of the heroin available across our country.
1121 And what are we doing to ensure that -- -I go back to the
1122 cooperation that we have, sharing intelligence information,
1123 making sure that we work on organizations. For us to be
1124 successful, we have to stop the street level, which leads to
1125 violence, but at the same time, we have to ensure that we follow
1126 those cases wherever they take us, whether it is into
1127 Central/South America, working with our counterparts overseas,
1128 our agents on the ground to stop it at the source, and at the same
1129 time, to go after the reason they are in business, and clearly
1130 that is the profit. And that is just as important a part of what
1131 we are doing. So are we getting better? I certainly feel we are,
1132 but as I said before, this is a marathon, not a sprint. We are
1133 in it for the long haul, but we need everybody's help.
1134 Mr. Pitts. The gentleman yields back. The chair
1135 recognizes the gentlelady, Mrs. Brooks, from Indiana, 5 minutes

1136 for questions.

1137 Mrs. Brooks. Thank you, Mr. Chairman. And thank you all

1138 for your work on this issue. Mr. Botticelli, as I mentioned in

1139 my opening and as you also talked about, we have an issue with

1140 respect to the prescribing practices beginning with medical

1141 school education, or not just with med schools because it is not

1142 just physicians who are prescribers, there are a whole category

1143 of healthcare providers who are prescribers.

1144 In ONDCP's 2011 report 4 years ago, it was epidemic,

1145 responding to America's prescription drug crisis, and one of the

1146 issues in that report was that we were going to encourage medical

1147 and health professional schools to continue expanding their

1148 continuing education programs to include instruction on measuring

1149 pain and prescribing to treat it. What efforts have been made

1150 since 2011, if not before, with our medical education schools?

1151 Because I talked to our med school in Indiana just a couple of

1152 months ago and still yet less than 5 hours, if even 3 hours, of

1153 education is dedicated to those who are prescribing. What is the

1154 resistance? Why are our medical education providers, not just

1155 for physicians, but for nurses and for nurse practitioners and

1156 others, what is the resistance, and why haven't we gotten that

1157 done?

1158 Mr. Botticelli. There are two issues that you and Dr.

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1159 Bucshon have articulated, and I think one is getting to the root
1160 cause about how do we make sure that healthcare providers, not
1161 just physicians but nurses, have embedded in their training
1162 programs good information on substance use disorders and safe
1163 prescribing? We have actually been working with the American
1164 Board of Addiction Medicine and all of the specialty medical
1165 societies and the AMA, as well as the deans of medical schools
1166 to look at embedding good medical education as part of --
1167 Mrs. Brooks. Okay.
1168 Mr. Botticelli. -- their curriculum.
1169 Mrs. Brooks. Excuse me for interrupting, but why hasn't it
1170 been done yet, when we have known for now a number of years this
1171 has been a problem? You all identified it at least in 2011, if
1172 not before. What is their resistance in embedding it in their
1173 curriculum this academic year? Why isn't it there yet?
1174 And what do we need to do with our State medical associations,
1175 with the medical school associations, and so forth, what do we
1176 need to do to get it embedded in education initially? Healthcare
1177 providers don't want to be helping cause the problem, but yet when
1178 they give a 30-day prescription for a pain med after a minor
1179 procedure when you might need 4 to 6 or 7 days -- I don't know,
1180 I'm no doctor -- why do we give 30 days of prescription? Why are
1181 the med schools resistant?

1182 Mr. Botticelli. Having been doing this for quite a while,
1183 I think there has been just an overall hesitancy and resistance
1184 to think about substance use disorders as part of someone's
1185 overall health conditions, and not seeing the impact of what we
1186 are seeing. You know, when we look at referrals to treatment,
1187 only 7 percent of referrals to treatment are coming from our
1188 healthcare providers. And I think we will continue to pursue
1189 opportunities not just to embed medical education but look at the
1190 testing requirements of those medical educations to make sure that
1191 we are having competencies as part of medical examinations.
1192 And this is why I think, you know, being into this epidemic
1193 why we have been calling at least for mandatory education. We
1194 have seen states -- about 10 States have passed medical education
1195 laws as it relates to pain prescribing, and we are seeing some
1196 remarkable results.
1197 Mrs. Brooks. Excellent. Could you please provide us with
1198 the list of which 10 States have done that? Because that is
1199 something that I would like to explore further.
1200 Mr. Botticelli. Happy to do that.
1201 Mrs. Brooks. Mr. Riley, I want to thank you for your many
1202 decades of service with the DEA. I am a former U.S. attorney from
1203 2001 to 2007. Crack cocaine was the epidemic of the day in the
1204 '80s, '90s, and early 2000s, but it has obviously shifted. And

1205 I am curious, because the synthetic drugs that are coming into
1206 this country, you said in your written testimony, is primarily
1207 from China. And while we have this unprecedented -- I am curious
1208 about the unprecedented cooperation with Mexico. Really? I
1209 would like to know a little bit more about why is it so much better
1210 now than it was 5 years ago? And how is China cooperating with
1211 us with respect to synthetics?

1212 Mr. Riley. Thank you, ma'am. In terms of China, we are
1213 beginning to make inroads there. It has been a tough road. Many
1214 of the synthetic drugs that are seized here are very difficult
1215 to origin, and that is by design. But we have made inroads. We
1216 have had several high-level meetings with the Chinese on this
1217 issue, dating back, I think, several years ago. So this is an
1218 ongoing dialogue.

1219 Part of our issue there, as it has been in Mexico, is to make
1220 sure both the Mexican authorities and the Chinese authorities
1221 understand the damage that it is doing in the United States. In
1222 terms of our Mexican partnerships, I was the agent in charge of
1223 El Paso in the mid-2000s when Juarez was aflame, thousands of
1224 drug-related homicides.

1225 We have really developed a working relationship with part
1226 of the Mexican authorities, not all of them, unfortunately. But
1227 we have developed a working relationship that is based off trust,

1228 that is based off productivity, and I think they understand the
1229 importance that they can play, in both their own country and around
1230 the world. Our extraditions continue to be strong. Just a couple
1231 of weeks ago we were able to pull out two very high-level targets
1232 that, I got to tell you, 5 years ago I don't think they would have
1233 even consider doing it.

1234 So it is an ongoing process, ma'am. It is what keeps me up
1235 at night. I am really 35 years old, but this is what it has done
1236 to me. And I give you my word, around the world, our guys 24/7
1237 are on it, because it truly is the new face of organized crime.

1238 Mrs. Brooks. Mr. Chairman, before I yield back, I just want
1239 to commend the agents of the DEA who I have worked with for quite
1240 some time, and they do remarkable work. There just aren't enough
1241 of them, and I don't think we give them all the tools they need.
1242 And with that, I yield back.

1243 Mr. Pitts. The chair thanks the gentlelady, and now
1244 recognizes the gentleman from Massachusetts, Mr. Kennedy, 5
1245 minutes for questions.

1246 Mr. Kennedy. Thank you, Mr. Chairman. Mr. Riley, a couple
1247 of questions to start with. Mrs. Brooks and Mr. Lujan touched
1248 a little bit on the origins of the opium trade and heroin trade
1249 internationally, and I was wondering if you could quantify, to
1250 the best of your ability, the total dollar figure, if you will,

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1251 between the U.S. and Mexico for heroin.

1252 Mr. Riley. Well, that is very difficult to do, but I can

1253 tell you it is in the billions.

1254 Mr. Kennedy. Order of magnitude? Just so -- and I don't

1255 mean to pin you down too much, but a billion, 10 billion, 100

1256 billion?

1257 Mr. Riley. Definitely close to 50 billion. And I quantify

1258 that by saying just in Chicago, where I was the agent in charge

1259 and heroin has exploded in the last several years, it was billions

1260 of dollars when we really drilled down on it. And I think that

1261 is what is really important. And if you look at new England in

1262 particular, you are seeing this spread of violent organized crime,

1263 urban, in terms of street gangs, and their ability to interface

1264 almost as unwitting contractors with Mexican organized crime to

1265 put heroin on the street, to make it available and obviously

1266 causing violence. I mean, the way these organizations regulate

1267 themselves, sir, is with the barrel of a gun. And I think it has

1268 caused tremendous damage across the country.

1269 Mr. Kennedy. And, Mr. Riley, thank you, and thank you for

1270 your service. I want to touch on two other things. I just

1271 commend you briefly for bringing back, first off, the take-back

1272 days, and one day back on April 26 of 2014 Massachusetts residents

1273 alone, in a single day, dropped off nearly 23,000 pounds of drugs.

1274 And I believe nationally the figure was 390 tons in a single day.
1275 I think they are a tremendous asset for our country, and I
1276 appreciate you bringing them back.
1277 I also want to thank you for your work with New England around
1278 the HIDTA designation, the high-intensity drug trafficking area.
1279 It has helped with critical resources for law enforcement in the
1280 region, and I want to thank you and commend you for that.
1281 Mr. Frank, I wanted to touch base with you a little bit if
1282 I can somewhat briefly, my apologies. There are three
1283 FDA-approved medications for treatment of opioid dependence:
1284 methadone, buprenorphine, and naltrexone. I am interested in
1285 learning a little bit more from you about methadone, if you will.
1286 So could you describe a little bit about how methadone is used
1287 to treat individuals with opiate dependence?
1288 Mr. Frank. So methadone is a very powerful drug. It is a
1289 controlled substance. It is provided in a very controlled
1290 setting, so-called OTP, opioid treatment programs, that are very
1291 comprehensive. They provide the dose in person on the day. They
1292 provide counseling, they provide drug testing, they provide
1293 patient monitoring. And I think I said earlier that the reason
1294 that this is done is because the dosing and the management of
1295 methadone, particularly at the beginning of a treatment episode,
1296 must be done very carefully or risk mortality.

1297 Mr. Kennedy. And there are special restrictions on the
1298 ability to prescribe methadone?
1299 Mr. Frank. Yes, there is.
1300 Mr. Kennedy. And what are they, briefly, if you can?
1301 Mr. Frank. They have to be done within those programs, those
1302 certified programs.
1303 Mr. Kennedy. And are those requirements applied to
1304 treatment of individuals with opiate dependence with naltrexone
1305 or buprenorphine, or is the regulatory schema different?
1306 Mr. Frank. Yes, the regulatory schemes are quite different.
1307 The naltrexone sort of operates under the rules of DATA 2000 and
1308 -- did I say naltrexone? I meant buprenorphine. And
1309 naltrexone is not a controlled substance, and so it can be
1310 prescribed by any physician.
1311 Mr. Kennedy. And is there a medical rationale to separate
1312 the way that those drugs are actually regulated?
1313 Mr. Frank. I think there is. As I said, I think there are
1314 unique risks, in, particularly, the early stages of methadone
1315 treatment. Buprenorphine, as we have noted, is a drug that is
1316 a controlled substance, and there is diversion of that drug. And
1317 because naltrexone is not a controlled substance, it can be more
1318 broadly prescribed. So I think there is a logic to it.
1319 Mr. Kennedy. So if I could squeeze one last question in

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1320 here, do you think -- does that separation of that different
1321 regulatory environment make sense, or do you think bringing it
1322 all together and putting it under one -- basically abolishing
1323 the stovepipe regulations there makes sense, or is there rationale
1324 for keeping them separate?
1325 Mr. Frank. I think that even if you brought them together,
1326 you would see many of the same restrictions in place. I think
1327 that what we are trying to do is to particularly focus on
1328 buprenorphine right now, because I think that is an opportunity
1329 we have to rethink those rules so that we can expand access to
1330 MAT.
1331 Mr. Kennedy. Thank you very much, sir.
1332 Thank you, Mr. Chairman. I yield back.
1333 Mr. Pitts. The chair thanks the gentleman. Because Dr.
1334 Murphy is chairing a hearing downstairs, Mr. Guthrie is yielding
1335 him his 5 minutes. Dr. Murphy, you are recognized.
1336 Mr. Murphy. Thank you, Mr. Chairman. I appreciate that.
1337 I wanted to be here because, although downstairs we are having
1338 a hearing on Volkswagen and devices put in cars that affect
1339 emissions testing, this is a life-and-death matter, so I wanted
1340 to be here.
1341 The first thing I wanted to ask, Mr. Chairman, I ask unanimous
1342 consent that this letter, signed by multiple members of the Energy

1343 and Commerce Committee, be submitted into the record. It was sent

1344 today to HHS and calls for a comprehensive review and additional

1345 rules on buprenorphine providers before HHS unilaterally lifts

1346 the DATA provider cap.

1347 Mr. Pitts. Without objection, so ordered.

1348 [The information follows:]

1349

1350 ********** COMMITTEE INSERT 11 **********

1351 Mr. Murphy. Thank you.

1352 Now, I just want to make sure none of you are physicians,

1353 none of you are people who are involved in the treatment of people

1354 with addiction disorders. Am I correct?

1355 Mr. Botticelli. [Nonverbal response.]

1356 Mr. Frank. [Nonverbal response.]

1357 Mr. Riley. [Nonverbal response.]

1358 Mr. Murphy. Okay. But you are involved with policymaking

1359 on these issues, correct?

1360 Mr. Botticelli. [Nonverbal response.]

1361 Mr. Frank. [Nonverbal response.]

1362 Mr. Riley. [Nonverbal response.]

1363 Mr. Murphy. Okay. I am a psychologist. I have dealt with

1364 people with addiction disorders. And I want to start off by

1365 saying one of the problems we have in this country is that money

1366 that is sent to states that is being used for mental health funding

1367 for block grants and substance abuse block grants are not allowed

1368 to be used together. The serious problem that comes with that

1369 is many people with substance abuse disorders also have mental

1370 health disorders,, and yet we create a barrier there.

1371 Now, we are talking about increasing the number of

1372 prescriptions a physician can write. Dr. Frank, do you know how

1373 many -- so we are talking about someone going from like 30 or

1374 so a month, a week, a day? What is it? Up to -- -

1375 Mr. Frank. Thirty patients at any one time.

1376 Mr. Murphy. Up to 100, and they can potentially go beyond

1377 that. Do you see a maximum with that?

1378 Mr. Frank. Right now, there is a limit to 100 after a year.

1379 Mr. Murphy. Right, but after that, they are looking to do

1380 more, to lift that cap, right?

1381 Mr. Frank. We are in the process of sort of reviewing the

1382 best way to expand access, and we are going to do it very

1383 cautiously.

1384 Mr. Murphy. I understand that. To what number?

1385 Mr. Frank. We don't have a number yet.

1386 Mr. Murphy. Okay. Now, throughout this process -- and

1387 you recognize that buprenorphine is the third-most diverted drug.

1388 That is people get it and they sell it, and they make money and

1389 then they will go out and buy heroin or something else. What

1390 attention is being given to make sure that doesn't happen?

1391 Mr. Frank. That is exactly why we are taking a careful

1392 approach, because of that concern. But let me give you an

1393 additional concern. So we want to expand access. We are

1394 concerned that too often you don't get the full package of

1395 services, the counseling, the supports, and in the testing and

1396 monitoring, and so we want to make sure that the evidence-based

1397 package is in place and that the risks of diversion are minimized.
1398 And so what we are trying to do is to collect evidence about where
1399 are the places, and under what conditions are you most likely to
1400 be able to significantly expand capacity while minimizing the
1401 risks of diversion, and maximizing the probability that
1402 evidence-based treatment will be provided.
1403 Mr. Murphy. So let me ask about some of those. How much
1404 time do you think the average amount of time is that one of the
1405 physicians who is prescribing will actually be face to face with
1406 a patient?
1407 Mr. Frank. I think that --
1408 Mr. Murphy. Well, let me put it this way: is that something
1409 that will be assessed?
1410 Mr. Frank. Yes. Well, we want to consider sort of what it
1411 takes and what are the environments that get you combination of
1412 treatments, so that means you have to have the counseling, you
1413 have to have the -- -
1414 Mr. Murphy. Right. Well, let me go into just a couple
1415 things. I talked to one clinic and they said the average amount
1416 of time physicians may spend actually discussing and prescribing
1417 is about one and a half minutes. Now, during that amount of time,
1418 you have to assess those very things. Is this a diversion issue?
1419 Is the person in recovery? Are they seeing a counselor or

1420 therapist? Are they really engaged in treatment?

1421 And also then in many of these cases the person who is perhaps

1422 the addictions counselor does not even communicate with the

1423 physician, except maybe to write a note in the chart in treatment.

1424 Or they may have someone there in some places where it is a nurse

1425 or someone sitting in the waiting room, and while people are there

1426 waiting for their prescription, they have a chat and they write

1427 that down as group therapy. You are aware that some of these

1428 things take place. Knowing you, I would assume you would be as

1429 distressed as anyone to say that is not tolerable, that is not

1430 treatment. And such people not only should not have expanded

1431 prescription privileges, they should have zero.

1432 Mr. Frank. I completely share your concerns, but even more

1433 importantly, Secretary Burwell shares those concerns.

1434 Mr. Murphy. Yes, she does.

1435 Mr. Frank. And she has emphasized sort of a careful approach

1436 to make sure that both the evidence-based treatment and the risk

1437 of diversion are addressed carefully.

1438 Mr. Murphy. One more final thing in my final seconds here,

1439 I know Secretary Burwell is dedicated to this, too, but I am also

1440 concerned that the amount of training that these physicians get,

1441 deal with addictions, is minimal. Very few of them are actually

1442 addictions counselors, addiction trainers, and many times other

1443 people there have minimal training.

1444 In my area of southwestern Pennsylvania I have heard
1445 proctologists, plastic surgeons, pediatricians, and others who
1446 do not have extensive board certification in these things. I
1447 think it is a dangerous issue for something that is growing as
1448 a deadly issue in America. And I hope we can continue our
1449 conversation. I want to work with you on this, but we are all
1450 concerned that just expanding the number of prescriptions can be
1451 written without total assurances of other things is a dangerous
1452 issue. Thank you. And I yield back.

1453 Mr. Frank. And we thank you for your support and agree.

1454 Mr. Pitts. The chair thanks the gentleman and now
1455 recognizes the gentleman from Maryland, Mr. Sarbanes, 5 minutes
1456 for questions.

1457 Mr. Sarbanes. Thank you, Mr. Chairman. I want to thank all
1458 of you for being here today. I have introduced the Co-Prescribing
1459 to Reduce Overdoses Act, which would create a demonstration
1460 project to encourage co-prescribing opioid overdose reversal
1461 drugs like naloxone.

1462 So let me talk a little bit about the need first, which you
1463 all are very familiar with. Over 100 Americans every day are
1464 dying from preventable drug overdose, and that kind of fatality
1465 is now the leading cause, the leading cause of accidental death

1466 in the country. In 2013, more than 16,000 people died due to
1467 prescription opioids overdose, and an additional 8,000 died from
1468 heroin overdose. In Maryland, we are having the same experience.
1469 We had 192 heroin overdoses in the City of Baltimore, in Anne
1470 Arundel County, which I also represent. There were 49 fatal
1471 overdoses from opioids, and that was part of 360 overdoses overall
1472 that occurred.
1473 So this is an epidemic. There is no question about it. And
1474 we have to put real resources behind it. We have to put it behind
1475 workable and strategic solutions that we can identify. I will
1476 mention that, today, the State of Maryland released a $680,000
1477 grant from the U.S. Department of Justice to help address this
1478 epidemic in our State.
1479 Let me talk about naloxone now. It is a drug that safely
1480 and effectively reverses both opioid and heroin-induced overdoses
1481 if administered in time. It has been used by nonmedical personnel
1482 with only minimal training for over 15 years and has been proven
1483 to reduce lower overdose mortality by almost 50 percent. More
1484 people need access to lifesaving medication, obviously.
1485 And while efforts to distribute naloxone to first responders
1486 and community organizations are important, and we have talked
1487 about that today, it is critical that we also take a more proactive
1488 approach. One idea, one part of that proactive approach is the

1489 idea of co-prescribing naloxone to patients who are taking opioids
1490 and are at high risk of overdose. And this is supported by the
1491 American Society of Addiction Medicine, the American Medical
1492 Association, the Veterans Health Administration.
1493 The bill that I have introduced, the Co-Prescribing to Reduce
1494 Overdoses Act, would create a demonstration project for federally
1495 qualified health centers, opioid treatment centers, and other
1496 providers to encourage co-prescribing naloxone. Funds could be
1497 used for training to purchase opioid overdose reversal drugs, to
1498 offset copays, and to conduct community outreach and raise
1499 awareness to connect patients who have experienced a drug overdose
1500 with appropriate treatment, and track individuals that are
1501 participating in the program. And all grant recipients, of
1502 course, would be required to evaluate the outcomes of the program.
1503 A second program would allow States or local health
1504 departments to develop guidelines on co-prescribing opioid
1505 overdose reversal drugs like naloxone. So there is no question
1506 that opioid overdose is a public health epidemic. I believe
1507 strongly that increased access to naloxone, particularly this
1508 co-prescribing opportunity to patients at high risk of overdose,
1509 is a key element of any approach to successfully decrease
1510 prescription drug and heroin overdoses.
1511 I would like to get the thoughts of the three members of the

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1512 panel, certainly Mr. Botticelli and Dr. Frank, on this question
1513 of whether co-prescribing naloxone is an effective strategy that
1514 we should try to encourage and support going forward.
1515 Mr. Botticelli. Thank you for your leadership on this
1516 issue. I don't think we could agree with you more in terms of
1517 the opportunities that we have for supporting co-prescribing in
1518 a wide variety of settings, and particularly for people who are
1519 at highest risk.
1520 We share your goals. We have actually continued to take
1521 action to support co-prescribing. We have hosted webinars with
1522 the American College of Emergency Rooms Physicians to support
1523 co-prescribing. We continue to work with our treatment programs
1524 to encourage co-prescribing. So this is, I think, a particularly
1525 important area for people who are at high risk.
1526 Our overall policy goals are to ensure that anyone who is
1527 at high risk for an overdose also has access to naloxone. It has
1528 been truly remarkable in terms of its ability to save lives and
1529 actually motivate many people to go seek care and treatment. So
1530 we would love to continue to work on that to look at that
1531 legislation.
1532 Mr. Sarbanes. Dr. Frank, I have 15 seconds if you have a
1533 comment. Yes.
1534 Mr. Frank. Yes. I obviously am not going to say what he

1535 said, but there are some things that you need to do to go along
1536 with co-prescribing and other measures to really expand supply
1537 here, and one of them is making sure that we have user-friendly
1538 versions of naloxone so that non-medically trained people can
1539 administer it. Two, I think we need to make sure that once
1540 somebody gets naloxone, they get the treatment. Just recovering
1541 and walking away isn't the right thing to do. We have to get them
1542 to see --
1543 Mr. Sarbanes. No, it is the first step is what you are
1544 saying.
1545 Mr. Frank. It is the first step, and it is an important first
1546 step -- -
1547 Mr. Sarbanes. Yes.
1548 Mr. Frank. -- but we would like to complement that with
1549 links to treatment.
1550 Mr. Sarbanes. Great. Thank you. I yield back.
1551 Mr. Pitts. The chair thanks the gentleman. The chair
1552 recognizes Mr. Lance 5 minutes for questions.
1553 Mr. Lance. Thank you, and good morning to the panel. And,
1554 Mr. Riley, did you say you are 35 years old? Is that what you
1555 said?
1556 Mr. Riley. Yes.
1557 Mr. Lance. Yes, I am 35 as well, but what keeps me up at

1558 night is leadership elections. You discussed challenges in
1559 carrying out a criminal prosecution pursuant to the Federal
1560 Analogue Act. It is my understanding that there is a very high
1561 burden of proof to establish that a compound is in fact a
1562 controlled substance analogue. Could you please elaborate on
1563 that standard and what changes can be made to the Analogue Act
1564 that would make it more effective as a tool in combating the spread
1565 of synthetic drugs?
1566 Mr. Riley. Well, first of all, just the mere amount of these
1567 synthetic drugs that we are encountering is mind-boggling, and
1568 our ability to test those through our scientific arm and get an
1569 identifier on them sometimes is very prolonged. So what we are
1570 doing now is we are really trying to look at how can we be
1571 effective? What is the best possible way that we can move this
1572 process along? But I have got to be honest with you. We are not
1573 one step behind the bad guys, we are three steps behind the bad
1574 guys.
1575 Mr. Lance. Thank you. Is there anyone else on the
1576 distinguished panel who would like to comment on this?
1577 Mr. Botticelli. I completely agree. I think it has been
1578 a challenge from both a prevention standpoint and a scientific
1579 standpoint to stay ahead of the chemical tweaks that manufacturers
1580 make to do that. I think that opportunities to lower the burden

1581 of proof around scheduling, around these analogues are important.
1582 I think despite Congress and state best attempts to deal with this
1583 issue, that look at expediting the scheduling and thinking about
1584 the criteria with which we schedule those drugs is particularly
1585 important.
1586 Mr. Lance. Thank you. Director Botticelli, as you
1587 mentioned in your testimony, New Jersey, where I live, is one of
1588 a handful of States that requires greater use by prescribers of
1589 the State's Prescription Drug Monitoring Program. Specifically,
1590 Governor Christie recently signed into law a requirement for
1591 prescribers to check the program and patients returned for a
1592 second resale on a prescription opiate. What is your office doing
1593 to ensure that both State officials and prescribers are able to
1594 utilize effectively their Prescription Drug Monitoring Programs?
1595 Mr. Botticelli. So I will start, and I know that this is
1596 an important initiative for the Secretary, too, so there is more
1597 action.
1598 Mr. Lance. Certainly.
1599 Mr. Botticelli. When this Administration started, we had
1600 20 PDMP programs, 20 states. Today, I am happy to report that
1601 we have 49 States that have Prescription Drug Monitoring Programs.
1602 We continue to focus opportunities on increasing the interstate
1603 operability so that we can share information across state lines

1604 but also increase the utility and usability of these programs.
1605 And I will defer to Dr. Frank on that.
1606 But one of the things that I think we are seeing promising
1607 practice, and particularly in States that require some level of
1608 mandatory check of their Prescription Drug Monitoring Program,
1609 we are seeing a decrease -- in Florida, we saw a significant
1610 decrease in overdose deaths, and we have seen a significant
1611 decrease in doctor-shopping, people going from one doctor to
1612 another to get their medications when we have good, robust
1613 Prescription Drug Monitoring Programs.
1614 Mr. Lance. Thank you. Dr. Frank?
1615 Mr. Frank. Thank you. This here, we are investing $20
1616 million in State grants really to focus on improving Prescription
1617 Drug Monitoring Programs in the States. We have a proposal in
1618 for 2016 to put in 45 million in order to bring it to all 50 states.
1619 And we are hoping to build off the progress of some very successful
1620 pilots in addition that have integrated Prescription Drug
1621 Monitoring Programs in clinical health information technology.
1622 Mr. Lance. Thank you very much. And, Mr. Chairman, I yield
1623 back the balance of my time.
1624 Mr. Pitts. The chair thanks the gentleman and now
1625 recognizes the gentleman from New York, Mr. Engel, 5 minutes for
1626 questions.

1627 Mr. Engel. Thank you, Mr. Chairman. You know, gentlemen,
1628 first of all, thank you all for excellent testimony. Really, all
1629 of you have just been terrific. And, you know, through my perch
1630 on the Foreign Affairs Committee when I was chairman of what we
1631 called the Western Hemisphere Committee, which dealt with Latin
1632 America, and we did a lot of work involving the drug trade in Mexico
1633 and some of the other places. And we fund money for treatment
1634 programs and we fund a lot of money to go after the bad guys, but
1635 so much of the consumption comes from us that I have always felt
1636 that we didn't do enough in terms of education, and in terms of
1637 that side of it rather than going after the bad guys after they
1638 have done it.

1639 And the one thing that is stark for me is that there are so
1640 many people in this country that use drugs. I mean it is just
1641 mind-boggling. And young people, because when you are young, you
1642 think you are going to live forever and you think nothing is going
1643 to happen to you and so you are more likely to experiment, but
1644 this is an epidemic. I mean, this is just beyond the pale. You
1645 know, I don't make judgments on anybody, but I just know that we
1646 can't continue like this. I mean, we have got to do a better job
1647 of educating people and letting them understand that this is a
1648 life-ruining situation.

1649 And you have really driven the point home, all three of you,

1650 about it. I mean I have some other questions to ask, but in
1651 general, I think, you know, if you could expand on that because
1652 it is really just shocking, the extent of the abuse. And so not
1653 only are we keeping these criminal enterprises going, but we are
1654 destroying lives of American citizens.
1655 Mr. Botticelli. I will start. Thank you, Congressman, for
1656 your comments. I think, yes, what you have described is the
1657 entire approach, the Obama Administration's view of drug policy
1658 that, while supply reduction and law enforcement has a big role
1659 to play, that we need and will continue to pay more attention to
1660 prevention, treatment, and recovery efforts for people here in
1661 the United States. If you look at our entire drug control budget,
1662 we are actually spending now more on those public health
1663 strategies than we have had during the entire time of our office,
1664 so this is particularly important.
1665 I will say, however, that I think our heroin situation is
1666 a good example between the nexus of supply and demand, that because
1667 of the purity levels, because of the price, because of the
1668 widespread availability of heroin that we have, it really does
1669 combine both a public health and public safety approach. And I
1670 have really been heartened, as I travel around the country, to
1671 see law enforcement and police wanting to partner with public
1672 health to really come up with holistic strategies, knowing that

1673 arrest and incarceration are really ineffective in dealing with
1674 this issue.
1675 Mr. Engel. You know, every time I see a young person smoke
1676 a cigarette, a regular cigarette, I think to myself, you know,
1677 why are they doing this? Because we have evidence now that we
1678 didn't have maybe when I was a kid that regular smoke just is
1679 terrible for your health. And you think, well, why would a young
1680 person do that? We are not getting through. And of course when
1681 you take it a notch up and you are talking about heroin or
1682 prescription drugs, it is that much worse. So we are failing as
1683 a society, and it is just shocking.
1684 So let me ask you, Dr. Frank. The bill proposed by
1685 Congresswoman Brooks and Congressman Kennedy tasks an interagency
1686 coalition with developing best prescribing practices, and it is
1687 certainly needed. My district -- New York's Lower Hudson
1688 Valley contains a portion of my district, and according to the
1689 New York State Office of Alcoholism and Substance Abuse Services,
1690 the number of New Yorkers admitted to hospitals on account of
1691 heroin skyrocketed 136 percent between 2004 and 2013, and in 2013
1692 alone, nearly 90,000 New Yorkers were admitted to hospitals for
1693 heroin and prescription opioid. This is shocking. It is
1694 absolutely, absolutely shocking.
1695 So given how varied the populations affected by this epidemic

1696 are, how would you, Dr. Frank, suggest that we ensure that any
1697 best practices created as a result of this bill or other bills
1698 will suit physicians and patients from contrasting backgrounds?
1699 You know, I worry about a one-size-fits-all approach. Do we need
1700 to tailor best practices to different populations?
1701 Mr. Frank. Thanks for that question. Our approach is very
1702 much aimed at two things. One is matching policies to context,
1703 locally, but also matching patients to actual treatments, and we
1704 want to do both. And so, for example, just a couple weeks ago
1705 we had a 50-State convening where we brought all the States
1706 together, all 50 states and the District of Columbia together,
1707 to talk about how to share best practices.
1708 And what we did is we had breakout sessions where we had
1709 regional breakouts, so in fact people who bordered one another
1710 could talk about sort of common approaches that met their
1711 particular circumstances. Likewise, we try to have a full
1712 armamentarium of treatments available so that we can match
1713 patients and their circumstances in the best possible way, and
1714 our mechanism for doing this is largely grant support through the
1715 States.
1716 Mr. Engel. Thank you. Thank you all. And, Mr. Riley,
1717 thank you for all you do.
1718 Mr. Pitts. The chair thanks the gentleman. The gentleman

1719 yields back. Without objection, the chair recognizes Mr. Tonko,
1720 a member of the full committee, who wishes to ask questions for
1721 5 minutes.
1722 Mr. Tonko. Thank you, Mr. Chair. As I mentioned in my
1723 opening statement, access to effective addiction treatment is the
1724 biggest obstacle we face today in preventing more deaths in this
1725 epidemic. We know that nearly 80 percent of persons with an
1726 opioid addiction do not receive treatment. While the reasons for
1727 these gaps are multifaceted, it is clear that capacity in our
1728 current treatment system play some role.
1729 A study published recently in the American Journal for Public
1730 Health estimated a gap between treatment need and treatment
1731 capacity between 1.3 and 1.4 million individuals in the year 2012.
1732 This is why I joined with my colleagues in introducing the TREAT
1733 Act, which would raise the arbitrary cap on buprenorphine
1734 prescribing for certain providers and allow physician assistants
1735 and a nurse practitioners the ability to be waivered providers.
1736 As such, I was very encouraged by Secretary Burwell's
1737 announcement to start the rulemaking process to address opioid
1738 addiction and specifically addressed treatment hurdles such as
1739 the DATA 2000 caps. Dr. Frank, what is the expected time line
1740 and process for this rulemaking change?
1741 Mr. Frank. You are not going to like this answer, but we

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1742 are going to move as fast as we can. But I can guarantee you that
1743 this is extraordinarily high on my office's agenda and the
1744 Secretary's agenda, and literally, we are meeting every week to
1745 kind of get this pushed through.
1746 Mr. Tonko. Thank you. And, Director Botticelli, we have
1747 heard a number of concerns expressed today over the diversion of
1748 buprenorphine. Is that the most commonly diverted opioid?
1749 Mr. Botticelli. I will defer to my DEA partners on this in
1750 terms of diversion. I would suspect that probably pharmaceutical
1751 opioids are far more diverted than --
1752 Mr. Tonko. Pharmaceutical?
1753 Mr. Botticelli. -- buprenorphine diversion.
1754 Mr. Tonko. Okay. And what actions does the Administration
1755 recommend to address that diversion?
1756 Mr. Botticelli. Part of, I think, what we need to look at
1757 -- and I have to be careful not to get ahead of the HHS rulemaking
1758 authority here- - but I think that looking at how we can continue
1759 to support access to buprenorphine and other medications but also
1760 being mindful of ensuring quality treatment and minimizing
1761 diversion become really important. And I think you have heard
1762 a willingness on the part of the Administration to work with
1763 Congress on how do we strike that balance as we move forward,
1764 thinking about how many people who can prescribe, what is the

1765 quality care setting that we can do it. I have seen models across
1766 this country where we have been able to expand the number of people
1767 who get access to medications through a wide variety of, I think,
1768 really innovative state practice. And I think we can use some
1769 of that thinking and some of that guidance to help with the process
1770 about how we go forward.
1771 Mr. Tonko. Let me ask you, Director Botticelli, why do you
1772 think we make it so much harder for individuals to get the
1773 treatments that help them recover than the drugs that get people
1774 addicted in the first place?
1775 Mr. Botticelli. I think there is a wide variety of -- you
1776 know, both as a person in recovery and as someone who has been
1777 doing this for a long time, I think stigma plays a huge role. And
1778 I think, quite honestly, that we had viewed people with addictive
1779 disorders and their families as less deserving of care, and I think
1780 for a long time public policy has reflected that. And I think
1781 now with the opioid epidemic I think we are finally understanding
1782 some of the long-standing issues that we have had in this country
1783 as it relates to how we have treated people with addictive
1784 disorders. I think that is why our jails and prisons, quite
1785 honestly, unfortunately, our de facto treatment programs, that
1786 we viewed people with addictive behaviors as morally flawed or
1787 bad people. And I don't think we have seen them as deserving as

1788 a response, as people with a disease.

1789 Mr. Tonko. Well, I think all of you gave powerful testimony,

1790 and it reminds us that we need to see addiction as a disease. And

1791 until we do, we won't get the results we require. And finally,

1792 Director, does the Administration support mandatory prescriber

1793 education on pain management and substance use, prior to an

1794 individual being able to prescribe controlled substances?

1795 Mr. Botticelli. We do and we look forward to working with

1796 Congress in terms of how we might make that happen.

1797 Mr. Tonko. And there are things that Congress can do to help

1798 with that effort?

1799 Mr. Botticelli. Absolutely.

1800 Mr. Tonko. And you will direct us?

1801 Mr. Botticelli. And we look forward to working with you on

1802 that.

1803 Mr. Tonko. Absolutely. I thank you all again for your

1804 testimony. It, I think, was very instructive. And with that,

1805 Mr. Chair, I will yield back the balance of my time.

1806 Mr. Pitts. The chair thanks the gentleman. That concludes

1807 the questioning of members present. We have had members going

1808 in and out all morning because we have another hearing on Energy

1809 and Commerce being conducted downstairs, so apologize for that.

1810 But I want to thank the first panel of witnesses. This is

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1811 a very important issue and we look forward to working with each

1812 of you as we proceed on the legislation. And we will have some

1813 follow-up questions, so we will send those to you in writing. We

1814 ask that you please respond promptly. I remind members that they

1815 have 10 business days to submit questions for the record. Members

1816 should submit their questions by the close of business on

1817 Thursday, October 22. I have a U.C. request, a statement for the

1818 record, on behalf of the Opioid Treatment Program Consortium.

1819 Without objection, so ordered.

1820 [The information follows:]

1821

1822 ********** COMMITTEE INSERT 12 **********

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1823 Mr. Pitts. The subcommittee will stand in recess until the
1824 week of October 20 when we will convene our second panel on this
1825 issue.
1826 The subcommittee stands in recess.
1827 [Additional materials follow:]
1828
1829 ********** INSERT 13 **********
1830 [Whereupon, at 12:03 p.m., the subcommittee was adjourned.]