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6 FEDERAL EFFORTS TO COMBAT OPIOID CRISIS: A
7 STATUS UPDATE ON CARA AND OTHER INITIATIVES
8 WEDNESDAY, OCTOBER 25, 2017
9 House of Representatives
10 Committee on Energy and Commerce
11 Washington, D.C.

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15 The committee met, pursuant to call, at 10:00 a.m., in Room
16 2123 Rayburn House Office Building, Hon. Greg Walden [chairman
17 of the committee] presiding.

18 Members present: Representatives Walden, Barton, Upton,
19 Shimkus, Burgess, Blackburn, Latta, McMorris Rodgers, Harper,
20 Lance, Guthrie, Olson, McKinley, Kinzinger, Griffith, Bilirakis,
21 Johnson, Bucshon, Flores, Brooks, Mullin, Hudson, Collins,
22 Cramer, Walberg, Walters, Costello, Carter, Duncan, Pallone,
23 Eshoo, Engel, Green, DeGette, Doyle, Schakowsky, Butterfield,
24 Matsui, Castor, Sarbanes, McNerney, Welch, Lujan, Tonko,
25 Loeb sack, Schrader, Kennedy, Cardenas, Ruiz, Peters, and Dingell.

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26 Staff present: Jennifer Barblan, Chief Counsel, Oversight
27 and Investigations; Ray Baum, Staff Director; Mike Bloomquist,
28 Deputy Staff Director; Adam Buckalew, Professional Staff Member,
29 Health; Karen Christian, General Counsel; Kelly Collins, Staff
30 Assistant; Zachary Dareshori, Staff Assistant; Jordan Davis,
31 Director of Policy and External Affairs; Paul Edattel, Chief
32 Counsel, Health; Adam Fromm, Director of Outreach and Coalitions;
33 Caleb Graff, Professional Staff Member, Health; Jay Gulshen,
34 Legislative Clerk, Health; Brittany Havens, Professional Staff,
35 Oversight and Investigations; Zach Hunter, Director of
36 Communications; Peter Kielty, Deputy General Counsel; Alex
37 Miller, Video Production Aide and Press Assistant; Christopher
38 Santini, Counsel, Oversight and Investigations; Kristen
39 Shatynski, Professional Staff Member, Health; Jennifer Sherman,
40 Press Secretary; Alan Slobodin, Chief Investigative Counsel,
41 Oversight and Investigations; Danielle Steele, Counsel;
42 Christina Calce, Minority Counsel; Jeff Carroll, Minority Staff
43 Director; Waverly Gordon, Minority Health Counsel; Tiffany
44 Guarascio, Minority Deputy Staff Director and Chief Health
45 Advisor; Chris Knauer, Minority Oversight Staff Director; Jourdan
46 Lewis, Minority Staff Assistant; Miles Lichtman, Minority Policy
47 Analyst; Jessica Martinez, Minority Outreach and Member Services
48 Coordinator; Kevin McAloon, Minority Professional Staff Member;
49 Tim Robinson, Minority Chief Counsel; Samantha Satchell, Minority
50 Policy Analyst; Andrew Souvall, Minority Director of

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51 Communications, Outreach and Member Services; and Kimberlee
52 Trzeciak, Minority Senior Health Policy Advisor.

53 The Chairman. If our members and guests would take their
54 seats, it is 10 o'clock. We want to get started on time. I want
55 to thank our witnesses for being here. Before I start, I
56 especially want to thank the head of the FDA, Dr. Gottlieb. I
57 think we are going to have to give you an office you have been
58 here so much this week, the third or fourth time, and we really
59 appreciate your cooperation with our committee and your
60 assistance in this and many other matters.

61 Okay, I will call to order the Energy and Commerce Committee.
62 This is, I think, our first full committee on a matter and I
63 think it points to the concerns we have about this issue as a
64 committee and as a country.

65 Each day, more than a thousand people are treated in
66 emergency rooms for misusing prescription opioids. Each day,
67 91 Americans die from an opioid overdose. In last year alone,
68 opioid overdoses have claimed the lives of more Americans than
69 the entire Vietnam War. In my home state of Oregon, more people
70 died last year from drug overdoses than from car accidents.

71 We hear these statistics over and over again at roundtables
72 throughout my district, most recently in Grants Pass in Southern
73 Oregon and Bend in Central Oregon. I have heard the stories of
74 Oregonians, put names and faces to these data points. Addiction
75 and overdoses are happening at alarming rates in every community
76 in our nation. Just scan the headlines on any given day and you
77 will hear about a life destroyed by addiction or about a raid

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78 that seized obscene quantities of prescription painkillers or
79 illicit drugs.

80 The United States is in the midst of a crisis that has become
81 a national emergency. The number of individuals dying from
82 opioid overdoses has reached epidemic proportions and even more
83 individuals with substance use disorders have become estranged
84 from their families, they are unable to work, or living as shells
85 of their former selves because of their addiction. It is truly
86 heartbreaking.

87 To respond to this growing epidemic, the Energy and Commerce
88 Committee has held countless conversations and numerous hearings
89 with experts and stakeholders, law enforcement, individuals in
90 recovery, and family members of opioid abuse victims in order
91 to improve the prevention and treatment of this terrible
92 addiction.

93 From the earliest hearings before our Oversight and
94 Investigation Subcommittee to legislative solutions tested in
95 our Health Subcommittee, our multiyear, multi-Congress findings
96 have led to bills that are now law, namely the Comprehensive
97 Addiction and Recovery Act known as CARA, and the 21st Century
98 Cures Act.

99 This year, this committee has initiated multiple bipartisan
100 investigations into allegations of pill dumping in West Virginia
101 and patient brokering schemes elsewhere in the country. We have
102 held hearings on the growing threat of fentanyl, innovative ideas

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103 in the States, we have heard directly from more than 50 members
104 of Congress both on and off this committee just 2 weeks ago, but
105 more work needs to be done and we must redouble our efforts to
106 combat the growing crisis.

107 The primary purpose of this hearing is to hear from the
108 federal agencies charged with implementing the provisions of CARA
109 and the 21st Century Cures Act and we appreciate you all being
110 here, but it also allows this committee to have an important
111 conversation with the DEA, first, to discuss recent news reports
112 that suggested a bipartisan bill that passed through this
113 committee and signed into law by President Obama has negatively
114 impacted the DEA's ability to combat the opioid crisis. Second,
115 we are looking for some long overdue answers to basic questions
116 and requests for data that this committee has made to the DEA
117 related to our ongoing investigation into alleged pill dumping
118 in the state of West Virginia.

119 I am going to be very blunt. My patience is wearing thin.
120 Our requests for data from DEA are met with delay, excuses and,
121 frankly, inadequate response. People are dying, lives and
122 families are ruined. It is time for DEA to get to this committee
123 the information we need and to do it quickly. No more dodges,
124 no more delays. We look forward to finally hearing directly from
125 DEA on these matters. In addition to the DEA, we will be hearing
126 testimony from officials at the Food and Drug Administration,
127 the Substance Abuse and Mental Health Services Administration,

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128 the Centers for Disease Control and Prevention, and the National
129 Institute on Drug Abuse at the National Institutes of Health.

130 It is our hope that today's testimony will allow us all to
131 learn more about the government's shared efforts to address this
132 crisis, allowing us the opportunity to drill deeper to learn about
133 what is working and what is not working. It is our job to always
134 do that oversight and fix problems. We will also have an
135 opportunity to discuss how we can better prevent lawful
136 prescription use from spiraling into abuse and, more importantly,
137 we will discuss what more we can do to reduce overdoses and save
138 lives.

139 To the witnesses before us today, consider this another call
140 to action. We need your help as we pursue both our investigative
141 and our legislative work. It is imperative we confront this
142 problem from every side and it is crucial that everyone remembers
143 we are on the same team. This crisis requires an
144 all-hands-on-deck response.

145 We all want to end this scourge but we must be willing to
146 work together. From the most basic requests for data to crafting
147 and implementing laws, the lines of communication must be open.

148 If there are changes we need to make in the law, please tell
149 us. We have a duty to our constituents and the American people
150 to combat the epidemic from all angles. Everyone has a stake
151 in this fight.

152 And with that I yield back the balance of my time and I

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153 recognize my friend from New Jersey, the ranking member of the
154 committee, Mr. Pallone, for an opening statement. Mr. Pallone.

155 Thank you, Mr. Chairman, for calling today's hearing. It
156 provides the opportunity to hear from several agencies within
157 the Department of Health and Human Services as well as the Drug
158 Enforcement Administration about the opioid abuse epidemic and
159 the status of federal efforts to combat the crisis, including
160 the implementation of CARA and 21st Century Cures.

161 While I am pleased to hear from the witnesses before us today,
162 I am disappointed that you did not invite the Centers for Medicare
163 and Medicaid Services or CMS. Most people access substance abuse
164 treatment through their health insurance coverage and it is a
165 fundamental link and one without the other leaves the millions
166 of people of all ages that struggle with this addiction out in
167 the cold.

168 Between Medicare, Medicaid, CHIP, and the ACA marketplace,
169 it is well over a third of the population receives health insurance
170 through the programs that CMS oversees. Medicaid alone is the
171 single largest payor for behavioral health services in the U.S.

172 Put simply, a full and appropriate review of this issue requires
173 the presence of CMS.

174 Unfortunately, we all are too familiar with the tragic
175 consequences of the opioid crisis. Ninety one Americans lose
176 their lives to opioid overdose every day and millions more are
177 battling this chronic and potentially deadly health condition.

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178 No community is immune. I know that like me each member here
179 today has heard far too many tragic stories about lives cut short,
180 families torn apart, and people left with few places to turn as
181 they struggle to find treatment.

182 In New Jersey, more than 1,900 people died from opioids last
183 year. The crisis has taken such a toll in my community that we
184 are hearing cries for help from some unlikely places. Earlier
185 this year, Peter Kulbacki, the owner of the Brunswick Memorial
186 Funeral Home in East Brunswick, New Jersey, published a blog on
187 the funeral home's website expressing his frustration with the
188 monthly calls he receives telling him that someone has passed
189 away from an opioid overdose.

190 I would like to share a brief excerpt from his blog because
191 I think it helps capture the true toll of this epidemic on
192 families, and I quote, I am witness to the parents left with
193 inexplicable grief. I am witness to the spouses left to carry
194 the emotional and economic burden of raising a family alone.
195 I am witness to the children who are left wondering why, and
196 experiences like this reinforce the need for federal action to
197 address this crisis.

198 I am happy that last year we were able to work together on
199 a bipartisan basis to pass CARA and 21st Century Cures. These
200 laws are expanding access to treatment and recovery support
201 services as well as advancing efforts to prevent the misuse and
202 abuse of opioids. For example, New Jersey is using the \$13

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203 million it received as part of the larger CURES law to expand
204 treatment and support services, invest in primary and secondary
205 prevention and training. Through CARA we also took steps to
206 reduce the amount of opioids in circulation by permitting for
207 the partial fill of controlled substance subscriptions and
208 supporting the expansion of drug disposal sites for unwanted
209 prescriptions.

210 These were positive steps in the right direction, but
211 committee Democrats have repeatedly stated that they were never
212 enough and, sadly, the growing epidemic proves that today. These
213 laws were a down payment on the types of efforts and increased
214 funding that Congress must support to respond and eventually end
215 this epidemic.

216 In addition to supporting positive bipartisan laws and
217 increase funding for substance abuse initiatives, Republicans
218 must end their pursuit of taking away health coverage for millions
219 of Americans. This is the very thing that ensures people can
220 actually access treatment. Republicans have spent all year
221 sabotaging the Affordable Care Act and attempting to gut the
222 Medicaid program by more than \$800 billion.

223 This week, House Republicans including most on this
224 committee will support a budget that includes these cuts and more.

225 If successful, these actions by Republicans would have an
226 immediate and harsh impact on those struggling with addictions
227 and I will continue to fight these efforts. Advancing

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228 efforts to respond to this crisis also means Congress has a
229 responsibility to figure out what went wrong, how it went wrong,
230 and how to make sure something like this never happens again.

231 That is why this committee is conducting a bipartisan
232 investigation into the role drug distributors may have played
233 in the ongoing opioid crisis and what systems failed to protect
234 communities.

235 The committee has sent a number of letters to several
236 distributors and DEA requesting information about drug
237 distribution practices including the amount of opioids shipped
238 into certain communities. Unfortunately, however, up to this
239 point we have had difficulty getting answers from DEA. In fact,
240 I asked a number of follow-up questions to DEA following a
241 committee hearing in March about opioid distribution in rural
242 West Virginia.

243 After 6 months, DEA just last night sent us the responses
244 to these questions. Of course there are also still many questions
245 in our letters to DEA that remain unanswered and DEA has pledged
246 its cooperation to work with the committee. So I hope, moving
247 forward, they can help us determine what systems failed in West
248 Virginia and what needs to be done to make sure other communities
249 are protected from such abusive practices.

250 So it is clear, Mr. Chairman, the nation is in crisis and
251 Congress must do more to address the opioid epidemic. And I thank
252 you and yield back. The Chairman. The gentleman yields back.

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253 We now go to our witnesses. Full committee hearing, only The
254 Chairman and the ranking member give opening statements just for
255 our committee's benefit, so now we go to our witnesses. We want
256 to thank you all for being here today and taking time to testify
257 before the committee. Each witness will have the opportunity
258 to give an opening statement followed by a round of questions
259 from members.

260 So today we will hear from Dr. Elinore McCance-Katz,
261 assistant secretary for Mental Health and Substance Abuse and
262 Mental Health Services Administration, easily known as SAMHSA;
263 Dr. Anne Schuchat, principal deputy director, Centers for Disease
264 Control and Prevention at CDC; Dr. Nora Volkow, I believe -- is
265 it Volkow? -- who is the director of National Institute on Drug
266 Abuse, NIDA, at National Institutes of Health, NIH; and Dr. Scott
267 Gottlieb, commissioner of Food and Drug Administration, FDA; and
268 Mr. Neil Doherty, deputy assistant administrator, Office of
269 Diversion Control, Drug Enforcement Administration.

270 We appreciate you being here today and we look forward to
271 your testimony. We will start at this end of the table with the
272 gentleman who has been here at least one other time this week
273 and maybe more.

274 Dr. Gottlieb, thank you for your work with our committee.

275 We greatly value your work there and at FDA and we look forward
276 to hearing your testimony this morning on this matter, sir.

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277 STATEMENTS OF SCOTT GOTTLIEB, M.D., COMMISSIONER, FOOD AND DRUG
278 ADMINISTRATION; ELINORE MCCANCE-KATZ, M.D., ASSISTANT SECRETARY
279 FOR MENTAL HEALTH AND SUBSTANCE USE, SUBSTANCE ABUSE AND MENTAL
280 HEALTH SERVICES ADMINISTRATION; ANNE SCHUCHAT, M.D., PRINCIPAL
281 DEPUTY DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; NORA
282 VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE,
283 NATIONALS INSTITUTES OF HEALTH; AND, NEIL DOHERTY, DEPUTY
284 ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG
285 ENFORCEMENT ADMINISTRATION.

286

287 STATEMENT OF SCOTT GOTTLIEB

288 Dr. Gottlieb. Thank you, Chairman Walden, Ranking Member
289 Pallone. Thank you for the opportunity to testify today before
290 the committee. The epidemic of opioid addiction that is
291 devastating our nation is the biggest crisis facing public health
292 officials, FDA included. As this crisis grew many of us didn't
293 recognize the consequence of this threat. In the past we missed
294 opportunities to stem its spread so we find ourselves at a tragic
295 crossroad.

296 We have a crisis of such massive proportion that the actions
297 we need to take are going to be hard. We will need to touch
298 clinical practice in ways that may make certain parties
299 uncomfortable. This may include steps such as restrictions on
300 prescribing or mandatory education on providers. Long ago we
301 ran out of straightforward options.

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302 At FDA we are working across the full scope of our regulatory
303 obligations to impact this crisis. That means updating and
304 extending the risk management plans and educational requirements
305 that we impose on sponsors as a condition of a product's approval.

306 It means doubling our efforts to promote the development of new,
307 less addictive pain remedies as well as opioids that are harder
308 to manipulate and abuse. It means updating our risk benefit
309 framework to take measure of the risks associated with misuse
310 and abuse of opioids and using this information to inform our
311 decisions, including recommending that products be withdrawn from
312 the market.

313 These steps and others are needed to prevent new addiction,
314 but given the scale of this epidemic with millions of Americans
315 already affected, prevention is not enough. We must also help
316 those who are suffering from addiction by expanding access to
317 lifesaving treatment. I would like to announce three new steps
318 today towards this goal.

319 First, FDA will issue guidance for product developers as
320 a way to promote the development of new addiction treatments.

321 As part of this guidance we will clearly lay out our interest
322 in the development and use of novel, non-abstinence-based
323 endpoints as part of product development. We also want to make
324 it easier to develop new products that address the full range
325 of symptoms of addiction such as craving.

326 Second, FDA will take steps to promote more widespread use

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327 of existing, safe and effective, FDA-approved therapies to help
328 combat addiction. There are several FDA-approved treatments.

329 All of these treatments work in combination with counseling and
330 psychological support. Everyone who seeks treatment deserves
331 the opportunity to be offered all three options as a way to allow
332 patients and providers to select the treatment best suited to
333 the needs of each individual patient.

334 Unfortunately, far too few people who are addicted to opioids
335 are offered an adequate chance for treatment that uses
336 medications. In part, this is because insurance coverage for
337 treatment with medications is often inadequate. To tackle the
338 treatment gap, FDA plans to convene experts to discuss the
339 evidence of treatment benefits at the population level such as
340 studies that show community-wide reductions in overdose following
341 expansion of access to therapy.

342 There is a wealth of information supporting the use of these
343 medications. We are focusing on the data and the drug labeling
344 that can help drive broader appropriate prescribing, so one
345 concept that FDA is actively pursuing is the research necessary
346 to support a label indication for medication-assisted treatment
347 for everyone who presents with an overdose based on data showing
348 a reduction in death at a broader population level. Such an
349 effort would be a first for FDA. We believe that granting such
350 an indication can help promote more widespread use of and coverage
351 for these treatments.

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352 A common question that arises with treatment is the proper
353 duration of medical therapy. Clinical evidence shows that people
354 may need treatment with medications for long periods of time to
355 achieve a sustained recovery. Some may even need a lifetime of
356 treatment. Recognizing this, FDA is revising the labels of these
357 medical products to reflect this fact.

358 Now I know all this may make some people uncomfortable.
359 That is why the third step I am announcing today is that FDA will
360 join efforts to break the stigma associated with medications used
361 for addiction treatment. This means taking a more active role
362 in speaking about the proper use of these drugs. It is part of
363 our existing public health mandate to promote the appropriate
364 use of medicine.

365 Misunderstanding around the profile of these products
366 enables stigma to attach to their use. This stigma serves to
367 keep many Americans who are seeking a life of sobriety from
368 reaching their goal. In this case, in the setting of a public
369 health crisis, we need to take a more active role in challenging
370 these conventions around medical therapy. This stigma reflects
371 a view some have that a patient is still suffering from addiction
372 even when they are in full recovery just because they require
373 medication to treat their illness. This attitude reveals
374 a flawed interpretation of science. It stems from a key
375 misunderstanding that many of us have about the difference between
376 a physical dependence and an addiction. Because of the biology

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377 of the human body, everyone who uses opioids for any length of
378 time develops a physical dependence, meaning there are withdrawal
379 symptoms after the use stops. Even a cancer patient requiring
380 long-term treatment for the adequate treatment of metastatic pain
381 develops a physical dependence to the opioid medication. That
382 is very different than being addicted.

383 Addiction requires the continued use of opioid despite the
384 harmful consequences. Addiction involves a psychological
385 craving above and beyond a physical dependence. Someone who
386 neglects his family, has trouble holding a job, or commits crimes
387 to obtain the opioids has an addiction. But someone who is
388 physically dependent on opioid as a result of the treatment of
389 pain but is not craving more or harming themselves or others is
390 not addicted.

391 The same principle applies to medications used to treat
392 opioid addiction. Someone who requires long-term treatment for
393 opioid addiction with medication including those that cause a
394 physical dependence is not addicted to those medications. Here
395 is the bottom line. We should not consider people who hold jobs,
396 re-engage with their families, and regain control over their lives
397 through treatment that uses medications to be addicted.

398 Committee members, we need to embrace long-term treatment
399 with proven therapies to address this crisis. At FDA we will
400 step up our efforts to do our part to promote these goals. I
401 look forward to discussing these issues with the committee and

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402 appreciate the opportunity to be hear today.

403 The Chairman. Dr. Gottlieb, thank you for your testimony
404 and your good work at FDA.

405 We will now go to Dr. Elinore McCance-Katz, assistant
406 secretary for Mental Health and Substance Use, Substance Abuse
407 and Mental Health Services Administration, SAMHSA.

408 Dr. McCance-Katz, thank you for being here today, please
409 go ahead with your opening statement.

410 STATEMENT OF ELINORE MCCANCE-KATZ

411

412 Dr. McCance-Katz. Thank you. Chairman Walden, Ranking
413 Member Pallone, and members of the House Energy and Commerce
414 Committee, thank you for inviting me to testify at this important
415 hearing. I am honored to testify today along with my colleagues
416 from the Department of Health and Human Services and the Drug
417 Enforcement Administration on federal efforts to combat the
418 opioid crisis, a status update on CARA, and other initiatives.

419 Over the past 15 years, communities across our nation have
420 been devastated by increasing prescription and illicit opioid
421 abuse, addiction, and overdose. In 2016, over 11 million
422 Americans misused prescription opioids, nearly one million used
423 heroin, and 2.1 million had an opioid use disorder due to
424 prescription opioids or heroin. Most alarming are the continued
425 increases in overdose deaths, especially the rapid increase in
426 deaths involving illicitly made fentanyl and other highly potent
427 synthetic opioids since 2013.

428 The Trump administration is committed to bringing everything
429 the federal government has to bear on this health crisis. HHS
430 is implementing five specific strategies that are guiding our
431 response.

432 The comprehensive, evidence-based strategy aims to improve
433 access to treatment and recovery services to prevent the health,
434 social, and economic consequences associated with opioid

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435 addiction and to enable individuals to achieve long-term
436 recovery; to target the availability and distribution of these
437 drugs and ensure the broad provision of overdose-reversing drugs
438 to save lives; to strengthen public health data reporting and
439 collection to improve the timeliness and specificity of data and
440 to inform a real-time public health response as the epidemic
441 evolves; to support cutting edge research that advances our
442 understanding of pain and addiction and leads to the development
443 of new treatments and identifies effective public health
444 interventions to reduce opioid related health harms; and to
445 advance the practice of pain management to enable access to high
446 quality, evidence-based pain care that reduces the burden of pain
447 for individuals, families, and society while also reducing the
448 inappropriate use of opioids and opioid-related harms.

449 HHS appreciates Congress' dedication to this issue as
450 evidenced by passage of the 21st Century Cures Act and the
451 Comprehensive Addiction and Recovery Act. In my role as
452 Assistant Secretary for Mental Health and Substance Use at HHS,
453 I lead the Substance Abuse and Mental Health Services
454 Administration. I appreciate the opportunity to share with you
455 a portion of SAMHSA's portfolio of activities in alignment with
456 HHS's five strategies and how SAMHSA is implementing CARA and
457 the 21st Century Cures Act.

458 SAMHSA is administering the Opioid State Targeted Response
459 grants program created by the 21st Century Cures Act. By

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460 providing \$485 million to states in fiscal year 2017, this program
461 is increasing access to treatment, reducing unmet treatment need,
462 and reducing opioid overdose-related deaths through the provision
463 of prevention, treatment, and recovery services. HHS is working
464 to ensure the future funding allocations and policies are as
465 clinically sound and evidence-based, effective, and efficient
466 as they can be.

467 SAMHSA has several initiatives aimed at advancing the
468 utilization of medication-assisted treatment for opioid use
469 disorder. For example, in the past 4 years, more than 62,000
470 medical professionals have participated in online or in-person
471 SAMHSA-funded trainings on medication-assisted treatment for
472 opioid use disorders. SAMHSA regulates opioid treatment
473 programs and provides waivers to providers that prescribe
474 buprenorphine. Last year, SAMHSA published a final rule allowing
475 qualified physicians to obtain a waiver to treat up to 275
476 patients. SAMHSA has also implemented the CARA provision that
477 allows nurse practitioners and physician assistants to prescribe
478 buprenorphine.

479 SAMHSA has been actively implementing new initiatives to
480 address the opioid crisis made possible by CARA. In September,
481 SAMHSA awarded \$4.6 million over 3 years in the Building
482 Communities of Recovery grant program created by CARA. Last
483 month, SAMHSA also awarded \$9.8 million over 3 years for new State
484 Pilot Pregnant and Postpartum Women grants authorized by the CARA

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485 act and \$49 million over 5 years in new service grants to help
486 pregnant and postpartum women and their children.

487 SAMHSA has been a leader in efforts to reduce overdose deaths
488 by increasing the availability and use of naloxone to reverse
489 overdose. SAMHSA is currently providing grants to prevent opioid
490 overdose related deaths which are being used to train first
491 responders as well as to purchase and distribute naloxone. In
492 September, SAMHSA awarded additional grants authorized by CARA
493 including almost \$46 million over 5 years to grantees in 22 states
494 to provide naloxone and related resources to first responders
495 and treatment providers. SAMHSA's National Survey on Drug Use
496 and Health provides key national and state level data and is a
497 vital part of the surveillance effort related to opioids.

498 Thank you again for the opportunity to share with you our
499 work to combat the opioid epidemic and I look forward to answering
500 any questions you may have.

501 The Chairman. Thank you very much. We appreciate your
502 testimony. We are going to stay on the healthcare side of this
503 and go to Dr. Anne Schuchat now, the principal deputy director,
504 Centers for Disease Control and Prevention, CDC.

505 Dr. Schuchat, thank you very much for being here and the
506 good work you do. Please go ahead with your statement. You might
507 pull the microphones a little closer. Thank you.

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508 STATEMENT OF ANNE SCHUCHAT

509

510 Dr. Schuchat. Good morning Chairman Walden, Ranking Member
511 Pallone, and members of the committee. CDC has vast experience
512 in defending Americans against epidemics and I appreciate the
513 opportunity to be here today to speak about the issues surrounding
514 the opioid crisis facing our nation. CDC's expertise as the
515 nation's public health and prevention agency is essential in
516 reversing the opioid overdose epidemic. CDC is focused on
517 preventing people from becoming addicted in the first place.
518 CDC has the unique role of leading prevention by addressing opioid
519 prescribing, tracking trends, and driving community-based
520 prevention activities.

521 America's opioid overdose epidemic affects people from every
522 community and it is one of the few public health problems that
523 is getting worse instead of better. Drug overdoses have
524 dramatically increased, nearly tripling over the last 2 decades.

525 The opioid overdose crisis has led to a number of other problems
526 including increases in babies born withdrawing from narcotics
527 and a drop in life expectancy for the first time since the AIDS
528 epidemic in 1993. But today's overdose fatalities are just the
529 tip of the iceberg.

530 [Chart.]

531 Dr. Schuchat. For every one person who dies of an opioid
532 overdose, over 60 more are already addicted to prescription

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533 opioids. Almost 400 misuse them, and nearly 3,000 have taken
534 one. Using a comprehensive approach as outlined in the HHS
535 priorities, we will work together to stop this epidemic.

536 CDC has been on the front lines since the beginning. Over
537 a decade ago, after hearing alarming news from medical examiners
538 about increases in overdose deaths and after an outbreak
539 investigation in North Carolina, CDC scientists made the
540 connection to prescription opioids. Today, we are working
541 closely with state health departments and providing guidance on
542 best practices so states can rapidly adapt as we learn what works
543 best in this evolving epidemic.

544 CDC now funds 45 states and Washington, D.C., to advance
545 prevention in key areas at the community level including improving
546 prescription drug monitoring programs, improving prescribing
547 practices, and evaluating policies. In Kentucky, prompts were
548 added to the prescription drug monitoring program to alert to
549 high doses, which resulted in a 25 percent reduction in opioid
550 prescribing to youth. Illinois has expanded efforts to integrate
551 patient health information into their prescription drug
552 monitoring programs improving the completeness of data available
553 to prescribers and leading to much greater PDMP use.

554 These are just a few examples of the great work being done.
555 These are the kind of improvements that can literally save lives.
556 CDC is also leading improvements to the public health data we
557 rely on to understand the crisis. We are now releasing

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558 preliminary overdose death data and have improved reporting
559 significantly from a lag of 2 years down to a lag of 7 months.

560 As part of our funding to states, we are ramping up efforts
561 to get more reliable and timely data from emergency rooms, medical
562 examiners, and coroners through our enhanced surveillance
563 program. For the first time, we are tracking non-fatal opioid
564 overdoses so that we have a better understanding of the changing
565 epidemic so that states can respond accordingly.

566 This is the value of nimble public health. States call on
567 CDC to provide on-the-ground assistance when they experience an
568 opioid-related crisis. We helped Massachusetts identify that
569 a surge in opioid deaths was caused by fentanyl and we assisted
570 Indiana to identify and contain an HIV and hepatitis C outbreak
571 related to injections of prescription opioids.

572 We truly appreciate the support we received from this
573 committee for our guideline for prescribing opioids for chronic
574 pain which we released last March 2016. Now we are focused on
575 making the guideline easy for clinicians to implement through
576 interactive trainings, mobile apps, and other ways. We are also
577 focusing on patients and their families. Just last month, CDC
578 released Rx Awareness, a communication campaign aimed to raise
579 awareness about the risk of prescription opioids. The campaign
580 features real-life stories like the one you described, accounts
581 of individuals living in recovery, and those who have lost someone
582 to an overdose.

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583 CDC's unique approach to surveillance and prevention will
584 be key in reducing the opioid epidemic. We continue to be
585 committed to the comprehensive priorities outlined in the HHS
586 strategy and to saving the lives of those touched by this epidemic.

587 Thank you.

588 The Chairman. Thank you, Doctor. We appreciate your
589 testimony. Now we go to Dr. Nora Volkow, director, National
590 Institutes on Drug Abuse in the National Institutes of Health.

591 Doctor, thank you for being with us as well, please go ahead
592 with your opening statement. Well, you need to push the little
593 button there. There you go.

594 STATEMENT OF NORA VOLKOW

595

596 Dr. Volkow. So good morning, everybody. Chairman Walden,
597 Ranking Member Pallone, and distinguished members of the
598 committee, I am extremely grateful for your support and commitment
599 to addressing the opioid crisis and for having me here along with
600 my colleagues to actually try to integrate our efforts. You have
601 already heard about the devastating scope of the opioid epidemic.

602 Today, I would like to discuss how science is helping us address
603 this crisis.

604 The story of a patient named Jeff illustrates the impact
605 research can make in the lives of those suffering from addiction.

606 Jeff developed a heroin use disorder after returning from serving
607 in the war in Afghanistan. He ended up homeless in the streets
608 of Seattle and eventually sought treatment. NIDA-funded
609 researchers at the VA in Seattle enrolled him a pilot
610 buprenorphine treatment program. Unlike traditional treatment
611 programs with long waiting lists, Jeff was started right away
612 on oral buprenorphine which immediately helped him stop using
613 heroin. The treatment helped Jeff recover. He has not used
614 heroin since for several months, he is no longer homeless, and
615 now has a regular job.

616 Unfortunately, Jeff's story is not typical. Most people
617 who suffer from an opioid addiction do not receive treatment and
618 when they do it is frequently not evidence-based. Jeff's story

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619 illustrates how implementing research findings can significantly
620 improve treatment outcomes.

621 Addiction is a brain disease that is associated with
622 disruption of brain sequence that make it progressively more
623 difficult to stop using drugs even at the risk of losing one's
624 own life. When people suffering from addictions seek help, we
625 owe it to them and their families to provide the treatments that
626 research has proven most effective.

627 Thanks in part to NIDA support there are now three
628 FDA-approved medications for opioid use disorders:
629 buprenorphine, methadone, naltrexone. While significantly
630 improving outcomes, these medications are vastly underutilized
631 and relapse rates are still too high. Thus, more research is
632 needed to develop new treatments so we can reduce relapse rates
633 in all patients.

634 NIDA has a successful record of partnering with industry
635 to develop new treatments. For example, NIDA and the FDA partner
636 with Lightlake and other pharma to develop a user-friendly
637 naloxone. Anyone can use this and it will deliver very rapidly,
638 very high concentrations of naloxone into the bloodstream which
639 is what you need in order to reverse an overdose. This product
640 which was done in partnership with pharmaceutical, as I mentioned,
641 was taken from concept into a product in basically 3 years. So
642 we can do it.

643 In the face of this opioid crisis, NIH wants to expand on

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644 these alliances and is working on establishing a public-private
645 partnership in collaboration with the FDA, academic research
646 centers, and the pharmaceutical industry that will focus on two
647 major goals: Goal number one, to develop effective non-addictive
648 pain medications to prevent Americans from developing opioid use
649 disorders while providing them relief from the pain condition
650 that they suffer.

651 The second goal is to expand medication options to treat
652 opioid addictions and to prevent and reverse overdoses. A
653 short-term focus will be the development of new formulations of
654 existing medications to facilitate compliance and the treatment
655 of hard-to-reach populations. Weekly and monthly depot
656 formulations of buprenorphine have already been submitted to FDA
657 approval. It would be a real gamechanger especially for people
658 who live in rural communities and face significant logistical
659 challenges accessing treatment. Other research is building on
660 our growing understanding of the neurobiology of addiction to
661 identify potential targets for treating it. This includes not
662 only medications, but also known pharmacological therapies
663 including vaccines.

664 In parallel and in collaboration with SAMHSA, we are
665 expanding services and implementation research to develop new
666 strategies for delivery of addiction treatment across healthcare
667 and criminal justice settings. An example is a story that
668 recently showed that initiating buprenorphine in the emergency

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669 room to help ensure people will prevent them from overdoses and
670 effectively engage them in ongoing treatment.

671 We have an urgent crisis and as stated by the Chairman, an
672 all-hands-on-deck approach is needed to solve it. NIH and NIDA
673 are fully committed to integrate our efforts with those from other
674 federal agencies, industry, community organizations, patients
675 and their families, and Congress to solve it. Thanks very much.

676 [The prepared statement of Dr. Gottlieb, Dr. McCance-Katz,
677 Dr. Schuchat, Dr. Volkow and Mr. Doherty follows:]

678

679 *****INSERT 1*****

680 The Chairman. Thank you, Doctor.

681 And now our final witness, Mr. Neil Doherty, deputy assistant
682 administrator, Office of Diversion Control, Drug Enforcement
683 Administration. We appreciate your being here as well.

684 Mr. Doherty, please go ahead with your opening statement.

685 STATEMENT OF NEIL DOHERTY

686

687 Mr. Doherty. Chairman Walden, Ranking Member Pallone, and
688 distinguished members of the committee, thank you for holding
689 this hearing today to discuss the opioid epidemic and DEA's
690 response to this ongoing threat. For DEA, the opioid is the top
691 drug threat facing our nation. This unprecedented epidemic
692 includes not only prescription opioids otherwise known as
693 controlled prescription drugs, or CPDs, but also the
694 proliferation of heroin and fentanyl trafficking, ultimately
695 leading to record levels of overdose deaths.

696 I believe that all of us at this table are collectively making
697 progress on CPDs, but I fear we are witnessing a fundamental shift
698 towards cheaper, easier to obtain heroin and fentanyl. With
699 illicitly produced fentanyl you have substances up to 50 times
700 more potent than heroin, sold as heroin, mixed with heroin, and
701 increasingly and often with a fatal result, pressed into pill
702 form by criminal networks as counterfeit prescription
703 painkillers. Of the estimated 64,000 Americans who overdosed
704 in 2016, 54 percent died of an opioid overdose. That is one life
705 taken every 15 minutes. Mexican cartels are continuing to
706 exploit the opioid use epidemic and are continuing to produce
707 and transport heroin across the Southwest border. These cartels
708 are aggressively purchasing illicitly produced fentanyl from
709 China, shipping it into Mexico, mixing it with heroin and other

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710 substances, pressing it into pill form, and shipping it into the
711 U.S. through established distribution networks.

712 What is the motivation behind the often deadly tactics
713 employed by the cartels regarding fentanyl? In a word, profit.

714 Fentanyl and associated analogues provide criminal
715 organizations with highly elevated margins for illicit revenue.

716 For example, one kilogram of fentanyl in China costs between
717 3- and \$5,000, yet yields approximately 1.5 million on the streets
718 of the United States.

719 DEA stands with our interagency partners including those
720 represented here today to combat this epidemic across all fronts.

721 For DEA and our federal, state, and local partners to be
722 successful in dealing with this threat we need a balanced, whole
723 of government approach, one that attacks supply and also works
724 to reduce demand. We need to continue to lean forward and use
725 all available tools to identify, infiltrate, indict, capture,
726 and convict all members of these organizations, foreign and
727 domestic. With 221 domestic offices, 21 field divisions, and
728 92 foreign offices in 70 countries, DEA is well positioned to
729 engage in this fight. Foreign-based fentanyl manufacturers
730 and domestic distributors often operate with impunity as they
731 exploit loopholes in the analogue provisions of the Controlled
732 Substance Act and capitalize on the lengthy, resource-intensive
733 process to temporarily or permanently control these dangerous
734 substances. Every day, criminal chemists in foreign countries

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735 are altering the molecular structure of different fentanyl
736 analogues keeping the same dangerous pharmacological properties
737 as the substances that are already controlled.

738 Despite these challenges there is good news. Our
739 partnership with our counterparts in China has resulted in the
740 scheduling of 128 new psychoactive substances since October 2015
741 including numerous fentanyl and fentanyl analogues. In
742 addition, you probably heard last week that two Chinese nationals
743 were indicted as part of an investigation conducted by DEA and
744 other agencies and these individuals were designated as CPOTs,
745 Consolidated Priority Organization Targets, the designation
746 reserved for the most prolific drug traffickers in the world.

747 Our investigators remain relentless in their pursuit to
748 dismantle these organizations and bring those responsible to
749 justice. DEA along with our global network of enforcement
750 partners will go after these types of criminals wherever they
751 operate. The DEA will continue to address these threats by
752 investigating and bringing to justice not those suffering from
753 opioid use disorders, but those who are exploiting human frailty
754 for profit.

755 DEA will use all criminal and regulatory tools available
756 to identify, target, disrupt, and dismantle organizations and
757 individuals responsible for the diversion and illicit
758 distribution of pharmaceutical controlled substances in
759 violation of the CSA. We will also work to reduce demand with

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760 our community outreach and prevention efforts throughout the
761 country.

762 One example of such efforts is the DEA 360 Strategy which
763 brings together three distinct pillars of law enforcement aimed
764 at addressing the opioid, heroin, and violent crime crisis:
765 traditional enforcement, diversion control, and community
766 outreach. Now in its 2nd year, this strategy has been deployed
767 to some of the hardest hit communities in the nation.

768 The brave men and women of the DEA remain committed to doing
769 everything they can to address this threat. One pill is enough;
770 one life is worth it. Every pill that we stop from hitting the
771 street through diversion or counterfeiting potentially stops it
772 from getting into the hands of a young American and saves them
773 from opioid dependency, heroin use, and possibly a fatal overdose.

774 Thank you for the opportunity to appear before you today
775 and I look forward to answering any questions you may have.

776 [The prepared statement of Mr. Doherty follows:]

777

778 *****INSERT 2*****

779 The Chairman. Mr. Doherty, thank you. We certainly
780 appreciate the work that your agents and you all do in this cause
781 and they have dangerous work and it is important work and we do
782 appreciate what they do.

783 I do want to start with you, however, with a simple question
784 that this committee has been asking the DEA for months. Which
785 companies supplied the pharmacy in Kermit, West Virginia that
786 received nine million opioid pills in 2 years, and the pharmacy
787 in Oceana, West Virginia that received 600 times as many oxycodone
788 pills as another pharmacy just eight blocks away between 2005
789 and 2016? Can you give us the names of those companies?

790 Mr. Doherty. Thank you for that question, Chairman.
791 Currently, we are reviewing the request from the committee and
792 I do not have that data with me today. I apologize.

793 The Chairman. So we have asked for this information in a
794 meeting. We have asked for this information in an email. We
795 have asked this information in a letter and we have asked this
796 information now in a hearing. If you needed to get this
797 information for enforcement action, I suspect and hope you would
798 get it very quickly, right, within hours or days?

799 The bipartisan letter this committee sent to your agency
800 earlier this month asked the DEA to produce data and documents
801 answering this question and others that we asked by this Friday.

802 Is the DEA going to give us this information and documents that
803 we have requested by Friday?

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804 Mr. Doherty. Sir, thank you for the follow-up. To your
805 point, sir, the DEA, we realize the importance of all the requests
806 from the committee and we treat them as such in light of the opioid
807 epidemic. With respect to the questions, for the record, we did
808 turn those over last night, sir.

809 The Chairman. Questions from April, I think, right?

810 Mr. Doherty. Yes, sir. And in terms of a May 8th letter,
811 we have been providing the answers on a rolling basis as to not
812 delay an overall lengthy response. Those have been provided to
813 the committee on a rolling basis and we continue to work on the
814 few outstanding questions. And to your point, sir, the most
815 recent letter, we are in receipt of that and we are preparing
816 a response.

817 The Chairman. So I hope you can appreciate our frustration
818 on this side. We have been trying to get to the bottom of this
819 pill dumping issue.

820 Can we please silence our phones?

821 We have been trying to get to the pill dumping issue in West
822 Virginia for a very long time. To me, this is a pretty basic
823 question, who are the suppliers? Just yesterday, we finally
824 received answers to the questions as you mentioned that we asked
825 for back in April. We still don't have all the answers to the
826 bipartisan letter we sent in May.

827 Some of the responses the DEA provided, frankly, are not
828 adequate. For example, in the May letter we asked the DEA to

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829 produce documents about delayed or blocked enforcement actions.

830 Do you know how many documents your agency has produced? The
831 answer is zero. The agency responded and this is a direct quote,
832 DEA is unaware of documents related to the delayed or blocked
833 enforcement actions and suspension orders, close quote.

834 We obtained from another source a whole bunch of documents
835 that look pretty responsive to our request, and yet from the agency
836 we are told you are unaware of documents related to delayed or
837 blocked enforcement actions and suspension orders. This is a
838 problem. Enough is enough. Will you on behalf of the DEA commit
839 today to producing the documents and information we have requested
840 and soon, or do I simply need to issue a subpoena because we are
841 done waiting?

842 Mr. Doherty. Sir, we appreciate your concern and absolutely
843 we are treating it with the utmost importance as it should be
844 treated. There is no reason for the extended delay of the
845 questions for the record which is now in the possession of the
846 committee. We will make every effort to expedite every request
847 that is outstanding to the committee.

848 The Chairman. I mean just for members' awareness on both
849 sides of the aisle, the committee received yesterday a set of
850 documents from an anonymous source. Bipartisan committee staff
851 are now reviewing these documents.

852 Mr. Doherty, I have one more question before I move on.
853 Have you or anyone at the DEA that you are aware of received any

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854 instructions or directives to erase emails or otherwise destroy
855 documents on this matter or any others?

856 Mr. Doherty. No, sir. I am not aware of that nor have I
857 been involved in any conversation relative to that matter.

858 The Chairman. Dr. McCance-Katz, let me move to you. Given
859 SAMHSA's central role in much of the federal government's efforts
860 to combat the opioid epidemic, it is imperative that you and your
861 staff have all of the tools necessary to perform these duties.

862 Are there currently any obstacles or barriers hindering you and
863 your staff's ability to respond effectively to this crisis and,
864 if so, what can Congress do to help?

865 Dr. McCance-Katz. Thank you, Chairman Walden. We have --
866 we are very grateful, actually, for the legislation that has
867 recently been passed by Congress in the 21st Century Cures Act
868 and in CARA that adds to the armamentarium that SAMHSA had
869 available to it to work with states and communities on issues
870 related to mental disorders and substance use disorders, and so
871 at this point we are in the process of implementing the laws and
872 are looking to have feedback to then determine whether we need
873 more than what we have.

874 We have, as you know, through the Cures Act made \$500 million,
875 each of 2 years, available to the states. We are working with
876 the states to develop their plans for evidence-based
877 interventions and treatments in their communities and we are
878 following up with them to determine outcomes. We collect data

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879 as required by law and as we get that data we will be looking
880 at it to determine if more is needed.

881 The Chairman. Thank you very much.

882 Ms. DeGette. Mr. Chairman?

883 The Chairman. For what purpose does the gentlelady from
884 Colorado --

885 Ms. DeGette. I have a unanimous consent request.

886 The Chairman. -- seek recognition? Proceed with your
887 request.

888 Ms. DeGette. Mr. Chairman, I would ask unanimous consent
889 to place two letters into the record. One is the May 8th, 2017
890 letter that you referred to which the DEA gave incomplete
891 responses in particular documents to that was signed by you, Mr.
892 Pallone, Mr. Murphy, me, and Mr. McKinley. And then I would also
893 ask unanimous consent to put the October 13, 2017 letter in the
894 record. That is the one that was signed by you and Mr. Pallone
895 and Mr. McKinley and me which you referred to under which we have
896 received none of the documents that are referenced in that letter.

897 And I just think it would be really useful to this hearing
898 if the witnesses and the public would know that we have been trying
899 to get these documents out of the DEA for quite some number of
900 months now.

901 The Chairman. Without objection, those letters will be
902 entered into the record.

903 [The information follows:]

904

905

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

906 The Chairman. And I would encourage our colleagues and
907 others to avail themselves of those letters. I think they ask
908 pretty specific questions that shouldn't be this difficult to
909 get answers to.

910 Now I would turn to Mr. Pallone from New Jersey for 5 minutes
911 for questions.

912 Mr. Pallone. Thank you, Mr. Chairman. And let me just
913 reiterate again representing the Democrats in support of what
914 Chairman Walden has been saying that we have sent these bipartisan
915 letters to DEA requesting specific information, but we have had
916 a very difficult problem in getting any answers. So I guess I
917 just wanted to start out, Mr. Doherty, by getting a commitment
918 that you will provide the committee with timely information and
919 answers to our questions as we move forward because I totally
920 agree with everything that The Chairman has said. I just -- yes
921 or no, please.

922 Mr. Doherty. Ranking Member Pallone, you have our
923 commitment that we will take every request from this committee
924 seriously. We will review it carefully and we will try to make
925 every effort whatsoever to respond in a timely, timely fashion.

926 Yes, sir.

927 Mr. Pallone. Thank you. Now I wanted to move to another
928 issue here. Coverage of the response to the epidemic often
929 focuses on expanding access to treatment and increasing the
930 availability of naloxone and, however, there are two elements

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931 that must fit into a larger more comprehensive response.

932 Let me go to Dr. McCance-Katz. Could you briefly discuss
933 the importance of deploying a comprehensive response to this
934 epidemic spanning the entire spectrum from prevention to
935 recovery?

936 Dr. McCance-Katz. Yes, Ranking Member Pallone. What I can
937 say is that there are issues that we need to address in terms
938 of prevention, prevention in terms of working with children and
939 families around education, prevention that is targeted to
940 individuals at risk for opioid overdose that includes making
941 available the antidote naloxone widely available. It also
942 includes providing training to first responders and to family
943 members and to getting to physicians and other prescribers to
944 help them understand who is at risk given medications they may
945 be receiving in the course of treatment, and co-prescribing
946 naloxone when needed.

947 In addition, when people develop opioid use disorders they
948 also may be at high risk for overdose. They are at risk for
949 overdose death and they also need access to the naloxone antidote.

950 We address this in a number of ways. We do that through our
951 treatment programs that provide medication-assisted treatment
952 for opioid use disorder. And by the way that is a great way for
953 demand reduction. We need to increase access to treatment so
954 that people have less demand for illicit opioid use.

955 Mr. Pallone. Let me just -- I am just running out of time.

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956 Dr. McCance-Katz. Oh, sorry.

957 Mr. Pallone. Look, let me just say this. I know you
958 mentioned CARA, you mentioned the grants that had been available
959 with the 21st Century Cures bill, and obviously as I have said,
960 you know, I consider these down payments. I still think we need
961 a lot more funding for some of these things that you are mentioning
962 and that you know, we shouldn't just see those as down payments.

963 I know, tomorrow, the President is having an event at the
964 White House and he is going to talk about establishing a national
965 emergency, but I really think that we have to talk about more
966 funding for some of these things. Not just the grants that are
967 already out there, which are great, don't get me wrong, but there
968 just needs to be a lot more.

969 Let me just get to the second question, and this is my only
970 other question but I will ask it to you as well as to Dr. Volkow.

971 As previously mentioned, treatment must be part of our
972 comprehensive respond efforts. Could you discuss how limiting
973 access or creating barriers to treatment could hinder our ability
974 to respond to the crisis? I will ask you and then I will ask
975 Dr. Volkow the same question.

976 Dr. McCance-Katz. Individuals who have opiate addiction,
977 which means they are physically dependent on opioid as well as
978 have the behavioral dysfunction associated with addiction, are
979 at risk for overdose and death and cannot live productive lives.

980 If they cannot get access to evidence-based treatment, which

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981 includes medication-assisted treatment and psychosocial
982 interventions, then that places them at greater risk and it is,
983 I will just say it is very near impossible to recover without
984 getting assistance in the form of these evidence-based
985 interventions.

986 And by evidence-based interventions I do mean medication
987 and psychosocial services and one of the problems that we see
988 is that too often people do not get all of the components of
989 treatment that they need to recover.

990 Mr. Pallone. Dr. Volkow, did you want to add to that?

991 Dr. Volkow. Yes. No, I agree with Dr. McCance. And there
992 are three, I would add three things. One of them has to do with
993 the notion of how do you get access to medication-assisted
994 treatment? One of them is stigma, the other one is lack of
995 sufficient treatment programs to be able to deliver it, and the
996 third one is actually the lack of reimbursement for these
997 treatments.

998 And I think that there are unique opportunities to change
999 these and in particular, for example, one of the aspects that
1000 we are very much invested in partnership with SAMHSA is engaging
1001 the healthcare system in the expansion of the treatment of
1002 individuals with substance use disorders. And also I think an
1003 opportunity is to actually create policy to ensure that
1004 individuals are offered, as was mentioned earlier by Dr. Gottlieb,
1005 the opportunity of having access of to any one of the three

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1006 medications and that they will be reimbursed for them and there
1007 will be no place of limitations on that time that these medications
1008 are actually prescribed.

1009 Mr. Pallone. I thank you.

1010 And Mr. Chairman, just let me say again that my concern
1011 continues to be that if the effort continues on the Republican
1012 side to repeal or sabotage the ACA or cut back on Medicaid that
1013 this type of treatment will be even more difficult for people
1014 to access. But thank you, Mr. Chairman.

1015 The Chairman. The chair now recognizes the vice chair of
1016 the full committee, Mr. Barton, for 5 minutes.

1017 Mr. Barton. Thank you, Mr. Chairman.

1018 I wasn't aware until I listened to your questions the
1019 difficulty the committee has had in receiving answers to questions
1020 on a bipartisan basis, so I am going to direct what would normally
1021 be my question period and opening statement to Mr. Doherty.

1022 We represent the people of the United States. When you get
1023 a letter or your agency gets a letter from this committee that
1024 is signed by the chairman and the ranking member and maybe the
1025 subcommittee chairman you are supposed to answer it. You are
1026 not supposed to dodge it. Now I am a former subcommittee chairman
1027 of this committee and I am a former full committee chairman of
1028 this committee. I have issued subpoenas with the support of the
1029 minority to members of an administration of my own political
1030 party. I have had confrontations with cabinet secretaries, with

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1031 directors of agencies that were appointed by Presidents of my
1032 own political party.

1033 It is absolutely unacceptable to listen with a straight face
1034 to your answers to our chairman. Now if I were you I would go
1035 back, get the answers in plain English as quickly as possible.

1036 If you don't -- and I know you are just the spear carrier you
1037 are not the decision maker, it is your agency -- I am going to
1038 recommend to the chairman that we bring the wrath of this committee
1039 down on DEA. It is inexcusable when people are dying every day
1040 from opioid overdoses that we have got apparently a 3-month,
1041 4-month running dodge from the Trump administration.

1042 Now our Chairman is much more polite than I am, you know,
1043 but you look up the definition of subpoena, the Constitution of
1044 the United States and the American people, and get the answers.

1045 Can you say yes sir to that? I don't want a dodge answer, I
1046 want a yes or no answer. Are you going to go back and tell whoever
1047 is running the show to get the answers our committee chairman
1048 on a bipartisan basis wants, yes or no?

1049 Mr. Doherty. Yes, sir.

1050 Mr. Barton. Thank you. We will follow up on that.

1051 Now I want to go to Dr. Gottlieb. What percentage of the
1052 opioid crisis is prescription drugs versus illegal drugs? Which
1053 --

1054 Dr. Gottlieb. I will defer to my colleague from SAMHSA for
1055 the current data. It has shifted a lot.

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1056 Dr. McCance-Katz. So if we look at the most recent NSDUH
1057 data from 2016 there are about 11.5 million opioid misusers in
1058 the country, about 948,000 are heroin users. So that --

1059 Mr. Barton. So it is kind of 10 to 1?

1060 Dr. McCance-Katz. Yes, sir.

1061 Mr. Barton. Okay. On the legal prescriptions should we
1062 on this committee consider criminalizing the prescription, the
1063 prescribing of legal opioid prescriptions if it is considered
1064 excessive? Should that become a federal criminal act?

1065 Dr. Gottlieb. I don't know who the question is directed,
1066 I mean that would fall within the context of the Controlled
1067 Substances Act. We don't have jurisdiction over the
1068 criminalization of prescribing in that context.

1069 Mr. Barton. Well, we know we have a problem on the illegal
1070 side and we have been dealing or not dealing with it successfully
1071 for a number of years. But this excessive use of legal
1072 prescription drugs, at some point in time the finger points to
1073 the doctor that is prescribing the drug and that is currently
1074 not an illegal act. Should we make that an illegal act? When
1075 Chairman Walden says some pharmacy in West Virginia gets 11
1076 million pills or 9 million pills, somebody is prescribing those
1077 excessively. Should that be a criminal act, federal criminal
1078 act?

1079 Dr. McCance-Katz. So if I could, if there is excessive
1080 prescribing and there is harm to a patient or death of a patient

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1081 that does become a criminal act. If it is found to be excessive
1082 and negligent it can be charged as a criminal act. There have
1083 been many prescribers who have been prosecuted under current law.

1084 The difficulty becomes people who are not dying or having those
1085 kinds of adverse events that really get to public attention and
1086 so that excessive prescribing that puts you at risk for addiction.

1087 Mr. Barton. My time is expired. I know on an individual
1088 basis it is difficult to determine what is excessive prescription
1089 --

1090 Dr. McCance-Katz. Yes.

1091 Mr. Barton. -- you know, in terms of the patient. But
1092 the prescriber, if you have a prescriber who is routinely
1093 prescribing a hundred times opioid prescriptions to the average
1094 doctor in the area that is somebody I believe we ought to look
1095 at. With that Mr. Chairman, I yield back.

1096 The Chairman. I think Dr. Schuchat wanted to --

1097 Dr. Schuchat. I just wanted to say that quite a lot of the
1098 overprescribing is not at that very extreme level, but we are
1099 really just at the beginning of getting clinicians to do better
1100 prescribing. It is only a year and a half since the CDC guidelines
1101 on prescribing for chronic pain and in places that are
1102 implementing them we are seeing pretty rapid changes in
1103 prescribing. So I think we need to do a lot with prescribing
1104 that was sort of within the range of practice.

1105 The Chairman. All right, thank you. We will now go to my

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1106 friend from California, the gentlelady Ms. Eshoo, for 5 minutes
1107 for questions.

1108 Ms. Eshoo. Thank you, Mr. Chairman. Thank you to all of
1109 the witnesses. I read your testimony very carefully last night
1110 and I am left with the following observations. We have passed
1111 laws to address the opioid crisis in our country and those two
1112 laws have been mentioned. We have all of the respective agencies
1113 before us working on it. We have a raft of statistics that are
1114 the horrible of horrors in terms of what this is doing to the
1115 country, how many people are addicted, how it is ravaging
1116 families, communities, et cetera, et cetera.

1117 How much of the crisis is due to opioids being prescribed
1118 legally? I know that CDC handed this out and I think it tells
1119 part of the story. For every one prescription or illicit opioid
1120 overdose death in 2015, there were -- and then it goes through
1121 all of these numbers. But what I am trying to figure out is,
1122 are we a nation that is just almost hopelessly addicted to heroin
1123 -- and just say that out loud. How much is due what is legally
1124 prescribed for pain management, whatever, and versus how much
1125 is due to illegal use?

1126 And I ask that question because I think we need to direct
1127 what we are doing. If we are going to put in place new laws or
1128 see how the laws are already working we need to know this. So
1129 who can answer that question just very briefly?

1130 Dr. Schuchat. Yes. This is not an either/or situation.

1131 Ms. Eshoo. I am not presenting it that way.

1132 Dr. Schuchat. But to say that --

1133 Ms. Eshoo. But I want to understand it better.

1134 Dr. Schuchat. Sure.

1135 Ms. Eshoo. I mean is it tilted towards just prescriptions
1136 that are written?

1137 Dr. Schuchat. We got into this issue with the prescribing.

1138 Ms. Eshoo. Pardon me?

1139 Dr. Schuchat. We got into this issue with prescribing of
1140 opiates. We prescribe three times higher levels.

1141 Ms. Eshoo. No, I understand that. I want to know what the
1142 --

1143 Dr. Schuchat. And most people --

1144 Ms. Eshoo. -- where the dividing line is. Is it 10
1145 percent prescription drugs and 90 percent people that love heroin?

1146 Dr. Schuchat. Over the last 2 years we had a spike in illicit
1147 drug related overdose deaths.

1148 Ms. Eshoo. But can you tell me what the numbers are?

1149 Dr. Schuchat. And that was --

1150 Ms. Eshoo. Does anyone know?

1151 Dr. Schuchat. Yes. Well, we had 65,000 deaths in 2016.

1152 Ms. Eshoo. I know about the deaths.

1153 Dr. Schuchat. About 49,000 of them were --

1154 Ms. Eshoo. I want to know what is bringing it about though
1155 --

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1156 Dr. Schuchat. -- related to --

1157 Ms. Eshoo. -- in terms of usage.

1158 Dr. Schuchat. Yes. The increase in 2016 was fentanyl
1159 illicit laced with heroin. So the increase is the illicit drugs,
1160 but most of the people who are using illicit drugs became addicted
1161 through prescribing, through prescription opioids. That was
1162 their initial addictive product.

1163 Ms. Eshoo. Have the agencies come together to examine, set
1164 down the, you know, CARA and the 21st Century Act and what was
1165 contained in them kind of as an overlay on this whole issue on
1166 opioids and made any kind of determination as to the early
1167 effectiveness of these laws; do we know? We don't know.

1168 Dr. Volkow. No. We don't know, but we know that --

1169 Ms. Eshoo. We don't know because it is too early?

1170 Dr. Volkow. It is too early.

1171 Ms. Eshoo. It is too early to know. In the area of
1172 treatment how much in terms of federal health insurance programs
1173 contain the money for this for treatment overall, does anyone
1174 know? Well, maybe someone can respond later in writing. It
1175 would be good to know, because if we are busy cutting and
1176 undermining that then it upends the underlying purpose of this
1177 hearing. I mean we can talk and talk and talk. We know we have
1178 a tremendous problem. People are dying daily. But if we are
1179 undermining the treatment at the same time, I think we need to
1180 have that documented.

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1181 Mr. Doherty, how many -- you testified that your agency is
1182 doing everything you can possibly do, overwhelming commitment,
1183 et cetera, et cetera. I believe you or I would like to believe
1184 you. How many opioid-related cases have actually been
1185 successfully adjudicated and how many open, active cases are there
1186 coming out of your agency and its work doubling down on the opioid
1187 crisis in our country?

1188 Mr. Doherty. Ma'am, historically, in the --

1189 Ms. Eshoo. No, I don't want to know historically. I want
1190 to know up to date.

1191 Mr. Doherty. Well, ma'am, during the last year there have
1192 been approximately 2,000 arrests made with respect to diversion
1193 control cases and that would represent approximately 1,600 cases
1194 that were initiated. Those represent sweeping enforcement
1195 actions such as a week-long action that took place this past July
1196 in partnerships with HHS and the FBI, the National Health Care
1197 Fraud Takedown initiative.

1198 This was the first year the DEA was a full partner, 120 of
1199 the 412 --

1200 Ms. Eshoo. Does it include the companies that you haven't
1201 identified yet?

1202 Mr. Doherty. I am sorry, ma'am?

1203 Ms. Eshoo. Does it include the companies that you have not
1204 identified yet?

1205 Mr. Doherty. That did not include companies. These were

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1206 120 individuals prescribing opioids of which 115 of the 412 were
1207 medical professionals.

1208 Ms. Eshoo. I am way over my time. Thank you, Mr. Chairman.

1209 The Chairman. Thank you. We now go to the gentleman from
1210 Illinois, Mr. Shimkus, for 5 minutes on questions.

1211 Mr. Shimkus. Thank you, Mr. Chairman. Thanks for the
1212 hearing. Thank you all for being here.

1213 I am going to shift some of the tone. Just a couple days
1214 ago I tweaked my back. I was in pain. When we went through this
1215 process last Congress, I was visited by a lot of patient groups
1216 who were just concerned that the pendulum would shift. And we
1217 use the term chronic pain you know people who have it forever
1218 and I want to make sure that we don't lose them in this debate,
1219 people who wouldn't be able to get out of bed without some
1220 assistance.

1221 So I do have a statement for the record, Mr. Chairman, I
1222 would ask unanimous consent, from the American Physical Therapy
1223 Association addressing this.

1224 The Chairman. Without objection.

1225 [The information follows:]

1226

1227 *****COMMITTEE INSERT 4*****

1228 Mr. Shimkus. Because then it goes into my first question
1229 for Dr. McCance-Katz. In your question and answer and some of
1230 your comments you talked about all of the components of treatment,
1231 which as I am getting more educated in this process it seems to
1232 me that we are not always considering all of the components, or
1233 maybe physicians, they may get stovepiped into one delivery
1234 system. And every patient is different, every pain issue, and
1235 that is kind of where the physical therapists are saying, hey,
1236 this should be part of some treatment.

1237 So can you for the sake of all of us kind of talk about the
1238 difference between naltrexone, Suboxone and methadone, just
1239 briefly?

1240 Dr. McCance-Katz. I will try. Yes, so naltrexone is an
1241 opioid antagonist. What that means is that it will block the
1242 effects of an opiate. So if somebody is opiate-addicted and they
1243 are withdrawn from those opioids and then started on naltrexone
1244 and then they use an opioid again they will not get the effect
1245 that they were expecting, so it will block them from getting high.

1246 So that is the value of naltrexone. It is often seen as a
1247 medication that gives a person a chance to get back to counseling
1248 because they may relapse while they are in their regular using
1249 environments --

1250 Mr. Shimkus. Okay, just pushing you -- Suboxone.

1251 Dr. McCance-Katz. I am sorry? Oh, you want me to go on.

1252 Mr. Shimkus. Just pushing you.

1253 Dr. McCance-Katz. Okay, here you go. Suboxone is what we
1254 call an opioid partial agonist, and what that means is that it
1255 has lower abuse liability and has less potency in terms of euphoric
1256 effects --

1257 Mr. Shimkus. Okay, methadone.

1258 Dr. McCance-Katz. -- than does methadone which is what
1259 we call a full agonist and it is a medication that is only available
1260 for the treatment of opioid use disorder through federally
1261 regulated opioid treatment programs which my agency regulates.

1262 Mr. Shimkus. Okay, let me go to Dr. Schuchat. How does
1263 CDC inform evidence-based best practices? So if you are using
1264 these three different things how do you collect that data?

1265 Dr. Schuchat. CDC is working to evaluate the
1266 medication-assisted treatment and counseling efforts that SAMHSA
1267 has right now, so we actually have a study in the field with these
1268 different modalities, look at outcomes --

1269 Mr. Shimkus. So then the information can get out and people
1270 --

1271 Dr. Schuchat. Right, so that we can share --

1272 Mr. Shimkus. -- can make better determinations.

1273 Okay, let me go to Mr. Doherty. This will be a friendly
1274 question. Category II or III what is the difference?

1275 Mr. Doherty. Schedule?

1276 Mr. Shimkus. Schedule, yes, Schedule II or III on the drug
1277 listing.

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1278 Mr. Doherty. Yes, sir. So with respect to Schedule II,
1279 for instance, those are controlled prescription pain medications
1280 in the oxycodone, hydrocodone family and we certainly, they go
1281 in a range from III, IV, and so on.

1282 Mr. Shimkus. So what is the difference between a II and
1283 a III?

1284 Mr. Doherty. The difference is, sir, is that it is more
1285 strictly controlled within DEA on the schedule.

1286 Mr. Shimkus. Why?

1287 Mr. Doherty. Based on the scientific dependency of it too.

1288 Mr. Shimkus. Okay, dependency, what else?

1289 Mr. Doherty. Danger for abuse.

1290 Mr. Shimkus. Danger for abuse.

1291 Okay, let me go to Dr. Gottlieb, FDA black box labeling.

1292 It is my understanding there is no communication based upon
1293 Schedule and what might be labeled. Now you see where my whole
1294 thrust of these questions is more information, more different
1295 practices, and then that would also go to labeling. If DEA says
1296 Schedule III is less addictive, shouldn't that maybe be listed
1297 on the label?

1298 Dr. Gottlieb. I could certainly take it back to the agency.

1299 There is labeling language that reflects some of the qualities
1300 of the drugs that relate to their abuse potential currently.

1301 Mr. Shimkus. Do you agree that there may or, I mean I would
1302 hope that we would talk together and that our agencies would

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1303 communicate that. That might give the practitioners a little
1304 more information.

1305 Mr. Chairman, my time is expired. I yield back.

1306 The Chairman. I thank the gentleman's comments. It is
1307 interesting in Oregon, I think through the Oregon Health Plan,
1308 they actually often give the antidote naloxone with the
1309 prescription for opioids, which the people in the roundtables
1310 I have been in sends a real signal of seriousness about what people
1311 are being given to take, the opiates, because here is the antidote
1312 because it may kill you. And they tell me that gets the attention
1313 of those receiving the prescription.

1314 With that we will turn to the gentleman from New York, Mr.
1315 Engel, for 5 minutes for questions.

1316 Mr. Engel. Thank you, Mr. Chairman and Mr. Pallone for
1317 convening today's hearing.

1318 This epidemic has touched so many people in each of our
1319 districts in so many ways, so I would like to talk about the
1320 specific challenges in my district facing Westchester County in
1321 New York and the Bronx in New York City. I represent a large
1322 portion of Westchester where opioid-related deaths shot up more
1323 than 200 percent between 2010 and 2015, but that changed in 2016
1324 when the rate of opioid-related deaths in Westchester fell nearly
1325 30 percent and evidence suggests this was thanks to the overdose
1326 reversal drug naloxone. Naloxone. That is why I didn't go to
1327 medical school, law school was easier.

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1328 Between 2015 and 2016, Westchester EMS workers and law
1329 enforcement began using this medication much more frequently
1330 following state and local efforts to make it more accessible and
1331 ensure first responders know how to use it, so I believe this
1332 shows what is possible when we afford communities the resources
1333 they need. So Congress must continue to invest the necessary
1334 funds to respond to the opioid epidemic and support proven public
1335 health approaches spanning the entire spectrum from prevention
1336 all the way to recovery.

1337 I am so encouraged to see a devastating trend reversed in
1338 Westchester, but this battle obviously is far from over.
1339 Naloxone is certainly a lifesaver but it could also be a
1340 gamechanger, and if we can connect people with treatment after
1341 they have overdosed we might even save more lives.

1342 So Dr. McCance-Katz, how are we doing as a country with
1343 respect to connecting Americans with treatment after they have
1344 overdosed and how can Congress help us do even better?

1345 Dr. McCance-Katz. Yes. Thank you for that question.

1346 And so we have, SAMHSA has a number of programs that are
1347 demonstration programs across the country that address issues
1348 around the need for naloxone as an antidote. Treatment in EDs
1349 and what we are doing in the models that we are working with include
1350 bringing peers, people with lived experience of opiate addiction
1351 into the emergency departments so that they can talk with people
1352 who have experienced an overdose and provide them some guidance

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1353 and help and support to get them to treatment. And we are in
1354 the process of having these programs under -- they are ongoing
1355 right now and we will be evaluating those programs.

1356 I will tell you though I am from Rhode Island. I come to
1357 federal service having been a practicing physician, a
1358 psychiatrist in Rhode Island, and was involved with the opioid
1359 epidemic in Rhode Island. And one of the things that we observed
1360 in Rhode Island was that a lot of times when people are reversed
1361 they are not comfortable, that sometimes they will experience
1362 opiate withdrawal when they are given naloxone and they are not
1363 ready. They are not ready to commit to treatment at that time.

1364 And so what we started doing was getting consent from people
1365 so that our peers could follow up with them in communities. And
1366 we think this is going to be a key piece of connecting people
1367 to treatment and we will be expanding those kinds of models at
1368 SAMHSA.

1369 Mr. Engel. Well, thank you. And let me say the other part
1370 of my district is the Bronx. We are not seeing, unfortunately,
1371 the same signs of hope there. More New Yorkers die of overdoses
1372 in the Bronx than in any other city borough last year. Eighty
1373 five percent of those deaths involved opioids.

1374 And despite the proximity and attached to each other,
1375 Westchester and the Bronx have many differences. On average,
1376 communities in the Bronx have fewer resources, the uninsured rate
1377 is higher, and communities are more diverse. So the disparity

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1378 that we are seeing and the trajectory of these counties' opioid
1379 epidemics is also an economic disparity and a racial disparity.

1380 So the consequences of this disparity are really heartbreaking.

1381 Your ZIP Code should not determine your health or what you get
1382 to make you better. We need to do better.

1383 So on the basis of that statement, let me ask Dr. Schuchat
1384 and Dr. McCance-Katz again, how can Congress address these
1385 disparities and ensure that every person regardless of sex, race,
1386 location, or income has the same ability to get treatment?

1387 Dr. McCance-Katz. I will just say SAMHSA has an Office for
1388 Behavioral Health Equity. We are very involved in monitoring
1389 those kinds of issues and we work very hard to provide guidance
1390 to states and communities on culturally appropriate, culturally
1391 sensitive interventions, and we will be continuing that work.

1392 Mr. Engel. Dr. Schuchat?

1393 Dr. Schuchat. Yes. And one of the things CDC was able to
1394 do with the increased funding this past year was strengthen the
1395 syndromic surveillance goal from 12 states to 32. And what that
1396 has allowed is better data on where the problems are, hotspots
1397 or inequities can be followed up and so you can get more resources.

1398 Even the naloxone distribution can be targeted to where the
1399 overdoses are highest and expanding services into those areas.

1400 I know in the New York area, in New York City area that has
1401 been done, trying to figure out where the need is and get the
1402 clinical services closer to those hotspots.

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1403 Mr. Engel. Thank you both. Thank you, Mr. Chairman.

1404 The Chairman. Thank you, Mr. Engel. We will now go to the
1405 chairman of the Subcommittee on Health, the doctor from Texas,
1406 Dr. Burgess.

1407 Mr. Burgess. Thank you, Mr. Chairman, and thanks for
1408 holding this hearing. First off, I am going to ask unanimous
1409 consent to my opening statement being made part of the record.

1410 The Chairman. Without objection.

1411 [The information follows:]

1412

1413 *****COMMITTEE INSERT 5*****

1414 Mr. Burgess. And I will point out that your attention to
1415 this issue has been important. At the subcommittee level as you
1416 know we heard from over 50 members, not just from on the committee
1417 but throughout the Congress, 50 members. We held a Members' Day
1418 on problems that people were having with opiate abuse back in
1419 their districts and we did hear that it literally touches every
1420 part of the country.

1421 I am going to ask questions of the doctors on the panel.

1422 I have been on this committee long enough to remember when we
1423 had a hearing on the underprescribing of pain medicine in 2005,
1424 so just for those of you who are still in practice, what is a
1425 doctor to do? You have a patient that has a condition that is
1426 painful and you want to alleviate that suffering. How do you
1427 now approach that? Are you not going to use an opiate where you
1428 might have otherwise thought it was appropriate?

1429 Dr. Gottlieb, you referenced that it is going to cause us
1430 to think in some uncomfortable ways because we have run out of
1431 reasonable options. So starting with you I would just like to
1432 go down the panel and hear from you.

1433 Dr. Gottlieb. Thank you for the question, Congressman.
1434 There is a role for these medications in medical practice and
1435 there is patients who have acute pain conditions where these
1436 medications can be effective. There are some patients with
1437 chronic conditions like metastatic cancer pain that are going
1438 to require long-term treatment with opioids. But I do think that

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1439 there was a generation of physicians trained, and I think it was
1440 my generation of physicians trained, to make more indiscriminate
1441 use of these drugs than we should have. I remember when I
1442 was practicing in the hospital as a resident and that is not too
1443 long ago, every patient had a standing order for Percocet. Every
1444 6 hours a patient had a standing order for two tabs of Percocet
1445 that could be prescribed at the nurse's discretion, almost every
1446 patient. That wasn't good medical practice we now know. That
1447 sensitized a lot of patients who were hospitalized for 5 or 6
1448 days to round-the-clock immediate release formulations of opioids
1449 and some of those patients left the hospital addicted.

1450 So I think we need to rethink how we use these drugs and
1451 I think we are in the process of doing that. But that is going
1452 to also require to reeducate a generation of physicians and that
1453 is what we are doing.

1454 Mr. Burgess. Since you brought up your residency I will
1455 bring up mine. My generation of doctors was able to put a refill
1456 on a prescription that we sent home with the patient and somewhere
1457 along the line that ended. Now I realize those are state laws,
1458 but the inability to refill a prescription, and really this is
1459 for any of you, the inability to refill a prescription without
1460 going back and seeing the doctor and having that face-to-face
1461 encounter, I mean it seems to me that human behavior might dictate
1462 that a doctor would -- I don't want to get calls for a refill
1463 on a pain medicine so I will write it for twice the amount that

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1464 I used to write it for. Does that happen?

1465 Dr. Gottlieb. Look, I will defer to my colleagues who have
1466 more substantive data on these issues. But when we look at the
1467 epidemiology we see too many 30-day prescriptions being written
1468 for indications for which, you know, the proper course would be
1469 a 4- or 5-day prescription. You have dental procedures, minor
1470 surgical procedures, so we do see that happening.

1471 And to the extent that we believe that addiction correlates
1472 with exposure, and one of the keys to solving the new addiction
1473 crisis is to reduce overall exposure to opioid drugs, you would
1474 want to encourage approaches that make it easier if not try to
1475 create more direct incentives to prescribe shorter duration uses.

1476 That includes packaging. It includes proper education. These
1477 are things we are looking at doing.

1478 Mr. Burgess. Sure. I am going to have to jump ahead so
1479 I am going to ask all of you to respond to that question in writing
1480 to me if you would, because I do need to ask Mr. Doherty a question
1481 on -- you used a term that I was not familiar with, the CPOT;
1482 is that right?

1483 Mr. Doherty. That is correct, sir.

1484 Mr. Burgess. And that stood for?

1485 Mr. Doherty. CPOT stands for Consolidated Priority
1486 Organization Target, and it is a Department of Justice term
1487 designated for our most prolific trafficking organizations in
1488 the world.

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1489 Mr. Burgess. And what legal tools do you have? When you
1490 arrest a CPOT and bring a successful prosecution what are you
1491 charging them with, just the drug laws or are you able to charge
1492 them with injury to a person or murder?

1493 Mr. Doherty. Well, with respect to your question, sir, and
1494 thank you, the CPOT designation is typically affiliated with
1495 organizations, mainly international organizations, our large
1496 target list in China, our target list in Mexico. So to point
1497 out the press release last week of the two Chinese nationals that
1498 I mentioned in my opening statement --

1499 Mr. Burgess. Right.

1500 Mr. Doherty. -- these individuals are prolific in nature
1501 shipping massive amounts of fentanyl to our country.

1502 Mr. Burgess. So if you are successful in prosecuting them,
1503 what statute are they prosecuted under?

1504 Mr. Doherty. Sir, they would be prosecuted under a variety
1505 of violations, importation.

1506 Mr. Burgess. So how long do they go away for?

1507 Mr. Doherty. Sir, I can't comment on that particular case.

1508 Mr. Burgess. But in general what would the sentencing
1509 guidelines be?

1510 Mr. Doherty. Generally speaking, if we were to go after
1511 a CPOT and either arrest him in the United States or have him
1512 extradited, potentially, hypothetically he could stand RICO
1513 charges. He could stand murder charges. He could stand money

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1514 laundering charges. He could stand wire fraud charges. So
1515 really --

1516 Mr. Burgess. Is it theoretically possible to bring murder
1517 charges against someone in that situation?

1518 Mr. Doherty. If we can definitely prove, and again I realize
1519 this is a hypothetical situation.

1520 Mr. Burgess. Sure.

1521 Mr. Doherty. If we can definitely prove that either he
1522 was directly involved, he or she was directly involved in murder
1523 or supplied fentanyl to individuals in this country that overdosed
1524 and died, we would definitely, unequivocally, bring murder
1525 charges, death resulting charges on these individuals.

1526 Mr. Burgess. And I would make that widely known and
1527 dispersed. Thank you, Mr. Chairman. Thank you, sir.

1528 The Chairman. Thank you, Mr. Chairman. And one of those
1529 folks, an Oregonian overdosed related to that case where the
1530 indictments came down, so it is personal to our state. We will
1531 go now to the gentleman from Texas, Mr. Green, for 5 minutes.

1532 Mr. Green. Thank you, Mr. Chairman and our ranking member
1533 for this really important hearing today. The 21st Century Cures
1534 Act contained a billion dollars to fight the opioid epidemic.
1535 This is substantial but certainly not enough to win the fight.

1536 Dr. Schuchat, can you talk about how this funding is being
1537 used on the ground?

1538 Dr. Schuchat. Well, the 21st Century Cures Act didn't

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1539 actually provide funding to the CDC, so I probably want to let
1540 my colleagues talk about that. The committee in last year's 2017
1541 appropriation did give, separately give CDC a \$50 million increase
1542 which has been incredibly helpful in our reaching out to more
1543 states to speed up the timing of the quality data that helps them
1544 know what they are doing and to increase the consumer awareness
1545 with the communication effort.

1546 But I should probably let my colleagues talk about the
1547 funding.

1548 Mr. Green. Whichever has the information, I was wondering
1549 what the outreach was. You know, it is relatively soon for even
1550 though the bill was passed, but what are we seeing changed now
1551 because of that?

1552 Dr. McCance-Katz. Yes. So SAMHSA is responsible for the
1553 State Targeted Response. This is the 500 million a year for each
1554 of 2 years. The first year was allocated to the states. We have
1555 been working with the states on developing their plans based on
1556 their assessments of their communities and their needs related
1557 to prevention, treatment, and recovery services.

1558 We review those. We make sure that evidence-based practices
1559 are being used and then the states will procure the services that
1560 they need to implement those plans and we are at that point right
1561 now, sir.

1562 Mr. Green. Okay. I would hope you would continue because,
1563 you know, we want to see where this -- and you are learning I

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1564 guess from different states on what works and what doesn't.

1565 Dr. McCance-Katz. Yes. And we would be happy to provide
1566 additional information as time goes on to this committee.

1567 Mr. Green. Okay, thank you.

1568 Dr. Volkow, I understand that NIH is partnering public and
1569 private stakeholders to accelerate the research in the
1570 non-opioid, non-addictive therapies. I also understand that Dr.
1571 Gottlieb has taken proactive steps to provide information and
1572 to reshape the provider behaviors as it relates to prescribing
1573 practices for opioid.

1574 This panel would be the experts who are actively engaged
1575 in fighting the public health battle, so I want to ask you what
1576 I believe is a key question on the strategy going forward. How
1577 do we elevate the value and utilization of alternatives of the
1578 opioids across the healthcare system? Some alternatives do exist
1579 today and are we hearing more are in the development?

1580 But given the rampant rate of prescribing and use of opioids
1581 how do we change that part of the problem? And that was any --

1582 Dr. Volkow. Yes. No, and I think that the point has to
1583 do with how do you change the practice of clinicians that have
1584 been overrelying on the utilization of opiate medications for
1585 a variety of reasons to treat severe pain and become actually
1586 to treat not so severe pain.

1587 So one of the big challenges is how do you implement the
1588 CDC guidelines, number one. And number two, among one of the

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1589 challenges is to ensure that physicians will be reimbursed for
1590 actually following the guidelines. Because what they recommend
1591 is a multi-pronged approach for the management of pain, integrated
1592 response that is much more expensive than what it would cost to
1593 give you an opioid prescription.

1594 So as we are discussing the notion of changing and educating
1595 and training physicians on the use of prescription opioids and
1596 management of pain, we need to change the structure of
1597 reimbursement so that the doctors can do the right thing for their
1598 patients and get reimbursed for it.

1599 Dr. Gottlieb. I will just, I can pick up just to add that
1600 we do see innovations in the pipeline that could provide
1601 alternatives to opioids and provide opioids that are harder to
1602 manipulate in ways that could help defeat abuse. We see
1603 technologies that where the opioid-like drugs but are biased at
1604 the mu-opioid receptor in ways that might not have the same
1605 addictive potential. We see second and third generation abuse
1606 deterrent formulations that are potentially much harder to abuse,
1607 things like prodrugs in development. So there are very
1608 interesting, very promising technologies available that could
1609 potentially treat chronic and acute pain in ways that don't lead
1610 to the same addiction.

1611 And I would also offer that there is a lot of medical device
1612 alternatives. We have approved about 200 different medical
1613 devices that have components that treat pain, about ten of those

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1614 are very novel devices. And so we see a lot of opportunity looking
1615 across the continuum of medical devices as well to help address
1616 painful syndromes locally rather than systemically.

1617 So there is a lot of opportunity and we have fast tracked
1618 some of these products. These products would be also eligible
1619 for the breakthrough therapy designation that this committee made
1620 available to the agency.

1621 Mr. Green. Thank you, Mr. Chairman.

1622 Mr. Burgess. [Presiding.] The gentleman's time has
1623 expired. The gentleman yields back. The chair recognizes the
1624 gentlelady from Tennessee, 5 minutes for questions, please.

1625 Mrs. Blackburn. Thank you, Mr. Chairman. We appreciate
1626 that all of you are here. As you have heard from everybody, this
1627 is work we have been working on for years and trying to figure
1628 out how to best get a handle on this issue and end this epidemic
1629 and it is so important that we hear from you.

1630 What I want to start with, and this is to each of you on
1631 this panel, are there any existing statutes that prevent your
1632 agency, your respective agencies, from effectively responding
1633 to the opioid crisis?

1634 Dr. Gottlieb. Well, Congresswoman, we would be delighted
1635 to work with the committee to look across the range of our
1636 different authorities and what more we can be doing. The one
1637 that I would just point out in response to your question is where
1638 we are trying to take some new steps to think about how we step

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1639 up our oversight in the international mail facilities to target
1640 synthetic drugs coming in through the mail. And in this regard
1641 we have worked very closely with Customs and Border Patrol, the
1642 commissioner there has been a very good colleague to FDA.

1643 But there is the potential that we might want to take a look
1644 at some point at some of the seizure authority we have --

1645 Mrs. Blackburn. Okay.

1646 Dr. Gottlieb. -- to perhaps make it more efficient to
1647 operate inside those IMFs.

1648 Mrs. Blackburn. Okay, anyone else have any existing statute
1649 that is an impediment?

1650 Mr. Doherty. Ma'am, from DEA's standpoint, and I will
1651 address what was recently reported in the media, one of our
1652 administrative tools, an immediate suspension order recently came
1653 under report in the media.

1654 We would be happy to work with Congress and we look forward
1655 to working with Congress with Department of Justice oversight
1656 to ensure that from an enforcement, criminal enforcement
1657 perspective, a civil sanction perspective, and an administrative
1658 perspective, which are all tools that we use to prevent the
1659 diversion of illicit pharmaceuticals, we would be more than happy
1660 to work, as I said, with Congress with Department of Justice
1661 oversight to ensure that we have the most updated and applicable
1662 tools moving forward to attack the opioid crisis.

1663 Mrs. Blackburn. Okay, anyone else?

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1664 Dr. Volkow. Well, I think that on following my DEA
1665 colleague, I think one of the issues that becomes very important
1666 on the aspect of research is our ability to work with substances
1667 that are being abused, illicit substances that are very, very
1668 dangerous. And that is important because if we don't understand
1669 it from microbiological properties we cannot actually develop
1670 treatments. And one of the aspects on it is that because they
1671 are Schedule I substances then it can become very, very difficult
1672 to actually do research on them.

1673 So being able to generate the category that allows us to
1674 protect the public from these substances what allows us to do
1675 that research would facilitate our ability to respond to this.

1676 Mrs. Blackburn. Okay. That is great. And if any of you
1677 would like to submit something to us in writing that would be
1678 helpful.

1679 And Dr. McCance-Katz, you mentioned and I will just ask you
1680 to submit this in writing, you talked about implementation of
1681 21st Century Cures. If you will give us your timeline for where
1682 you are on that because, and you can just give it to us in writing.

1683 Dr. McCance-Katz. I will.

1684 Mrs. Blackburn. We are all interested in that because that
1685 is getting the money out to our states and that is an imperative
1686 for us.

1687 Mr. Doherty, I am coming back to you on the Ensuring Patient
1688 Access and Effective Drug Enforcement Act. It required, it

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1689 required the DEA and HHS to submit a report to Congress identifying
1690 current issues with diversion efforts including information on
1691 whether coordination between the industry and law enforcement
1692 has helped. And that report was due to us in April, so it is
1693 now 6 months late.

1694 I sent a letter over this week asking about this report,
1695 so why don't you -- and Mr. Chairman, I would like to submit for
1696 the record the letter that was sent over requesting the delayed
1697 report.

1698 Mr. Burgess. Without objection, so ordered.

1699 [The information follows:]

1700

1701 *****COMMITTEE INSERT 6*****

1702 Mrs. Blackburn. And what I would like to hear from you is
1703 what is the status of that report? You have heard the frustration
1704 with this panel for not getting information we need from the DEA,
1705 so we are adding this to the list. Where is the report? What
1706 is the status of it, when should we receive it?

1707 Mr. Doherty. Congresswoman, thank you for that question.
1708 And with respect to the report that you mentioned, DEA has engaged
1709 with Health and Human Services on that report and it is my --

1710 Mrs. Blackburn. Engaging isn't getting a report to us that
1711 is now 6 months late. So when do we get the report?

1712 Mr. Doherty. It is my understanding, ma'am, that HHS has
1713 the lead on this report that you reference.

1714 Mrs. Blackburn. Have you all submitted your needed
1715 information to HHS to write this report?

1716 Mr. Doherty. I believe we have and we have been actively
1717 working on our part of the report with them.

1718 Mrs. Blackburn. Okay, thank you, yield back.

1719 Mr. Burgess. The chair thanks the gentlelady. The
1720 gentlelady yields back. The chair recognizes the gentlelady from
1721 Colorado, Ms. DeGette, for 5 minutes for questions, please.

1722 Ms. DeGette. Thank you, Mr. Chairman.

1723 Mr. Chairman, we have been talking today about 21st Century
1724 Cures and the billion dollars that Fred Upton and I were pleased
1725 to put into that bill for state funding to develop opioid
1726 prevention programs. Just for the record, in Colorado we have

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1727 a program called the Consortium for Prescription Drug Abuse
1728 Prevention. They are already taking this money from Cures and
1729 they are already doing work to reduce overdose deaths. It is
1730 really important that we do this on a state-by-state level because
1731 the states have different needs, and I would hope that we would
1732 work as a committee to extend that funding out past 2018 because
1733 it expires in 2018.

1734 I want to, Mr. Doherty, I just want to follow up -- I am
1735 over here. I want to follow up on a couple of the Chairman's
1736 questions and others. We have been talking to you about that
1737 May and that October letter that we sent to the DEA asking for
1738 responses and documents. Were you aware that the Chairman and
1739 several other members also met with the acting director of the
1740 DEA in July, on July 28th of this year? Were you aware of that
1741 meeting?

1742 Mr. Doherty. Yes, ma'am.

1743 Ms. DeGette. And were you aware that at that meeting we
1744 also asked him to provide that documentation and those answers
1745 and he said he would?

1746 Mr. Doherty. Ma'am, I am generally aware of the meeting.
1747 I am not sure what was discussed at the meeting.

1748 Ms. DeGette. Okay. Well, I will tell you that is what
1749 happened. Now I also want to ask you, as the Chairman said we
1750 have been investigating reports of shipments of large amounts
1751 of opioids to Kermit, West Virginia. Can you tell us today which

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1752 distributor, or distributors, supplies those large amounts of
1753 opioids to the pharmacies in Kermit, West Virginia?

1754 Mr. Doherty. Ma'am, as I said before I don't have that
1755 information with me.

1756 Ms. DeGette. When can we expect to get that information
1757 from you?

1758 Mr. Doherty. And we will expedite that information and
1759 after the hearing.

1760 Ms. DeGette. 1 week, 1 month, 1 year; when can we expect
1761 to get it?

1762 Mr. Doherty. Ma'am, I would not be able to put a timetable
1763 on that.

1764 Ms. DeGette. You are not going to tell me.

1765 Mr. Doherty. I will --

1766 Ms. DeGette. Chairman, I think that subpoenas may be really
1767 considered in this point.

1768 Let me ask you another question. On the October 13th letter
1769 which I put into the record a little awhile ago, the committee
1770 using DEA's collected ARCOS data looked at the amount of
1771 hydrocodone and oxycodone that went into the various regions of
1772 West Virginia and they show that from 2000 to 2010 there were
1773 dramatic increases in the distribution of opioids to the regions
1774 examined by the committee. Would you agree that some of these
1775 trends are troubling?

1776 Mr. Doherty. Yes, ma'am. I would.

1777 Ms. DeGette. Okay. And has the DEA conducted its on
1778 analysis of its ARCOS data regarding the trends in West Virginia
1779 and does the DEA know which distributors were responsible for
1780 this?

1781 Mr. Doherty. Ma'am, the DEA has upgraded our office --

1782 Ms. DeGette. I think yes or no will work. Do you know who
1783 did this?

1784 Mr. Doherty. Ma'am, with respect to the shipments, the
1785 ARCOS data provides information and we are currently unable to
1786 determine definitively --

1787 Ms. DeGette. So you don't know.

1788 Mr. Doherty. It is my understanding currently that we have
1789 information relative to companies involved and we are reviewing
1790 that data to determine what we can legally --

1791 Ms. DeGette. And I assume we will get that answer too,
1792 correct?

1793 Mr. Doherty. Yes, ma'am.

1794 Ms. DeGette. Okay.

1795 Dr. Volkow, I wanted to ask you a question about the naloxone.
1796 You had a really snappy spray of the naloxone that you used,
1797 but I think you can probably tell us that most of the people who
1798 are distributing naloxone cannot afford that; isn't that
1799 accurate?

1800 Dr. Volkow. Thanks for the question because I think it is
1801 very important.

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1802 Ms. DeGette. Okay.

1803 Dr. Volkow. We can have very fancy scientific tools that
1804 are so expensive that nobody can afford it.

1805 Ms. DeGette. Right.

1806 Dr. Volkow. This thing costs \$37.50.

1807 Ms. DeGette. Well, unfortunately, I -- what is the
1808 manufacturer of that?

1809 Dr. Volkow. This is Opiant and it is in partnership with
1810 the Adapt Pharma, so.

1811 Ms. DeGette. Okay. So the Adapt price in 2016 according
1812 to the New England Journal of Medicine was \$150. And in fact,
1813 in the August recess this year, I went over to the Harm Reduction
1814 Center in Denver. I actually got trained how to use naloxone
1815 and they gave me some naloxone that they give out to people.
1816 They told me they can't afford to use that. And what they gave
1817 me was this little vial of chemicals and they gave me a syringe
1818 and another little vial which I actually learned how to inject
1819 somebody, and the reason they use that is because that one costs
1820 only \$39.50. And so my point to you and the point I want to
1821 make to the chairman, we are going to have to do some more
1822 investigation in this committee. This is where it intersects
1823 with the increase in prescription drug prices. Because the auto
1824 injector was \$690 and now it is \$4,500, the one that you have
1825 got there it is \$150. Even the one I have here, between I think
1826 2014 and 2016 has gone up to 39.60.

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1827 So it is great to have naloxone for people, but if you don't
1828 have something that is easy to administer because the prices are
1829 just going up, then it is not going to be usable.

1830 Dr. Volkow. And I completely resonate with you we want to
1831 do things that are affordable. But I want to comment on the notion
1832 that this implementing the syringe does not deliver naloxone at
1833 sufficiently high concentrations because it is very diluted.
1834 So we not only have to give something that is affordable, but
1835 we need to give something that is effective.

1836 Ms. DeGette. You are totally right. I agree, thank you.
1837 Thanks, Mr. Chairman.

1838 Mr. Burgess. The chair thanks the gentlelady. The
1839 gentlelady yields back. The chair recognizes the gentleman from
1840 Ohio, Mr. Latta, 5 minutes for questions, please.

1841 Mr. Latta. Well, thank you very much, Mr. Chairman. And
1842 thank you very much to our panel today. We really appreciate
1843 you being here and this is a very, very important hearing that
1844 we are having today. Ohio, in 2015, we lost 3,050 people because
1845 of opioid overdoses and last year that total went up to 4,050.
1846 And our county coroners are now predicting that unfortunately
1847 we are on a pace to exceed the 2016 numbers.

1848 And I have my second opioid forum and that was held last
1849 week and, you know, when you are talking about these statistics
1850 of 3,050 or 4,050 people losing their lives, you know, those are
1851 the statistics but you put a face with them. And I talked with

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1852 a parent who had lost a child because of opioid overdose and it
1853 is, you know, it is heartbreaking. And so I am very happy that
1854 you are here today because this is a very important subject and
1855 we are in an epidemic across this country.

1856 And Dr. McCance-Katz, if I can start with you, CARA provided
1857 significant funding for states to expand substance use disorder
1858 treatment through grants administered by SAMHSA. In addition,
1859 CARA required that grantees submit data that will be posted online
1860 and easily searchable. Can you provide us with a status update
1861 of those requirements?

1862 Dr. McCance-Katz. Yes. So SAMHSA has awarded grants under
1863 the CARA initiative, the legislative requirements. Some of those
1864 we call this our MAT-PDOA program which is focused on
1865 medication-assisted treatment specifically for prescription
1866 opioids and heroin users. And so we are collecting data and that
1867 data will be available at the end of the program and it will be
1868 available to individuals to easily analyze, yes.

1869 Mr. Latta. Let me follow up too. And what accountability
1870 measures is SAMHSA requiring to make sure of states to make sure
1871 that that grant money is being wisely spent out there?

1872 Dr. McCance-Katz. Yes. Thank you for that question. What
1873 is required is that they submit to SAMHSA their plans for their
1874 states and what practices they intend to use. We review those.
1875 We provide guidance to them. And in the terms and conditions
1876 of grant award they are required to use evidence-based practices

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1877 going forward and so we will be working very closely with them.

1878 Now that requires that we provide them technical assistance
1879 and so that they can make determinations of what evidence-based
1880 practices are best for their communities, every state being
1881 different of course. And we are developing a new program of
1882 enhanced technical assistance where we will help states to get
1883 experts from the various fields that provide care in substance
1884 use disorder treatment -- psychiatrists, addiction medicine
1885 specialists, advanced practice nurse practitioners, physician
1886 assistants, social workers, peers -- that will be available to
1887 states to help them as they think through their needs and put
1888 evidence-based practices in place.

1889 Mr. Latta. Well, thank you. And when we had the forum last
1890 week in my district one of the things that came up, and this will
1891 pretty much be a yes or no answer for all of the panel that is
1892 here today, part of the issue is for a lot of the folks out there
1893 is a lack of reliable information and data that is available out
1894 there and it is difficult for many of especially smaller
1895 communities to find funding streams and access information on
1896 how effective government programs have been to combat opiate
1897 abuse. I am working on a bill right now that would create a
1898 publicly accessible electronic database to help mitigate these
1899 problems.

1900 And I would just like to ask each of you real quickly if
1901 yes or no would you all be, as we are working on this legislation

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1902 to collaborate with me to make sure we can get this information
1903 out there to the public, because again it is a very, very difficult
1904 thing for the smaller communities, smaller agencies to do. So
1905 if I could just go right down the line, if I could ask for your
1906 cooperation on that.

1907 Dr. Gottlieb. Yes, sir, Congressman.

1908 Dr. McCance-Katz. Yes, happy to do that.

1909 Mr. Doherty. Yes, sir. We would be happy to work on that.

1910 Dr. Schuchat. Absolutely.

1911 Dr. Volkow. We would be delighted.

1912 Mr. Latta. Well, thank you very much. And maybe if I can
1913 just follow up with the remaining time that I have with FDA.

1914 You know, when we were talking and you mentioning, Doctor, about
1915 that you know what we have with the epidemic we have in the United
1916 States, but looking around the world, do other countries have
1917 the same situation that we have with this opioid epidemic?

1918 Dr. Gottlieb. I would defer to my colleague from SAMHSA,
1919 but my experience with the data is no, Congressman, and
1920 prescribing in other countries isn't as rampant as it is here
1921 in the United States.

1922 Mr. Latta. So you are saying it is on the prescribing side
1923 because of where we have gone.

1924 Maybe I could, Mr. Chairman, I am a little bit over my time
1925 but --

1926 Dr. Gottlieb. Certainly that started on the prescribing

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1927 side. We still have, I think it is a fair assessment we still
1928 have too many prescriptions being written particularly for the
1929 IR formulations of these drugs, 190 million prescriptions a year
1930 represents 90 percent of all the prescriptions that are written
1931 for opioids. But increasingly, it is shifting to a problem of
1932 illicit drugs and low-cost alternatives which are the heroins
1933 and the synthetic fentanyls.

1934 Mr. Latta. Well, thank you very much, Mr. Chairman. My
1935 time is expired.

1936 Mr. Burgess. The gentleman is correct, his time has
1937 expired. The chair recognizes the gentleman from Pennsylvania,
1938 Mr. Doyle, 5 minutes for questions, please.

1939 Mr. Doyle. Thank you, Mr. Chairman.

1940 Based on CDC data in 2015, over 4,200 individuals age 15
1941 to 24 died of drug-related overdose deaths. This is an increase
1942 of almost 200 percent since 2000 when the number was less than
1943 1,500. So we know that children, adolescents, and young adults
1944 are part of this epidemic. Not just because they are losing
1945 parents and being sent to foster care, but because they are using
1946 drugs, getting addicted, and dying. The Children's Hospital of
1947 Pittsburgh has screened more than 31,000 children in the first
1948 3 months of their new program rollout and has already found 60
1949 children to be at high risk for or at levels of substance abuse.

1950 So my question for the panelists, and I would start with
1951 Dr. McCance-Katz, what resources are being directed across the

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1952 agency to the prevention and treatment of substance use disorder
1953 in children and adolescents?

1954 Dr. McCance-Katz. We have a number of initiatives that
1955 address substance abuse and substance abuse prevention in
1956 children and adolescence and I will just start with pregnant women
1957 who are opioid-dependent and we have programs to assist them with
1958 treatment. We also make technical assistance available to
1959 providers so that they can provide the best care to women and
1960 their infants who may be born physically dependent on opioids
1961 and need treatment. We also have a program that has just recently
1962 started that will address issues and what we call transitional
1963 age youth.

1964 And so the age group that you are speaking of and this would
1965 be 18 to 25 year olds is a difficult group to treat.

1966 Traditionally, they are more difficult to engage in treatment.

1967 We don't have a lot of information as we do in older, in adults
1968 as to what works best for them. And so we are bringing experts
1969 into SAMHSA to give us information about how to work best with
1970 this age group and to provide that guidance then to states and
1971 communities.

1972 In addition, we are also putting together a workgroup that
1973 will look at the effects of opioids on the developing fetus, and
1974 so what kinds of issues could be expected in terms of development
1975 of children who have been opioid-exposed in utero. That is an
1976 ongoing project.

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1977 I might though ask my colleague Dr. Volkow to mention some
1978 of the initiatives and research they are doing, some excellent
1979 research at NIH on these issues as well.

1980 Dr. Volkow. I want to highlight only one because I think
1981 that the issue of preventing the drug use among teenagers and
1982 young individuals is one of the most impactful things that we
1983 can do. So one of our main initiatives in partnership with other
1984 institutes is that a study that will be prospectively following
1985 10,000 children as they transition into adulthood and
1986 periodically assessing them for their brain development in order
1987 to understand how exposure to drugs actually influences the
1988 development and architecture of the brain.

1989 And that is very important, because if we understand it then
1990 that we can tailor intervention to try to reverse them, to reverse
1991 them and provide resilience for those that may have
1992 vulnerabilities. So this is one of our top priorities, to
1993 actually protect that adolescent from getting exposed to drug
1994 and if they get exposed how do we actually restructure it into
1995 one intervention that will provide them with resilience.

1996 Mr. Doyle. Yes.

1997 Dr. Schuchat. Maybe I could just say some of the CDC
1998 initiatives really do target that age group. In terms of improved
1999 prescribing, we know that a lot of people who become addicted's
2000 first prescriptions were for, you know, youth sports-related
2001 problems for instance. Our consumer-facing communication

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2002 campaign really targets the families of survivors, the parents
2003 who have lost a child.

2004 And then the last thing I would mention is a technical package
2005 that CDC released about efforts that can intervene against the
2006 problem of youth suicide which has an overlap with the opioid
2007 issue.

2008 Mr. Doyle. Thank you. I would just like to, you know, I
2009 appreciate all these answers, but I would just like to add that
2010 it seems a lot of what is being discussed also needs to be tied
2011 into children having health insurance and access to care.

2012 And in my state in Pennsylvania, over 1.2 million kids rely
2013 on Medicaid and CHIP for their health care and as we all know,
2014 we have spent a lot of time this year talking about huge cuts
2015 to Medicaid and this body, unfortunately, has yet to come to an
2016 agreement on how to fund CHIP. So I guess it really begs the
2017 question how much do all of these programs matter if children
2018 don't have basic health insurance.

2019 Mr. Chairman, with that I see my time is expired and I will
2020 yield back.

2021 Mr. Burgess. The gentleman yields back. The chair thanks
2022 the gentleman. The chair recognizes the gentleman from Kentucky,
2023 the vice chairman of the Health Subcommittee, 5 minutes for
2024 questions.

2025 Mr. Guthrie. Thank you, Mr. Chairman. Thank you for
2026 yielding. I appreciate everybody being here, this is important.

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2027 Kentucky is like a lot of states has had its share of
2028 tragedies through the heroin and opioid overdoses. Our state
2029 legislators, our governor, and everybody is working very hard,
2030 our physicians, trying to move forward, and our Drug Task Force
2031 folks, I mean it is all-out effort and it is still a very, very
2032 serious problem as that is why we are here today.

2033 Dr. McCance-Katz, I wanted to ask you a question. A
2034 behavioral health provider in my district reported that it is
2035 not uncommon -- not uncommon, I guess that means it is a little
2036 less than common, but not uncommon -- for some of the managed
2037 care organizations to request up to 70 pages of authorizing
2038 paperwork from their board-certified addiction specialists to
2039 treat one patient with medication-assisted treatment. This
2040 provider stated that it can require 2 to 3 hours of staff time
2041 to submit the requested paperwork to treat one patient.

2042 In your testimony you mentioned the Medication Assisted
2043 Treatment for Prescription Drug and Opioid Addiction grants
2044 within SAMHSA. Would you please elaborate on this program and
2045 inform me of what SAMHSA is currently doing to evaluate and ensure
2046 patients receive timely treatment and quality providers are able
2047 to deliver care to their patients?

2048 Dr. McCance-Katz. So SAMHSA has a number of initiatives
2049 to bring people to medical attention early on. We have a program
2050 that has been in place for a number of years. Not the program
2051 that you are speaking of, but it is called our SBIRT program which

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2052 is Screening, Brief Intervention, and Referral to Treatment.
2053 This is a paradigm that involves training primary care providers
2054 on how to screen for hazardous substance use or use that has
2055 evolved into a use disorder and get people to appropriate
2056 treatment. So we do a lot of work in that area.

2057 In addition, we have our what I said was our MAT-PDOA,
2058 Medication Assisted Treatment program that is funded through the
2059 CARA act and this is a program that allows states to develop
2060 programs that focus on medication-assisted treatment to getting
2061 that to their community. States can do this in any number of
2062 ways.

2063 In fact, before I had this position I had one of those
2064 MAT-PDOA grants in Rhode Island and what we did was we put together
2065 what we called a center of excellence for the treatment of opioid
2066 use disorder to stabilize people coming into treatment for serious
2067 opioid addiction and then to transfer them to community providers
2068 who were willing to take on this care. They previously were not
2069 willing to do that because, because they were concerned that they
2070 didn't have the skill set needed to deal with all of the aspects
2071 that addiction brings to care.

2072 And so every state will do this differently, but those are
2073 the types of programs and there are different iterations. We
2074 call them sort of hub and spoke models where you have -- well,
2075 I will stop there.

2076 Mr. Guthrie. Okay, thanks. Well, I think we agree that

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2077 patients have to receive timely treatment.

2078 Dr. McCance-Katz. Yes.

2079 Mr. Guthrie. And at the facility in my district they found
2080 that in 1-year follow up the majority of patients on
2081 medication-assisted treatment are still actively involved in the
2082 treatment and these individuals are less likely to be incarcerated
2083 and to relapse, and to be employed. So, you know, it is important.

2084 One more question for you then. One of the recommendations
2085 of the interim report of the President's opioid commission was
2086 to repeal the prohibition of Medicaid paying for services for
2087 some patients in an institution for mental diseases or IMD
2088 exclusion as we all refer to it here. I have heard from many
2089 that we should dial back this limitation in certain instances,
2090 if not entirely, particularly in the midst of a national opioid
2091 epidemic where only a small percentage of individuals who need
2092 treatment are getting it.

2093 Do you support some kind of repeal of the IMD exclusion and
2094 if so what should it look like?

2095 Dr. McCance-Katz. What I would say is that this is an issue
2096 for the President and Congress to deal with, and at HHS we would
2097 be happy to implement whatever you decide on in that area.

2098 Mr. Guthrie. Okay. One of the issues that when we deal
2099 with this repeal of the IMD exclusion has been the subject of
2100 a lot of debate for a couple years and the greatest barrier that
2101 is preventing is the cost to the federal government. In 2016,

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2102 CBO estimated a 40 to 60 billion year cost over 10 years. What
2103 do you think Congress and CMS and SAMHSA or the states could do
2104 to try to counter this major cost increase?

2105 Dr. McCance-Katz. Again this is not an area that the
2106 Administration has a position on that I can provide to you today,
2107 but certainly we would be happy to work with you on those kinds
2108 of issues. But I will say one thing. Not everything with
2109 addiction needs to be in an inpatient setting and in fact most
2110 people can be treated very effectively on an outpatient basis
2111 with medication-assisted treatment, psychosocial supports, and
2112 community supports.

2113 Mr. Guthrie. Okay, thank you very much. I appreciate those
2114 answers and I appreciate your position. And my time is expired
2115 and I yield back. Thanks.

2116 Mr. Burgess. The chair thanks the gentleman. The
2117 gentleman yields back.

2118 The chair recognizes the gentlelady from California, Ms.
2119 Matsui, 5 minutes for questions, please.

2120 Ms. Matsui. Thank you, Mr. Chairman, and I want to thank
2121 the witnesses for being here today.

2122 We all know the opioid epidemic affects us all and certainly
2123 no community is immune to this disorder. This committee has done
2124 important work to begin addressing the epidemic but I must
2125 reiterate the point that we can't talk about this crisis without

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2126 acknowledging the importance of protecting Medicaid. Addiction
2127 is a medical condition and requires treatment. And for many,
2128 that treatment is made available through the Medicaid program,
2129 which the ACA expanded to millions more adults in need. Taking
2130 away those critical services will certainly take us backwards.

2131 The Prevention and Public Health Fund created by the ACA
2132 to make targeted investments in prevention programs in our
2133 Nation's public health infrastructure now funds 12 percent of
2134 CDC's annual budget. If the Prevention Fund were to be repealed,
2135 states would lose billions of dollars to spend on programs in
2136 communities, including programs to address the opioid crisis.

2137 Dr. Schuchat, can you discuss the work that CDC has done
2138 on public health research and infrastructure relating to the
2139 opioid epidemic?

2140 Dr. Schuchat. CDC is really focused on strengthening
2141 prevention by improving prescribing implementation of our
2142 treatment guidelines for chronic pain, the use of opioids and
2143 chronic pain with efforts to find out how can we best implement
2144 them, making it easy for clinicians, doctors, pharmacists, nurse
2145 practitioners to prescribe carefully.

2146 We are also focused on evaluating the medication-assisted
2147 treatment that we hear about to understand what works best for
2148 different circumstances and evaluating the naloxone distribution
2149 program that SAMHSA has as well.

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2150 Lastly, we are focused on this consumer-facing campaign,
2151 evaluating its impact as we try to scale it up. Right now, we
2152 have been able to fund four states to launch the campaign and
2153 22 of the states that receive funding from CDC will be using their
2154 funds to mount it but we really hope that that will be able to
2155 go nationwide and reach the public.

2156 Ms. Matsui. Well would that be affected if CDC funding were
2157 cut by 12 percent across the board?

2158 Dr. Schuchat. No. Every dollar that goes for prevention
2159 is lifesaving and cost-saving. And so we will work with Congress
2160 with the resources that we get to do the most good.

2161 Ms. Matsui. Okay, in order to truly address the opioid
2162 crisis, we will need to build up our behavioral health system
2163 so that everyone has access to prevention and treatment in their
2164 communities. That is the goal of the Excellence in Mental Health
2165 Demonstration Project that my colleague, Representative Lance
2166 and I worked to create and that is now being administered by SAMHSA
2167 in eight states.

2168 Dr. McCance-Katz, can you give us an update on the
2169 implementation of Certified Community Behavior Health Clinics?

2170 Dr. McCance-Katz. Yes, I can. So those funds have been
2171 released to the states that were -- the eight states as you
2172 mentioned that were selected. These states are putting together
2173 what we call Certified Community Behavioral Health Centers, which

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2174 bring together the elements of treatment, evidence-based
2175 treatment for serious mental illness and for substance use
2176 disorders so that an individual can get all of the care they need
2177 because we know that co-occurring disorders are quite common in
2178 one place.

2179 We think the model is quite nice. It is a model that is
2180 not a standard fee for service model but it is a bundle payment
2181 similar to what goes on in community health centers. We are very
2182 hopeful that that is going to be a model that will yield positive
2183 results and we hope can be sustained.

2184 Ms. Matsui. Well, we hope so, too, absolutely.

2185 Now, in addition to the short-term funding we provided in
2186 21st Century Cures, we authorized additional funding for a variety
2187 of programs intended to address the mental health and substance
2188 use treatment system in a more long-term manner. For example,
2189 we authorized additional funding for treatment and recovery for
2190 homeless individuals, behavioral health integration and
2191 community health centers, mental health awareness training, and
2192 more.

2193 Dr. McCance-Katz, can you provide an update on some of these
2194 programs authorized or reauthorized in 21st Century Cures?

2195 Dr. McCance-Katz. So we are working with Federal partners
2196 to address issues of behavioral health and primary care. We have
2197 a strong alliance with HRSA. And as you know, HRSA just released

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2198 \$200 million in new grant funding to integrate substance abuse
2199 treatment into community health centers. SAMHSA works with them
2200 on technical assistance to assure that evidence-based practices
2201 are being used.

2202 We also continue our homeless grant initiatives at SAMHSA
2203 and we could get you the data if you would like to have it but
2204 --

2205 Ms. Matsui. That would be lovely.

2206 Dr. McCance-Katz. -- we see very positive results in
2207 getting people stably housed.

2208 Ms. Matsui. Okay, thank you very much and I see my time
2209 has expired. Thank you.

2210 The Chairman. The chair now recognizes the gentleman from
2211 New Jersey, Mr. Lance, for 5 minutes.

2212 Mr. Lance. Thank you, Mr. Chairman and good afternoon to
2213 the panel.

2214 Congresswoman Matsui and I are a tag team on the
2215 demonstration projects in the eight states and I am sure you are
2216 shocked to learn that New Jersey and California are two of the
2217 eight states.

2218 Now I am increasingly of the view that fee for services is
2219 outdated and outmoded. To Dr. McCance-Katz, do we have analysis
2220 yet on the bundled payment system for the eight states?

2221 Dr. McCance-Katz. No, sir, we don't. We don't but we will

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2222 be following that very closely and happy to share when we get
2223 it.

2224 Mr. Lance. Do you have any indication when that might be
2225 within the next year or --

2226 Dr. McCance-Katz. I think within a year but this has --
2227 really it has just started. And so I would say in a year, yes.

2228 Mr. Lance. Thank you. And the Congresswoman and I are
2229 working on expanding that program. I think we are both of the
2230 belief that this is the wave of the future and, certainly, I will
2231 continue to work with my colleagues in that area.

2232 According to CMS, the Medicare population has among the
2233 highest and fastest growing rates of diagnosed opiate use
2234 disorder; if I understand it, currently six of every one thousand
2235 beneficiaries. But CMS policy appears to be blocking access for
2236 our Nation's senior citizens to receive treatment for their
2237 substance use disorder with two primary treatment modalities,
2238 buprenorphine and methadone.

2239 I know this is not your agency, Dr. McCance-Katz, but in
2240 what ways, in your judgment, could CMS work with SAMHSA and other
2241 Federal partners to ensure that senior citizens utilizing
2242 Medicare who need treatment can get the help they need?

2243 Dr. McCance-Katz. Yes, so we do work collaboratively with
2244 all of our sister agencies within HHS, CMS being one of them.

2245 And SAMHSA has the ability to provide CMS any information on

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2246 the effectiveness of these treatments in all age groups and we
2247 would advocate for that.

2248 Mr. Lance. Thank you very much.

2249 Mr. Doherty, my understanding is, as the legal prescription
2250 drug supply is constrained the use of street heroin increases.

2251 I suppose this is logical because addicts seek to get the drugs,
2252 they, unfortunately, are addicted, and regardless of the source
2253 or the medium.

2254 Is there a direct statistical correlation between the
2255 availability of prescription opioids and increased usage rates
2256 of illegal heroin?

2257 Mr. Doherty. Yes, sir. As you correctly point out and we
2258 appreciate your question, the statistics show that 80 percent
2259 of first initiate heroin users, so 80 percent of first-time heroin
2260 users are now getting to that dark place through the use of
2261 prescription opioid pain killers.

2262 Mr. Lance. Eighty percent?

2263 Mr. Doherty. Eighty percent of first-time heroin users.
2264 Four out of five first-time heroin users are now using heroin
2265 and turning to cheaper heroin. And with the advent of fentanyl
2266 coming into our country in pill form, many times these individuals
2267 are playing Russian roulette. They truly do not know what they
2268 are getting and they truly are taking their own lives in their
2269 hands. And DEA is committed to not only stopping counterfeit

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2270 prescription pill manufacturing but also elicit importation of
2271 fentanyl, as I mentioned in my opening statement.

2272 Mr. Lance. Is there a way that we can use advanced data
2273 metrics to predict where users will seek illegal heroin so that
2274 we can direct interdiction resources to those places?

2275 Mr. Doherty. Sir, we have many programs currently initiated
2276 that normally use data analytics but also use investigative
2277 resources across the spectrum to show where places will eventually
2278 have heroin imported to.

2279 So in other words, our DEA 360 Strategy has hit some of the
2280 hardest communities in the country that have been plagued by this
2281 disease and this opioid scourge.

2282 Mr. Lance. Where would some of those places be in the
2283 country, the hardest hit places?

2284 Mr. Doherty. Dayton, Ohio; Albuquerque, New Mexico;
2285 Manchester, New Hampshire. These are places that our DEA 360
2286 Strategy has been deployed to. It is a three-prong strategy.
2287 We use traditional enforcement, data analytics, diversion
2288 control, and community outreach in bringing the communities back.

2289 Mr. Lance. So you mentioned Dayton, for example. So these
2290 are just average American cities with the same challenges that
2291 the rest of the country has.

2292 Mr. Doherty. Well, yes, sir. And certainly the opioid
2293 epidemic is exasperated by the controlled prescription drugs now

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2294 getting people to the point where they have an opioid disorder,
2295 switching to cheaper heroin and now really playing, as I said
2296 Russian roulette with respect to content.

2297 Mr. Lance. And my time has expired. I yield back.

2298 Thank you, Mr. Chairman.

2299 The Chairman. The chair thanks the gentleman. The chair
2300 recognizes the gentleman from California, Mr. McNerney, for 5
2301 minutes.

2302 Mr. McNerney. Well I thank the chair and I thank the
2303 witnesses.

2304 Ms. McCance-Katz, how would limiting access to treatment
2305 impact the opioid epidemic? So how is that going to affect it,
2306 limiting treatment?

2307 Dr. McCance-Katz. Well if treatment were limited, people
2308 would have more serious adverse events, deaths, inability to
2309 function in society, all of the fallout of opioid addiction.

2310 Mr. McNerney. What about limiting early intervention care?

2311

2312 Dr. McCance-Katz. I am sorry?

2313 Mr. McNerney. Early intervention.

2314 Dr. McCance-Katz. Early intervention.

2315 Mr. McNerney. Same story, right?

2316 Dr. McCance-Katz. Yes, sir.

2317 Mr. McNerney. Well the Affordable Care Act and Medicaid

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2318 expansion have been crucial for treatment for those with opioid
2319 use disorders and also for providing early intervention care.

2320 I know this has been the case in my district, which includes
2321 Stockton, California, a city where opioid overdoses up to six
2322 times higher than the State average.

2323 So I am very disappointed that instead of focusing on finding
2324 solutions to address the opioid epidemic, Republicans have been
2325 engaged in an nonstop effort to repeal Affordable Care Act, which
2326 would have a devastating impact on people struggling with opioid
2327 use disorders and would be catastrophic for combating the opioid
2328 epidemic.

2329 So, Ms. Volkow, your written testimony mentions the HHS
2330 5-Point Opioid Strategy. The fourth pillar of the strategy is
2331 to support cost -- support cutting-edge research that advances
2332 our understanding of pain and addiction. What are some examples
2333 of recent developments in this area of non-addictive pain
2334 management that resulted from your research?

2335 Dr. Volkow. This is quite extensive. And as Dr. Gottlieb
2336 was mentioning, in the area of pain, for example, one of our
2337 partnerships has been to develop abuse deterrent formulations
2338 of opioid medication so that the person cannot divert them and
2339 abuse them and there are several drugs already approved by the
2340 FDA.

2341 We are also working with pharmaceuticals to develop

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2342 non-opioid based medications that are going to be effective in
2343 addressing pain.

2344 And in the field of opioid use disorder, for example, we
2345 have partnered with pharmaceuticals to develop extended release
2346 formulation such that the patient does not need to go to the clinic
2347 on a daily basis to get their medication but can go every week,
2348 every month, every 6 months and that improves compliance. And
2349 as a result of compliance, they are also protecting them from
2350 actually overdosing.

2351 So these are some of the examples in terms of successful
2352 partnerships that are developing treatments for those that need
2353 them.

2354 Mr. McNerney. So what are the ultimate goals of this
2355 partnership, then?

2356 Dr. Volkow. To accelerate and incentivize pharmaceutical
2357 industry to get into these spaces. Pharmaceutical industry has
2358 not been traditionally engaged in developing medications for
2359 addictions. Addictions are too stigmatized. It was felt that
2360 they wouldn't recover their investment. So we have to reach them,
2361 by being a Federal agency to reach those products and then present
2362 it to pharmaceuticals so that they can bring them to the market.

2363 In the pain space, also, there is a need of energizing
2364 pharmaceuticals because they have been decreasing their
2365 investment on medications for brain-related diseases, including

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2366 pain. So how do we create a partnership engaging also FDA to
2367 ensure that they see an incentive to move forward and develop
2368 pain treatments? Because right now, of course, they are making
2369 already a lot of money from selling opioid medications. So it
2370 is a little bit they are in competition with themselves. So how
2371 do you incentivize them to go beyond that?

2372 Mr. McNerney. So it sounds like we would have -- Congress
2373 would have a role in --

2374 Dr. Volkow. Yes.

2375 Mr. McNerney. -- developing those practices.

2376 Dr. Volkow. And, indeed, there are ways in which Congress
2377 can help develop, facilitate. I mean for example, in terms of
2378 how do you make an incentive for a pharmaceutical to go into the
2379 development of medications for addiction, could you not treat
2380 them like you treat for example developmental vaccines? So can
2381 you get them expansion of their paths? Can you give them priority
2382 evaluation?

2383 So the Institute of Medicine did an analysis on how actually
2384 changes in policy could lead to incentivizing pharmaceuticals
2385 to help us develop better treatments for opioid addiction.

2386 Mr. McNerney. Thank you.

2387 Ms. Schuchat, do you think that high school sports are a
2388 significant role in opioid addiction?

2389 Dr. Schuchat. What I would say is I don't know. I think

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2390 that the principle issue is to change the culture in the doctor's
2391 office or the nurse practitioner's office to help people follow
2392 our recommendations about chronic pain. We say think twice
2393 before starting an opioid. Start low. Go slow, if you are
2394 increasing it. And follow-up regularly about whether the goals
2395 of treatment are being met.

2396 A lot of our history as docs over the past 15 years or so
2397 has been to begin with opioids, where we really don't think that
2398 is a good idea.

2399 Mr. McNerney. Thank you.

2400 Mr. Chairman, I yield back.

2401 The Chairman. I thank the gentleman.

2402 I now recognize the gentleman from Mississippi, Mr. Harper,
2403 for 5 minutes.

2404 Mr. Harper. Thank you, Mr. Chairman and thanks to each of
2405 you for being here on this very critical subject.

2406 I mean the opioid epidemic is certainly destroying our
2407 country and we see this every single day and how it is impacting
2408 lives and families. You know you have seen families that have
2409 been lost and destroyed because we haven't been able to provide
2410 perhaps the resources, perhaps the right action to take. And
2411 I know we have made great resources in making -- great strides
2412 in making those resources available. But one of the biggest
2413 concerns that I have -- and I will say this. I think this may

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2414 be some of the most important work that our committee is going
2415 to do this year is to try to assist and provide some guidance
2416 and those resources here.

2417 But one of the biggest problems that we see on the ground
2418 is how do you get those resources that we put out to the local
2419 level, particularly predominantly this country is still rural
2420 in most of our geography. So how do you get that to rural America?
2421 How do we do that?

2422 Because you know when you have, perhaps, a county with some
2423 small cities or municipalities, law enforcement is stretched so
2424 thin that these groups can operate with impunity on selling and
2425 destroying those lives.

2426 So that would be my question is, How do we get this down
2427 to rural America? And I would like each of you to give me your
2428 quick thoughts on that.

2429 Dr. Gottlieb. I would defer to my colleague from SAMHSA
2430 on that, Congressman, but I would echo the need to get the
2431 treatments into those settings.

2432 Dr. McCance-Katz. Yes, and so we have to use technologies
2433 to reach rural communities and we have a couple of programs at
2434 SAMHSA that address rural health directly. One of those is
2435 telehealth. That is an evolving way of providing care so that
2436 you can really extend the reach of a single practitioner who may
2437 be a distance away from where they are providing care but that

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2438 is a model that we are very much working on at SAMHSA with partners
2439 in various states and we are supporting efforts in developing
2440 those models.

2441 And the other way that we do this is through some of our
2442 training programs. We have a lot of very effective training
2443 programs that SAMHSA sponsors and one of them is something called
2444 Project ECHO. What that is is a program where at a site you will
2445 have experts that get together and will be able to do conferencing,
2446 conference calls, video conferencing, and be able to talk with
2447 clinicians in distant areas about problems that they are having
2448 and how to provide care to patients.

2449 Mr. Harper. You mentioned telehealth, which obviously is
2450 an amazing item and certainly very important in my home State
2451 of Mississippi because University of Mississippi Medical Center
2452 has been one of leading proponents of that for almost 15 years
2453 that have developed that in a great way.

2454 But then we are talking about rural America. So yes, we
2455 have telehealth but then we also have problems with broadband
2456 access in those same rural areas that are stretched for resources.

2457 So we have got to come up with a plan here that actually will
2458 help not only in law enforcement and prosecution. And while these
2459 things are here, usually you see these people after they have
2460 entered into a problem and are looking for treatment and help.

2461 We want to stop this before it can happen and so that is

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2462 why I think we are in a great need there.

2463 We are very limited on time. Dr. Schuchat, why don't you
2464 give me your response?

2465 Dr. Schuchat. Yes, just to say that CDC is funding 45 states
2466 and D.C. right now. And in many of those states, it is the rural
2467 populations that are being harder hit with the opioid epidemic.

2468 We just did a report on that in our Morbidity and Mortality Weekly
2469 Report.

2470 But we have injury control research centers, for instance
2471 in West Virginia, that have been doing rural pilots of
2472 distribution of naloxone, the Kentucky coalitions that are really
2473 looking at what works in those rural communities that have been
2474 hardest hit. I think we heard it before that every State is
2475 different and there are different solutions but we have really
2476 been trying to get resources out there to the front line so that
2477 the solutions will make sense for the communities.

2478 Mr. Harper. And you have had a rollout of communications
2479 program, obviously, that I know you have discussed. Is that
2480 having the right impact? Is that going to be something that will
2481 help on that preventive end?

2482 Dr. Schuchat. It is just beginning and the four states that
2483 we have just launched it in were hard-hit states, including
2484 Kentucky, New Mexico, Ohio, and Massachusetts. Those are areas
2485 that high burden. We are hoping, though, that it will get rolled

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2486 out much more widely.

2487 Mr. Harper. And we look forward to seeing the impact of
2488 that.

2489 With that, I yield back.

2490 The Chairman. I thank the gentleman.

2491 I now turn to the gentleman from Vermont, Mr. Welch, for
2492 5 minutes.

2493 Mr. Welch. Thank you very much. I am delighted to have
2494 you here and I want to talk to Mr. Doherty from the DEA.

2495 All of us on this panel were involved in hearings on the
2496 Ensuring Patient Access and Effective Drug Enforcement Act and
2497 it passed out of this committee unanimously. I was one of the
2498 co-sponsors, along with Mrs. Blackburn and Mr. Costello. And
2499 that was the subject of a commentary or a report by 60 Minutes
2500 and the Washington Post, both respected journalistic
2501 organizations.

2502 And those of us who supported the bill, and that is all of
2503 us here, were very concerned and we want to get to the bottom
2504 of it. In fact, I have sent a letter to Mr. Walden, the chairman,
2505 asking for a full investigation allowing the whistle blower to
2506 come in, allowing the DEA to get in because bottom line, we are
2507 on the same page. We want to do everything we can to stem the
2508 tide of illegal opioids and we want to pass legislation that by
2509 no means handcuffs the ability of your organization to do its

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2510 job.

2511 But I have got a chart here because I want to ask a couple
2512 of questions. The focus of that report had to do with the falloff
2513 in the use of immediate suspension orders. And as I understand
2514 it, that order was one where pretty much on any suspicion that
2515 the DEA had, they could close down a distributor. But if you
2516 look at the chart, the reduction went from 65 immediate suspension
2517 orders in 2011 down to five. That was a low point and that was
2518 in 2015, correct?

2519 Mr. Doherty. Yes, sir.

2520 Mr. Welch. And it went up to nine in 2016. So the law that
2521 we supported was signed into law in 2016. So here is my question.

2522 Unless the effect of the law occurred before the passage of the
2523 law, the law that we passed was after there had been already a
2524 decline in the use of that tool, one of many tools by the DEA.

2525 Is that correct?

2526 Mr. Doherty. That is absolutely correct, sir.

2527 Mr. Welch. So is it fair to say, because I think that we
2528 need some reassurance on this, that the law we passed, whatever
2529 its issues and I want to get to those, was not responsible for
2530 the preexisting decline in the use of that tool, the immediate
2531 suspension order.

2532 Mr. Doherty. Sir, to answer your question, the law that
2533 was passed in April of last year, it is too early to tell what

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2534 the demonstrative impact of the --

2535 Mr. Welch. No, wait. I am asking something else because
2536 I want to get to that.

2537 Mr. Doherty. Yes, sir.

2538 Mr. Welch. But isn't it irrefutable that the demonstrable
2539 impact on immediate suspension orders, that those started
2540 declining before the law was in effect in 2016? You went from
2541 65 to 5 before the law had passed.

2542 Mr. Doherty. That is correct.

2543 Mr. Welch. So the law, obviously, was not what caused the
2544 decline in the use of that tool. You had many other tools and
2545 were using them vigorously. Thank you. Correct?

2546 Mr. Doherty. We have many tools. You are correct, sir,
2547 yes, we are using --

2548 Mr. Welch. Right but the immediate suspension -- because
2549 this is the heart of the question and we really have to know.
2550 We have to know. All of us have to know. That law that we passed
2551 occurred after immediate suspension orders had already declined
2552 from 65 down to 5, right?

2553 Mr. Doherty. That is correct.

2554 Mr. Welch. And then after the law was passed, it went up
2555 to nine.

2556 Mr. Doherty. That is correct.

2557 Mr. Welch. Okay. So we all want to help. And do you have

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2558 some specific legislative recommendations for our committee that
2559 we could take that would give additional authority within the
2560 Constitution to assist you in getting your job done?

2561 Mr. Doherty. Sir, thank you for that follow-up. And let
2562 me say from the diversion control perspective, we use a variety
2563 of tools. The tool you mentioned is an administrative action
2564 and we certainly look forward to working with Congress with
2565 Department of Justice oversight to ensure we have the most
2566 up-to-date tools.

2567 Mr. Welch. Look, you have got a very important job. We
2568 support it. Do you have recommendations, including any specific
2569 things you suggest we should do to amend the law we passed or
2570 even repeal the law we passed?

2571 Mr. Chairman, I bet I speak for every single member of this
2572 committee. We want to know that information because we would
2573 take that up immediately.

2574 Mr. Doherty. Yes, sir, and DEA shares your concern. And
2575 that matter is under coordination with the Department of Justice
2576 as we speak.

2577 Mr. Welch. All right. We need a date certain. I mean time
2578 is marching on. This story shocked folks and rightly so because
2579 everybody in America is just devastated by what is happening to
2580 friends, to family, to loved ones. Okay? So, we are ready to
2581 go.

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2582 And Mr. Chairman, I will leave it up to you but we are having
2583 a hard time, at times, getting the responses back. And now that
2584 this question is out there about a law where the suggestion is
2585 we did harm, not good, I think all of us want to correct that.

2586 The Chairman. Correct.

2587 Mr. Welch. I will leave it to you.

2588 The Chairman. Yes, Mr. Welch. And on behalf of the
2589 committee, my view has always been, when we pass a bill that is
2590 just the starting place. By the way, that is why we are having
2591 the hearing today is to look at is CARA working. Is 21st Century
2592 Cures Working? You need to go back and do the oversight and see
2593 what is working. And if something is not working, we need to
2594 know so that we can fix it.

2595 My question is, What led to the decline in use of what you
2596 showed there on the graph? Was there an internal decision that
2597 led to that? Are there people that are upset about it? I mean
2598 because that clearly all happened, as you point out, the law ever
2599 was passed, unanimously, by the way, House, Senate, President
2600 Obama signed it.

2601 So the question is, Why did the agencies stop using that
2602 tool or dramatically reduce use of that tool? That is the heart
2603 of the matter here. Who made those decisions? But when we can't
2604 even get basic information about who is supplying a pharmacy or
2605 two in West Virginia nine million pills in 2 years, it leads me

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2606 to believe we have much bigger issues at stake here we also have
2607 to deal with.

2608 So we look forward to working in partnership with you on
2609 this, Mr. Welch.

2610 I will now go to the gentleman from Texas, Mr. Olson for
2611 5 minutes.

2612 Mr. Olson. I thank the chair and welcome to our witnesses.

2613 Mr. Chairman, this may be the most important hearing this
2614 committee has in the 115th Congress because we are dealing with
2615 life and death. Life and death. I will bet someone in this room
2616 knows someone who has been addicted to prescription opiates.

2617 Some in this room may know someone who has died from the addiction.

2618 Some in this room may know someone who is addicted to illicit
2619 opiates. I guarantee you the people watching on C-SPAN know these
2620 people and they are hurting.

2621 My first question is for you, Mr. Doherty. You mentioned
2622 that the opioid prescription crisis is now expanding to other
2623 illicit drugs, mostly heroin. It is roaring back with a vengeance
2624 with a new synthetic sidekick cousin, fentanyl. I have been told
2625 a piece of fentanyl the size of a grain of salt can be lethal
2626 to a human being. It is that dangerous.

2627 The cartels, as you mentioned, are mixing up down there with
2628 heroin with stuff coming from China. There is no quality
2629 assurance. It is the cartels. That poison is coming to America.

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2630 And that means it is coming across the southern border, my own
2631 State of Texas.

2632 I talked to our Border Patrol yesterday about their
2633 enforcement actions. They say right now they capture about 50
2634 percent of the traffic coming across our border. They can do
2635 better. They will do better with more resources and support from
2636 Congress.

2637 But the cartels, they are good at adapting. When I was in
2638 the Navy, we were trying to get them down in Panama. And I would
2639 see submarines. They would come up here, go across, come up
2640 Northern Mexico, go across by San Diego, pop up at night. You
2641 can't see them. They dig tunnels. They can get over.

2642 So my question is, What is DEA doing to combat the opioid
2643 crisis coming across the border working with CBP, probably some
2644 of the Drug Task Forces, and also local authorities? What are
2645 you doing right now to stop drugs from coming across, the fentanyl
2646 mixed with illicit opiates?

2647 Mr. Doherty. Congressman, thank you for that question.
2648 I would point directly to our Special Operations Division, our
2649 Fentanyl Heroin Task Force. It is a multi-agency task force that
2650 collates, coordinates, and deconflicts information across all
2651 of the United States and all over the world, quite frankly. And
2652 we work closely with CBP and all of our Federal, State, and local
2653 partners.

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2654 However, as a command and control targeting center, our SOD,
2655 Special Operations Division, is specifically designed to look
2656 at cartel activity, and to target them at the appropriate level,
2657 and then, obviously, bring those seizures to bear, and follow
2658 up on leads within the domestic United States. We stand with
2659 all of our Federal partners in combatting this and share
2660 information on a routine basis.

2661 I truly believe it is a whole of government approach in that
2662 DEA partnered with Federal, State, and local agencies. We need
2663 to redouble all of our efforts. We can do better and we should
2664 do better.

2665 Mr. Olson. Another question. What is DEA doing to combat
2666 online sales of fentanyl and new psychoactive substances via the
2667 dark web, online sales, getting around the border?

2668 Mr. Doherty. Thank you for the follow-up, Congressman.
2669 With respect to online pharmaceutical sales, fentanyl sales, NPS,
2670 new psychoactive substances, DEA has been very aggressive in this
2671 area.

2672 Just last month, there was a joint takedown of AlphaBay,
2673 the world's largest dark net network for criminal activity,
2674 however, selling fentanyl and other dangerous drugs. It was
2675 estimated that this network earned approximately \$1 billion
2676 annually. It was a sweeping investigation with DEA, and the FBI,
2677 and others. And we think that DEA, in partnership with other

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2678 Federal agencies, in concert with our state and local agencies
2679 can make a difference with respect to dark net trafficking and
2680 internet trafficking. And we will stand with all of our partners
2681 in doing so.

2682 Mr. Olson. Thank you. I am out of time. I want to conclude
2683 by saying the fact that thousands of Americans have died with
2684 these prescription drugs, illicit drugs is a collective failure
2685 of American society. And Americans know that failure is not an
2686 option. It never has been. It never will be. Let's get this
2687 fixed ASAP.

2688 I yield back.

2689 The Chairman. The gentleman yields back. The chair
2690 recognizes Mr. Tonko for 5 minutes.

2691 Mr. Tonko. Thank you, Mr. Chair. Thank you to our
2692 witnesses for your work on this critical issue.

2693 Something that keeps me up at night when thinking about this
2694 epidemic is the so-called treatment gap, the idea that when
2695 someone is struggling with the disease of addiction has that
2696 moment of clarity and attempts to get help, that they will be
2697 met with a closed door and a waiting list.

2698 This idea is not simply theoretical. Last year I toured
2699 and addiction clinic in my district, where I spoke to a person
2700 who had waited over a year to get off of the waiting list to access
2701 treatment. Nationwide, we know that only 20 percent of those

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2702 with opioid use disorder are engaged in any form of treatment.
2703 These delays are deadly. Our Nation wouldn't tolerate a
2704 diabetic having to wait 1 year to get insulin and we can't tolerate
2705 this delay.

2706 Now, this committee took some good first steps to address
2707 this issue last Congress by passing legislation offered by Dr.
2708 Bucshon and myself to expand buprenorphine prescribing privileges
2709 to nurse practitioners and physician assistants, an option that
2710 almost 4,000 NPs and PAs have utilized to date, however, I believe
2711 we need to do more.

2712 So Dr. McCance-Katz, would you agree that we currently lack
2713 the treatment capacity that we need as a nation to take care of
2714 everyone who is seeking help from this deadly disease without
2715 delay?

2716 Dr. McCance-Katz. I would agree with that.

2717 Mr. Tonko. Thank you. And with the passage of CARA and
2718 the new DATA 2000 regulations promulgated by SAMHSA IN 2016, NPs
2719 and PAs are now able to treat patients with buprenorphine and
2720 certain doctors are able to treat up to 275 patients at a time.

2721 How has the healthcare work force responded to these new
2722 authorities? And has SAMHSA heard any feedback from the provider
2723 community about barriers that still exist which are preventing
2724 additional providers from seeking a DATA 2000 waiver?

2725 Dr. McCance-Katz. So we do have some data. What I can tell

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2726 you is we checked. As of yesterday, we have 3,656 physicians
2727 who have asked for a waiver to prescribe to up to 275 patients.
2728 We have had over 3,000 nurse practitioners get the DATA waiver.
2729 And a little over 800 physician assistants get the waiver.

2730 There are multiple reasons that people in the healthcare
2731 professions don't get the waiver. There is still a lot of stigma
2732 attached to the treatment. We don't do a lot of training in
2733 medical and pre-graduate programs for advance practice clinicians
2734 in the area of addiction medicine and so we need to increase our
2735 workforce.

2736 Mr. Tonko. I thank you for that.

2737 I have heard from other advanced nursing professions, such
2738 as certified nurse-midwives who are willing and able to provide
2739 additional medication-assisted treatment capacity but are
2740 prevented from doing so under current law. An expansion of DATA
2741 2000 privileges to these professionals would, in particular, help
2742 vulnerable populations like pregnant and postpartum women.
2743 While this change would ultimately require new legislation to
2744 implement, would you commit to working with Congress in helping
2745 to examine the feasibility of including additional highly-trained
2746 medical professionals in the DATA 2000 waiver program?

2747 Dr. McCance-Katz. Oh, yes, indeed.

2748 Mr. Tonko. Thank you.

2749 And shifting gears, quickly, I wanted to talk about another

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2750 population that is particularly vulnerable to opioid overdose
2751 and that is individual reentering society after a stay in jail
2752 or prison. I have read research that indicates that these
2753 individuals are up to eight times more likely to die of an overdose
2754 during their first 2 weeks post-release than at other times.

2755 Can anyone on the panel validate that number and provide
2756 some context on why these individuals are at such high risk?

2757 Dr. Volkow. This is correct. And one of the reasons why
2758 they are at greater risk is once you actually have been away from
2759 taking opioids, you lose your tolerance but the addiction still
2760 persists unless you have actually attempted to treat it.

2761 So if you don't treat it, the prisoner leaves jail or prison
2762 and then they immediately relapse without the tolerance. And
2763 that is why the risk of overdose is much higher. And that is
2764 why we are proposing research that actually implementing the
2765 medication-assisted treatment at the time of release from jail
2766 or prison to protect them from overdosing.

2767 Mr. Tonko. Thank you. Anyone else?

2768 Dr. McCance-Katz. I would just add that SAMHSA has an
2769 offender reentry program. That is one of the focuses of that
2770 program. We are also working with the Bureau of Prisons on
2771 identification of inmates with opioid use disorder and how to
2772 address when they are about to leave.

2773 Mr. Tonko. Okay, might I just add -- I thank you for that.

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2774 I just want to add that I believe that Medicaid could play a
2775 key role in improving outcomes during reentry and I hope to work
2776 with our witnesses and my colleagues on this committee on
2777 legislation I have introduced to explore this concept further.

2778 In other words, providing Medicaid coverage 30 days before
2779 release so that we can get these individuals under some sort of
2780 structured program before they are released and at such high risk
2781 of overdose.

2782 With that, I yield back.

2783 The Chairman. I thank the gentleman.

2784 I will now turn to the gentleman from West Virginia, Mr.
2785 McKinley, for 5 minutes for questions.

2786 Mr. McKinley. Thank you, Mr. Chairman.

2787 I tried to come up with questions that haven't been raised
2788 so far with it and my first question primarily would be just how
2789 much Federal resources are truly being allocated to this issue.

2790 Do any of you have a grasp of how much money? I am talking from
2791 NIH, CDC, DOJ, DEA. How much money are we putting into this
2792 program nationally?

2793 Dr. Volkow. Well, I can speak for NIH because it is actually
2794 the agency that I am representing. And from the perspective,
2795 for example, there are two components to it, one of them addressing
2796 --

2797 Mr. McKinley. Can you just give me an amount, an approximate

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2798 amount?

2799 Dr. Volkow. For paying, we are putting \$500 million on
2800 opioid use disorders.

2801 Mr. McKinley. Collectively. Collectively. We have a
2802 short time. So collectively, are we talking \$2 billion, \$5
2803 billion?

2804 Dr. McCance-Katz. We have a little over \$2 billion in our
2805 block grants for substance abuse, prevention and treatment, plus
2806 discretionary.

2807 Mr. McKinley. But is there some way that one of you or
2808 however can collectively come up with how much money is the Federal
2809 allocating? Because Mr. Pallone suggested in his testimony --
2810 in his comments we need to put more money into it. I don't know
2811 how much money we are currently putting into it.

2812 If I could move on to the second -- so if someone could get
2813 back to me, maybe from CDC.

2814 Dr. Schuchat. We just have \$125 million at CDC.

2815 Mr. McKinley. Yes, okay but collectively. Everybody, what
2816 priority are we really setting on this issue?

2817 Secondly, I would like to know how much money is coming to
2818 West Virginia. We have been asking for over a year. We can't
2819 get answers from any of you.

2820 So here is a chart that shows it. We have opioid-related
2821 deaths. We are the highest in the Nation at 41 per 100,000.

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2822 That 30 percent -- 20 percent higher than the number two state
2823 and almost 40 percent higher than the number three state. It
2824 is nearly two and a half times the national average. I don't
2825 understand why more resources aren't flowing to help out a rural
2826 State like West Virginia.

2827 Let me give you an example, though, on the neonatal births
2828 with opioid dependency. The national average is six per thousand
2829 but in West Virginia it is 140, nearly 25 times worse than the
2830 national average.

2831 So when West Virginia applied for a grant from you all,
2832 SAMHSA, they were denied. I would sure like to know why because
2833 you all stood up, sat there and talked about how you are dedicated
2834 to this issue and here we are with a desperate situation, we are
2835 under water, and we put in a grant and we are turned down.

2836 We also were excluded under their first round of the CARA,
2837 \$180 million were supposed to be assured; \$144 million was
2838 distributed. West Virginia got zero in that first round.

2839 This has got to stop, this idea coming from the Beltway,
2840 you all sitting back here. We are on the front lines. And I
2841 want to build back on what Harper was talking about in rural
2842 America.

2843 I just came from a county, Taylor County, 27,000 people,
2844 125 arrests already this year. They have no resources from the
2845 Federal government for help on this. They have, for 5 years,

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2846 gotten not one dime to help out on the opioid problem they are
2847 having in Taylor County with 27,000 people.

2848 And then I went to another county, Preston County. Three
2849 little towns, all collectively, between the three of them have
2850 less than a thousand people. They don't have the resources to
2851 have a teleconference. They don't have the resources to apply
2852 for a grant, to seek money. They are getting zero. No money
2853 is going to that rural county because they can't apply for it.

2854 I would like to hear how we do this for rural America. Are
2855 we telling them you have got to file for an application? We did
2856 and we were denied by your group. What is the other group? Are
2857 we telling this little counties or towns that have 200 or 300
2858 people you have to get a grant writer to submit something for
2859 you? They can't afford it. They don't know how to do it.

2860 What is your suggestion? And get out of the Beltway and
2861 come with me back into rural America to find out how this
2862 physically works in a town of 200 people with an 84-year-old mayor.

2863 How are they supposed to address it when they know, the mayors
2864 talk, they know they are selling drugs in the Post Office parking
2865 lot and they don't have a police officer in that community to
2866 make an arrest? They physically see it every day drugs being
2867 sold there. How do we stop it?

2868 I am sorry, did I miss something?

2869 Dr. Schuchat. I can just say that CDC's funding the State

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2870 of West Virginia to work with all the counties. I am so sorry
2871 that the people in the towns you have been reaching haven't been
2872 getting support.

2873 Mr. McKinley. Zero.

2874 Dr. Schuchat. We need to do better. We are getting \$2.6
2875 million to the State of West Virginia to work statewide for --

2876 Mr. McKinley. We have got the worst situation in the country
2877 and we are saying file applications. Make an application. They
2878 don't know how to make an application. They don't have the
2879 resources to do it. There is no grant writer. And then when
2880 we did, we were denied. Twenty-five times worse than the national
2881 average and we were denied on neonatal. Someone has got to tell
2882 me what we did wrong or why we don't deserve to have more treatment.

2883 Dr. Volkow. And you deserve and I have actually gone to
2884 the communities in West Virginia and Kentucky. I am going to
2885 Ohio. I think that what we are trying to understand is the
2886 infrastructure and create partnerships.

2887 And also, interestingly, West Virginia learned from what
2888 the communities have developed that actually have been effective
2889 to help other communities with similar problems.

2890 But you are absolutely right, the needs of rural America
2891 are some that require special attention.

2892 Mr. McKinley. Thank you. I yield back.

2893 The Chairman. The gentleman's time has expired.

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2894 The chair recognizes the gentlelady from Michigan, Mrs.
2895 Dingle for 5 minutes.

2896 Mrs. Dingell. Thank you, Mr. Chairman. I want to thank
2897 all -- I have no voice. I have no voice because I did ten town
2898 halls in the last district work period on opioid drug addiction.
2899 And I thank all of you for your service.

2900 It is a really complicated issue, which we can tell by all
2901 the questions. And I put a human face on it. My father was a
2902 drug addict from prescription drugs before anybody ever talked
2903 about it or knew what it was. And my sister started young and
2904 there is nothing that I didn't do. I know what it was like to
2905 go look on the streets to see people selling the drugs, to have
2906 her in and out of drug treatment centers, and ultimately she lost
2907 the battle and died of a drug overdose.

2908 I am married to a man, who is not going to be happy I am
2909 saying this publicly, who this room is named after, who has a
2910 legitimate pain need. And I have learned more about pain drugs
2911 than I ever wanted to do and it is becoming an even more serious
2912 problem with people with chronic disease.

2913 And at these town hall meetings because I have said this
2914 is a complicated issue and we have to make sure that the pendulum
2915 doesn't go too far the other way, how do we make sure those who
2916 need pain pills and the oncologists are coming out -- I did a
2917 town hall with Joe Kennedy last week and I have been hearing at

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2918 every town hall -- and we have started community coalitions, and
2919 we have got the law enforcement, and the police, and the hospitals,
2920 and school teachers, and the kids all part of it. And we have
2921 all got to be part of it.

2922 But it is complicated and we all need to understand it is
2923 complicated. But how do we work together to start to address
2924 it?

2925 So my first question, Dr. Gottlieb, I am going to address
2926 it to you because you talked about it a little earlier. In order
2927 to mitigate the opioid crisis, we have got to change the paradigm.

2928 The other point I will make before asking this question,
2929 because there has been very little discussion about mental illness
2930 today, and the fact of the matter is too many people are
2931 self-medicating for anxiety and depression. And I will bet that
2932 half the constituents in West Virginia don't have jobs. They
2933 are turning to that for solace and now they can't get a job.
2934 People don't understand that most of the jobs in this country
2935 that are open are going unfilled because people are failing those
2936 urine tests. We need to start to do some reality but I want to
2937 make sure that people who have legitimate pain needs are getting
2938 treated, too.

2939 So what are we doing to change the paradigm for treating
2940 pain and addiction in America? One way to do this is to advance
2941 the understanding of the biology of pain and addiction in order

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2942 to enable the development of innovative treatments.

2943 Dr. Gottlieb, how are you partnering with industry in order
2944 to ensure that novel and safer treatments for pain and addiction
2945 are being developed?

2946 Dr. Gottlieb. Thank you, Congresswoman. I will just echo
2947 your comments.

2948 In economically- and socially-challenged environments where
2949 the drugs are abundant and treatment is scarce, I think widespread
2950 addiction only seems inevitable.

2951 We announced a series of steps today that we are going to
2952 take. Principle among them is trying to look at how we advance
2953 the guidelines that we have in place to help innovators and drug
2954 developers develop novel treatments for the treatment of
2955 addiction. We want to advance the endpoints that we use in those
2956 clinical trials to perhaps open up a full range of potential
2957 treatments that can address aspects of addiction like craving,
2958 and look at novel endpoints like perhaps reduction in overdoses,
2959 or hospitalization.

2960 But I will just close by saying that we also know that the
2961 medical treatments, while highly effective, need to be delivered
2962 in the context of psychosocial interventions and services that
2963 help them be most effective. The evidence shows us that these
2964 treatments are most effective when they are delivered in the
2965 context of services and also deliver other forms of treatment

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2966 that address some of the psychosocial aspects of addiction.

2967 And I would just point to my colleague from SAMHSA, who was
2968 a pioneer in developing these kinds of programs in Rhode Island
2969 and really developed a model for how this can be done successfully
2970 nationwide.

2971 Mrs. Dingell. I would come back at though and we are talking
2972 about the addiction that has happened. We need to be developing
2973 new ways to treat pain and come up with alternatives so we are
2974 using non-addictive pain medicine.

2975 Dr. Gottlieb. So I appreciate the question. I might have
2976 misunderstood it, Congresswoman.

2977 Mrs. Dingell. Well, it is both but we need to be talking
2978 about that.

2979 Dr. Gottlieb. I fully agree with you and you know there
2980 are products in development right now and products in the pipeline
2981 that address aspects of pain through pathways that we think might
2982 not have the same addictive potential as opioids. That,
2983 obviously, needs to be demonstrated scientifically. We are
2984 looking at abuse-deterrent formulations.

2985 I would also just point out to the committee that if you
2986 look at the clinical data on NSAID use in arthritic patients,
2987 it went down sharply after we imposed some additional warnings
2988 related to NSAID use. And I think we have to look at that in
2989 the context of the current crisis because it seems intuitive that

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2990 some of those patients who might have been prescribed NSAIDs now
2991 were prescribed immediate release formulations of opioids
2992 instead.

2993 And so I think we need to look at the risk benefit of all
2994 these drugs in concert. We sought to do that with the blueprint
2995 we advanced with respect to new educational requirements for
2996 physicians for the first time asking physicians to be educated
2997 not just on proper prescribing of opioids but proper prescribing
2998 of opioids in the context of all of the available therapy for
2999 treating pain.

3000 Mrs. Dingell. Thank you.

3001 The Chairman. I thank the gentlelady.

3002 I will now go to the gentleman from Illinois, Mr. Kinzinger
3003 for 5 minutes.

3004 Mr. Kinzinger. Thank you, Mr. Chairman. Again, all of you,
3005 thank you for being here.

3006 And I want to make it clear you know this is a tough hearing
3007 I think but we know that you guys all want to solve this problem.

3008 And you are working hard to do it whether it is whatever agency.

3009 This is something that we wish would go away but there is some
3010 difficulty in what we are dealing with.

3011 You know one of the conundrums we have is the idea that
3012 people, as was mentioned, have a legitimate need for pain
3013 medicine. Some people find themselves addicted with that. Some

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3014 people don't. And then we very strictly regulate how that pain
3015 medicine is put out. And in many cases they just transition to
3016 heroin, then, because they can't get access to the drugs that
3017 hooked them.

3018 In fact in my district, law enforcement agencies say that
3019 heroin is cheaper on the street than marijuana right now, which
3020 is incredible. And that is why you see a lot of what you do.

3021 I was just, about 3 or 4 weeks ago, I was leaving church
3022 going to the gym. And I pulled into the parking lot and there
3023 was a wrecked vehicle in the gym parking lot and somebody I knew
3024 was standing outside of it. So I went over and there was a guy,
3025 probably my age, slumped over in the car in an apparent heroin
3026 overdose. So EMS came over, we called 911, and they administered
3027 Narcan. And he came back and then proceeded to not talk about
3028 what happened at all.

3029 So I, in fact, as I think we all did, a lot of us did, in
3030 the last district work period, we had these opioid roundtables
3031 to hear from people what is going on. And I remember a funeral
3032 director in LaSalle County saying that he buried his own son to
3033 a heroin overdose and that it used to be 20 years ago they would
3034 have one death a year related to ODing and now it is one a month.

3035 And he says every time he has to deal with a family with something
3036 like this, it like reopens all his old wounds.

3037 And so I hear all these stories. You know but I am hopeful.

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3038 There are groups like The Perfectly Flawed Foundation in LaSalle,
3039 which is a recovery addict that started this to help folks, or
3040 Safe Passage, which is a program in Dixon, Illinois run by the
3041 police. So I know the communities are rising to the challenge.

3042 One of the concerns we have, though, is in rural areas like
3043 my district, the access to treatment facilities. You know
3044 usually if somebody wakes up from an overdose, or is pulled out,
3045 or whatever, they have about maybe 30 minutes to an hour where
3046 they want to recover. But then once that hour is up, the addiction
3047 takes back over. And so when you have a massive delay in being
3048 able to get people treatment, obviously in many cases they choose,
3049 at the time they can finally get in they have either gone back
3050 to drugs or the addiction has just taken back over.

3051 So I just want to kind of open it to the floor and just say
3052 you know what are your agencies doing to kind of address the unique
3053 challenges that are specific to rural communities. And I know
3054 this question may have been asked already but if you guys just
3055 want to take that over, we will start here.

3056 Dr. Volkow. Yes, from the perspective of research, we are
3057 actually funding researchers to develop new models of care that
3058 actually can address the unique needs of rural communities. And
3059 one of them is the spokes and hub, for example, where you can
3060 have one physician with expertise actually linked with nurse
3061 practitioners that deliver the care. The telehealth is another

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3062 approach that is actually quite widely utilized.

3063 We are also evaluating models that will expand our ability
3064 to provide with medication-assisted therapy, for example. In
3065 Rhode Island, we are funding a project where the pharmacists are
3066 actually not only dispensing the buprenorphine but actually
3067 following it up. And that gives the visibility of touching a
3068 much greater number of individuals. We are --

3069 Mr. Kinzinger. Could you keep it brief because I want to
3070 make sure everybody gets a chance here?

3071 Dr. Volkow. So we are taking this, providing these
3072 evidence-based treatments in communities and then we try to
3073 transfer them or translate them into other communities. So we
3074 are funding research on those in that model.

3075 Mr. McKinley. Okay, next?

3076 Dr. Schuchat. Yes, I would just say that the state funding
3077 that we give has a requirement that public health and public safety
3078 work closely together. And what that really means is at that
3079 local or town level you have the right people coming together,
3080 like in that parking lot that you were talking about.

3081 Mr. Kinzinger. Yes, sir?

3082 Mr. Doherty. Sir, from a law enforcement perspective, DEA,
3083 I would also say a 360 Strategy is effective in the rural areas.

3084 We are leveraging our state, local, and district partnerships
3085 with police departments. We have become adept, more adept, in

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3086 my opinion, at data analytics. We are putting out threat
3087 assessments to all 21 of our field divisions to look at every
3088 area of potential diversion of pharmaceutical controlled
3089 substances.

3090 DEA, along with HHS, and FBI is part of the Attorney General
3091 Opioid Fraud and Detection Unit that is in 12 select districts,
3092 Federal districts in this country. So we are getting better at
3093 intelligence, sharing intelligence, providing additional
3094 resources.

3095 Mr. McKinley is no longer with us in the room but I wanted
3096 to address his concerns about West Virginia. We have devoted
3097 tremendous resources to West Virginia in the last 2 years, namely,
3098 an upgrade in the office in terms of leadership, tactical
3099 diversion teams, mobile tactical diversion teams, and data
3100 analytics. So we are very concerned, as the committee is, with
3101 respect to rural areas and we are doing all we can. Thank you.

3102 Mr. McKinley. Thank you. And let me just conclude by
3103 saying I am still a pilot in the Air Guard and we do a lot of
3104 border stuff. And the amount of drugs coming over the border
3105 is just absolutely mind-blowing.

3106 With that, I will yield back.

3107 The Chairman. I thank the gentleman.

3108 I will now turn to the gentleman from New Mexico, Mr. Lujan
3109 for 5 minutes. Mr. Chairman?

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3110 Mr. Lujan. Mr. Chairman, thank you very much. I really
3111 appreciate you calling this important hearing, Mr. Chairman and
3112 I think I will begin where Mr. McKinley left off.

3113 I also represent a rural district, 47,000 square miles across
3114 the entire Colorado border, Arizona to New Mexico. I have heard
3115 at least two of the witnesses today talk about resources that
3116 they are taking to the state. We have a problem. And people
3117 at home don't feel like they are getting help. There is a big
3118 concern.

3119 I would highlight the handout that the CDC gave us today,
3120 which those red dots that follow that top brown dot show that
3121 there is 18 for every one; 18 heroin users for every one that
3122 we are also seeing with prescription or illicit opioid deaths
3123 in 2015 alone.

3124 Even as we take a step back, Mr. Chairman, I think that you
3125 know sometimes we need a history lesson, understanding that we
3126 tried to curb opium use and addiction in the 1800s. There was
3127 a response by a drug manufacturer in Germany to come up with
3128 morphine. And then in response to the morphine epidemic that
3129 we saw across America, a drug manufacturer said well, in 1874,
3130 we have another answer and it is called heroin. We will
3131 manufacture that and we will ship it to the United States.

3132 Then in 1937, another manufacturer said well, we can come
3133 up with methadone. And that hit the streets and hit the

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3134 communities.

3135 This isn't a new problem. And I just hope that we are asking
3136 are we doing something different.

3137 I appreciate the testimony associated with looking at
3138 non-addictive pain treatment. There is a letter, Dr. Gottlieb,
3139 that I sent to you. I appreciate your testimony today, the work
3140 that you are doing. I just put that on your radar so that way
3141 we can work with your team to get a response. And it is in the
3142 area of non-opioid drug products.

3143 We need to have something game-changing with all that we
3144 are doing in this space. We can't repeat what was done in 1800,
3145 and 1847 to 1850, to 1874, to 1927, and then 1947, and we wonder
3146 why people are dying in our communities. They are getting the
3147 same stuff.

3148 But that heroin that is coming in, we know that 90 percent
3149 of those poppies are grown in Afghanistan. We know that less
3150 than four percent of that is making its way to the United States.

3151 We know that Southeast Asia heroin is coming into the United
3152 States as well. We also know about the heroin from Mexico and
3153 from South America.

3154 We also know that it is coming in through Canada. It is
3155 not just the southern border. It is the norther border and it
3156 is the ports.

3157 We have a huge problem. And I hope that when we talk about

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3158 the expansiveness of what we are dealing with that we look at
3159 it through that lens.

3160 And I just, in the limited time that I have, one question
3161 that I wanted to bring to your attention is, like many of our
3162 colleagues, I went to visit a few facilities this last week.
3163 One is in Espanola, New Mexico in Rio Arriba County. It is called
3164 Hoy Recovery. Some incredible leaders committed to our community
3165 but, Mr. Chairman, this is going to impact all of us in rural
3166 communities.

3167 They told me about a few of these grants that they were going
3168 after, one in particular, by the way, that was trying to get
3169 someone to help them go after additional grants for capacity
3170 building but they were told that because they didn't have the
3171 person to write the grant that they were trying to get to expand
3172 capacity, that they didn't qualify.

3173 Another one that said that unless they were serving a
3174 community of 100,000 people, that they wouldn't qualify. These
3175 are small rural towns.

3176 We have got a problem and I am hoping that we can get a
3177 commitment to work with you, Dr. McCance-Katz, to work with you
3178 on this issue.

3179 And then the last question I would ask is the budget that
3180 you all submitted to us on behalf of the administration, are you
3181 getting what you need to do what we are talking about today?

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3182 Yes, no?

3183 Mr. Doherty. Sir, from a DEA perspective, we fully support
3184 the Department of Justice budget that we are a part of. Some
3185 of our major initiatives with respect to cartel infrastructure
3186 investigation, intelligence initiatives, and the --

3187 Mr. Lujan. Let me just interrupt, Mr. Doherty. It is not
3188 necessarily towards you, sir. This is towards the others around
3189 the table.

3190 The Trump administration budget cuts HHS by 60 percent.
3191 The CDC gets cut by 17 percent. The National Institutes of Health
3192 gets cut by 19 percent. The funding for addiction research
3193 treatment and prevention, even the White House Office on National
3194 Drug Control Policy takes a hit.

3195 So we are talking about not enough out of here. And I know
3196 we need to be smart. These are tough times. I get that. But
3197 as we dig in here and, Mr. Chairman, the impacts to these rural
3198 communities and what we can be doing across the country, this
3199 hearing and pulling everyone in here is critically important.

3200 And I just thank the chairman. I will submit my full
3201 statement and all my questions into the record, Mr. Chairman.

3202 The Chairman. Without objection.

3203 [The information follows:]

3204

3205 *****COMMITTEE INSERT 7*****

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3206 Mr. Lujan. But please, we need your help in a profound way.
3207 The Chairman. The gentleman's time has expired. I thank
3208 the gentleman.

3209 We will now go to the gentleman from Virginia, Mr. Griffith
3210 for 5 minutes.

3211 Mr. Griffith. Thank you very much, Mr. Chairman.

3212 Mr. Doherty, isn't it true an immediate suspension order
3213 is a law enforcement tool that can empower the DEA to freeze
3214 suspicious narcotics shipments from companies? Yes or no,
3215 please.

3216 Mr. Doherty. Yes, sir.

3217 Mr. Griffith. Thank you. And isn't it also true that a
3218 similar enforcement measure would be a show cause order?

3219 Mr. Doherty. Yes, sir.

3220 Mr. Griffith. Thank you. And all these questions are going
3221 to be yes or no. Thank you.

3222 The DEA told this committee, in response to an Oversight
3223 request dated May 8, 2017, that the "DEA is unaware of documents
3224 related to delayed or blocked enforcement actions and suspension
3225 orders."

3226 Over the last 6 years, have there been enforcement actions
3227 proposed by DEA personnel that were not approved by DEA; yes or
3228 no?

3229 Mr. Doherty. Yes.

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3230 Mr. Griffith. And if you could detail those for me at a
3231 later time, I will follow up with that after the hearing.

3232 Over the last 6 years, to the best of your knowledge, was
3233 there any communication within the DEA about suspension orders;
3234 yes or no?

3235 Mr. Doherty. Yes.

3236 Mr. Griffith. Likewise, we will want to get copies of those.
3237 Thank you.

3238 Over the last 6 years, to the best of your knowledge, were
3239 there any communications at DEA related to additional evidence
3240 needed to support a proposed suspension order that resulted in
3241 delays; yes or no?

3242 Mr. Doherty. I am not sure of that, sir. I would have to
3243 check.

3244 Mr. Griffith. I would appreciate that.

3245 Over the last 6 years, to the best of your knowledge, as
3246 a DEA enforcement official, when a DEA enforcement action is
3247 approved or not approved, was such a decision ever communicated
3248 writing; yes or no?

3249 Mr. Doherty. I would have to check on that as well, sir.

3250 Mr. Griffith. All right.

3251 Over the last 6 years, to the best of your knowledge, has
3252 a DEA enforcement official, when there were discussions by DEA
3253 enforcement officials with DEA attorneys about the need for

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3254 additional evidence in an enforcement action, would such concerns
3255 only be conveyed verbally and never in writing; yes or no? Were
3256 these communications oral only?

3257 Mr. Doherty. No.

3258 Mr. Griffith. No. So there are some written documents is
3259 what you are telling me; yes or no?

3260 Mr. Doherty. So are you referring to documents that would
3261 request additional evidence, sir?

3262 Mr. Griffith. Yes, sir.

3263 Mr. Doherty. Yes.

3264 Mr. Griffith. They were all oral or there are writings?

3265 Mr. Doherty. There would be documents --

3266 Mr. Griffith. Thank you.

3267 Mr. Doherty. -- that would have requested case-related
3268 evidence.

3269 Mr. Griffith. Thank you.

3270 Do you an attorney in the DEA by the name of Clifford Reeves;
3271 yes or no?

3272 Mr. Doherty. Yes, sir.

3273 Mr. Griffith. And did you ever have any communications with
3274 Mr. Reeves about cases brought by the DEA's Diversion Control
3275 Office; yes or no?

3276 Mr. Doherty. Yes, sir.

3277 Mr. Griffith. And were any of these communications with

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3278 Mr. Reeves in writing; yes or no?

3279 Mr. Doherty. Yes, sir.

3280 Mr. Griffith. Is it your experience with DEA lawyers that
3281 they never communicate in writing?

3282 Mr. Doherty. No, sir.

3283 Mr. Griffith. Thank you.

3284 Both 60 Minutes TV program and the Washington Post, in their
3285 reporting, featured former DEA law enforcement officials such
3286 as Mr. Jim Geldhof, who detained their concerns about the handling
3287 of enforcement cases at the DEA.

3288 Because of your denial of documents to this committee, should
3289 we assume that these officials never put anything in writing about
3290 their concerns while they were at the DEA; yes or no?

3291 Mr. Doherty. Sir, having not been assigned to the Diversion
3292 Control Division at that time, I don't know what the
3293 correspondence would have been. I don't have the background to
3294 answer that question.

3295 Mr. Griffith. You don't have the correspondence, don't have
3296 the background but it would be -- okay, never mind.

3297 Are you familiar with DEA's Chief Administrative Law Judge
3298 John Mulrooney; yes or no?

3299 Mr. Doherty. Yes, sir.

3300 Mr. Griffith. And were you aware that the Washington Post
3301 reported that Chief DEA Judge Mulrooney wrote in a 2014 quarterly

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3302 report that there was a decline in the number of orders to show
3303 cause or enforcement actions by the DEA?

3304 Mr. Doherty. And what was the date of that, sir?

3305 Mr. Griffith. June 2014.

3306 Mr. Doherty. I am unaware of that, sir.

3307 Mr. Griffith. You are not aware of that.

3308 Would such a quarterly report be in the form of a written
3309 document; yes or no?

3310 Mr. Doherty. Yes, sir.

3311 Mr. Griffith. Mr. Doherty, did you play any role in the
3312 development or clearance of the answer to the committee that "DEA
3313 is unaware of documents related to delayed or blocked enforcement
3314 actions and suspension orders?" Yes or no?

3315 Mr. Doherty. No, sir, that was provided by my staff, by
3316 the Diversion Staff.

3317 Mr. Griffith. By the Diversion -- somebody that works under
3318 your division?

3319 Mr. Doherty. Someone that works in the Diversion Staff,
3320 yes, sir.

3321 Mr. Griffith. All right. Mr. Doherty, were you asked to
3322 search your documents in your possession to respond to the
3323 committee's request; yes or no?

3324 Mr. Doherty. I don't believe I was asked directly, sir.

3325 Mr. Griffith. And do you personally have emails or document

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3326 going back to 2011; yes or no?

3327 Mr. Doherty. Yes, sir, but not on this subject. So I have
3328 documents from my employment prior to my assignment to the
3329 Diversion Control Division, yes, sir.

3330 Mr. Griffith. All right, thank you.

3331 And do you know if there was -- because former Agent Jim
3332 Geldhof told the Washington Post that before Reeves' arrival in
3333 the DEA Diversion Control Office in December of 2012, DEA
3334 investigators had to demonstrate that they had amassed a
3335 preponderance of evidence before moving forward with criminal
3336 enforcement cases which are administrative not criminal? And
3337 prior to December 2012, was there a preponderance of evidence
3338 standard for enforcement cases on opioid distribution; yes or
3339 no?

3340 Mr. Doherty. Yes.

3341 Mr. Griffith. Was that standard later changed to a beyond
3342 a reasonable doubt standard; yes or no?

3343 Mr. Doherty. I am not aware of that change, sir, no.

3344 Mr. Griffith. All right, I appreciate you answering the
3345 question. I see that my time has expired and I yield back.

3346 The Chairman. I thank the gentleman.

3347 All right, so we go to Mr. Cardenas next is what I am
3348 instructed. So the gentleman from California. I will let you
3349 two fight it out but --

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3350 Mr. Cardenas. We are both from California.

3351 The Chairman. Yes, there you go.

3352 Mr. Cardenas. Well, thank you, Mr. Chairman. I appreciate
3353 this opportunity for us to bring this important issue before the
3354 public with so many of our dedicated Federal individuals in
3355 various departments who are somehow involved in making sure that
3356 we get in front or on top of this epidemic.

3357 My first question is, Is there anybody on the panel that
3358 would like to defend whether or not we, in the United States of
3359 America, were in front of this issue and on top of this issue
3360 and it is already getting under control?

3361 [No response.]

3362 Mr. Cardenas. So the answer is no. Okay. So we have much
3363 work to do, correct?

3364 Is part of the effort of making sure that we go from crisis
3365 -- I would like to describe it as a crisis. I don't know if anybody
3366 on the panel is saying that it is not a crisis.

3367 Does anybody on the panel want to defend that it is not a
3368 crisis in the United States at the moment, this opioid epidemic?

3369 [No response.]

3370 Mr. Cardenas. Okay. So that being the case, if we,
3371 Congress, were to reduce the access, or in some way by policy,
3372 or allowing the providers of health care out there in the United
3373 States to reduce the current level of care, such as mental health

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3374 and/or substance abuse care that is now afforded individuals since
3375 the ACA has now become law, if we were to reduce that, would that
3376 make the situation better or worse in the United States for
3377 individuals and families who are faced with this crisis?

3378 Would anybody like to say whether it would be better or worse
3379 if we were to roll back the current status within the ACA law
3380 that many insurers today are now providing more substance abuse
3381 and mental health services today that they were not providing
3382 before the ACA?

3383 [No response.]

3384 Mr. Cardenas. Anybody that would like to say or give me
3385 an example of whether or not you believe it would be better to
3386 reduce those benefits to millions of Americans or worse?

3387 Please.

3388 Dr. Volkow. Well I think that evidently we need to address
3389 the treatment needs of those that are suffering from an opioid
3390 use disorder if we are going to solve the problem and we need
3391 to prevent the overdoses. But we also need to look at the
3392 structure and understand how changes that we are making ultimately
3393 are having an impact and that is where the data is still lacking.

3394 And I was expecting that there would be a significant
3395 increase in number of individuals given access to opioid use
3396 disorder with the expansion of the insurance to these individuals.

3397 And what is surprising is because many of these treatment

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3398 programs don't have the knowledge of how to get reimbursement,
3399 something as simple as that, they are not taking advantage of
3400 it.

3401 So my perspective in all of this is that we need to create
3402 a structure that will increase the likelihood of people that are
3403 suffering from the disease to get treatment. That is what we
3404 need to achieve.

3405 Mr. Cardenas. Okay. So if we were to reduce the access,
3406 that would not help, correct?

3407 Dr. Volkow. Anything that decreases access that does not
3408 provide an alternative -- that does not provide an alternative
3409 --

3410 Mr. Cardenas. Would it make the situation worse?

3411 Dr. Volkow. If it does not provide an alternative. And
3412 all evidence, good quality care, if you don't provide that,
3413 anything that doesn't provide that will not help us address the
3414 crisis.

3415 Mr. Cardenas. Will it make it worse; yes or no?

3416 Dr. Volkow. Without, it is --

3417 Mr. Cardenas. Okay, I am sorry. I only have 1 minute left.

3418 I contend that it would make it worse. I contend that it
3419 would make it worse. I understand that you went into a bit of
3420 a -- tried to go into detail in a limited amount of time as to
3421 the some of the issues that we still have yet to tackle. But

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3422 I truly do believe that, for example, by repealing mental and
3423 substance -- access to substance abuse disorder coverage,
3424 provisions that are currently in the ACA, this would impact
3425 working families across America.

3426 And one last question that I would like to ask in the limited
3427 time. Please point out to me what community in the United States
3428 of America is immune to this crisis. Has this affected every
3429 strata of the United States' individuals? Are rich people
3430 immune? Are poor people immune? Are people who work for a living
3431 immune? Are people who work on Wall Street immune?

3432 My point is this, ladies and gentlemen. This is something
3433 that is affecting every part of America and it is, in fact, a
3434 crisis. And I would venture to say that this was a crisis in
3435 what we believed, and we were wrong, we believed that this was
3436 a crisis of poor communities. And this has always been an
3437 American crisis and it is about damn time that we are actually
3438 facing this. But Congress a lot of work to do and with it comes
3439 the resources necessary to combat this crisis.

3440 I yield back.

3441 The Chairman. The gentleman yields back.

3442 The chair recognizes the gentleman from Florida, Mr.
3443 Bilirakis, for 5 minutes.

3444 Mr. Bilirakis. Thank you, Mr. Chairman; I appreciate it.
3445 And I really appreciate you holding this hearing. You know I

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3446 am glad for the most part it is a bipartisan hearing and this
3447 is a major issue. I can't think of a more important issue to
3448 tackle.

3449 So but I want to start with Mr. Doherty, if that is okay.
3450 The law has been written again about the Ensuring Patient Access
3451 and Effective Drug Enforcement Act. I want to take the
3452 opportunity to ask you a couple of questions. Yes or no, please,
3453 because of time.

3454 Was DEA part of the negotiation for the final language of
3455 this particular bill?

3456 Mr. Doherty. Yes, sir.

3457 Mr. Bilirakis. Okay. Did DEA recommend that President
3458 Obama veto the bill?

3459 Mr. Doherty. No, sir.

3460 Mr. Bilirakis. Okay. Has DEA made any communication to
3461 this committee, this particular committee, Energy and Commerce
3462 Committee, about the need to change statute?

3463 Mr. Doherty. Not to my knowledge, sir, no.

3464 Mr. Bilirakis. Did DEA include any requests for statutory
3465 changes in their budget submission this year, dealing with this
3466 particular law?

3467 Mr. Doherty. Not to my knowledge, sir.

3468 Mr. Bilirakis. Okay. Has DEA's ability to enforce our
3469 Nation's drug laws been compromised because of the passage of

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3470 this particular bill?

3471 Mr. Doherty. This changes the way we look at the ISO, sir,
3472 but we use an array of other tools.

3473 Mr. Bilirakis. All right. Let me ask you this briefly
3474 because I have other questions.

3475 Give us suggestions. Talk to us. We want to do the right
3476 thing. We all, everyone on this panel, wants to do the right
3477 thing and solve this public health crisis. I commend the
3478 President for addressing it tomorrow, as well.

3479 So, please, give us suggestions. We need to know the tools
3480 that you need to handle this. We are on the same team with regard
3481 to this. So please, I want you to respond to me, personally,
3482 but I am sure every member of the committee, particularly the
3483 chairman, would like a response as well.

3484 Okay, Dr. McCance-Katz, currently there isn't a clear
3485 standard for medication-assisted treatment, MAT, prescribing.

3486 And we have heard reports of an increasing number of rogue actors
3487 offering MAT. In many cases, these popup clinics actively
3488 recruit vulnerable client populations to provide substandard
3489 service with minimal oversight.

3490 While we support consumer choice and market competition,
3491 we also want to balance this with the consumer safeguards to ensure
3492 that this problem improves and not worsens -- so we need to solve
3493 this -- and that bad actors are not rewarded via Federal dollars.

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3494 Additionally, questions have been raised as to whether
3495 states are requiring evidence-based practices to be used in the
3496 STR Grant Program.

3497 The question is, What is SAMHSA doing to ensure rogue actors
3498 are not the recipient of Federal dollars and evidence-based
3499 practices are being used so that the funds expended go to providing
3500 the best possible treatment and recovery services?

3501 Dr. McCance-Katz. So, as I mentioned earlier, we have a
3502 program in place to review the State plans. The States make the
3503 decisions about what providers in their states they wish to fund
3504 with dollars that SAMHSA has oversight for. And we assist them
3505 with determining and making sure that evidence-based practices
3506 are being used.

3507 In terms of the kinds of rogue providers that you mentioned,
3508 SAMHSA has purview over a couple of things. One, we regulate
3509 opioid treatment programs and, two, we also certify physicians
3510 and other practitioners named in law that can provide office-based
3511 treatment of opioid use disorder, nurse practitioners,
3512 physicians' assistants. So we regulate and manage that.

3513 However, we don't have, we do not have any jurisdiction over
3514 these other types of providers within states. What we do is we
3515 try to inform states about what constitutes best practices so
3516 that they can decide how they want to regulate within their
3517 boundaries.

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3518 Mr. Bilirakis. Thank you.

3519 A question for Commissioner Gottlieb. Last August, FDA
3520 authorized a blog post titled FDA Supports Greater Access to
3521 Naloxone to Help Reduce Opioid Overdose Deaths. I know you are
3522 familiar with that.

3523 Can you provide this committee with an update on the
3524 development of any over-the-counter version of naloxone?

3525 Dr. Gottlieb. We have had conversations with a number of
3526 sponsors about naloxone over the counter. And as you know, we
3527 are working on an actual use study, where we would, I think for
3528 the first time, actually publish in the Federal Register the
3529 specifications, the scientific specifications on how a sponsor
3530 could demonstrate that a product can be properly labeled for the
3531 purposes of bring it over the counter.

3532 So rather than putting the obligation on the sponsors to
3533 go out and do that study, we would proactively, effectively
3534 publish the specification that they can follow to help facilitate
3535 a more rapid entry of an OTC alternative into the marketplace.

3536 And we are fully committed to that and working pretty actively
3537 on it.

3538 Mr. Bilirakis. I appreciate it. Please, we need to work
3539 together and solve this problem. It is a real crisis in this
3540 country.

3541 Thank you very much and I yield back.

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3542 The Chairman. The gentleman's time has expired.

3543 The chair recognizes the gentleman from Iowa, Mr. Loeb sack,
3544 for 5 minutes.

3545 Mr. Loeb sack. Thank you, Mr. Chair. This is one of those
3546 rare opportunities that we can take here in Congress, where we
3547 all have the same concerns, I think. And we may differ about
3548 how to resolve the problems but we share the very same concerns
3549 about this crisis.

3550 You know this epidemic is more than tragic, I think, and
3551 it has hit every corner of America, rural, urban, suburban areas
3552 alike. I am in a rural area. I have got 24 counties in my
3553 district. The chair likes to remind me that his district is
3554 bigger than the whole State of Iowa but, nonetheless, I have got
3555 a lot of rural areas.

3556 And I get around. This weekend, I am going to go with the
3557 police chief or one of his deputies, a small town in Iowa, in
3558 Pella, Iowa. And I hear these stories all the time more and more.

3559 I have been in -- this is my 11th year now and we really didn't
3560 think too much about opioids at that time but, clearly, we do
3561 now.

3562 Just some quick numbers, according to the University of Iowa.

3563 In the past 15 years, heroin deaths have increased nine-fold
3564 in the State of Iowa and prescription opioid overdose deaths in
3565 Iowa have quadrupled since 1999.

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3566 Clearly, we have got to do more about this. And maybe some
3567 folks -- I have to go sort in it now, maybe some folks have covered
3568 kind of the rural aspect of this but given that I represent so
3569 much rural area and I do hear of the same concerns in rural America
3570 as I do in some of my bigger towns and probably the bigger cities
3571 in the country.

3572 What are the differences, if there any, and I will open this
3573 up to the whole panel, that you are seeing in the rural opioid
3574 crisis compared to urban counterparts? And given the
3575 differences, if there are any, how do your agencies -- how do
3576 you strategize, if you will, for rural communities? How do your
3577 rural community strategies differ from our urban areas?

3578 I am going to open that up to whoever wants to answer that
3579 question.

3580 Dr. McCance-Katz. So we know that we have difficulty with
3581 getting providers to rural areas.

3582 Mr. Loeb sack. Definitely.

3583 Dr. McCance-Katz. And so we, as I mentioned earlier, we
3584 try to use innovative ways of reaching individuals by extending
3585 the ability of a practitioner, say in an urban area, to reach
3586 out to rural areas and provide care.

3587 We also try, as best we can, to leverage primary care. We
3588 do a lot more work now with integration of behavioral health care
3589 into primary care settings, which rural areas still don't have

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3590 as much as they need but are much more likely to have primary
3591 care services often than they would behavioral health services.

3592 Mr. Loeb sack. And I have a bill that attempts to address
3593 that by providing more behavioral health training for those
3594 primary care folks as well.

3595 Dr. McCance-Katz. And so that is where I was just going
3596 to go with that and talk about that we do have programs. We do
3597 work very hard to expand those programs as best that we can and
3598 we agree that that is one of the keys to providing care to those
3599 communities.

3600 Mr. Loeb sack. Thank you. And we did have, unfortunately,
3601 have something happen a few years back. Our governor did close
3602 down a couple of mental health institutes and one of them also
3603 dealt with substance abuse. And so that dual purpose is really,
3604 really critical, clearly there.

3605 Yes, anyone else? Yes.

3606 Dr. Schuchat. Just to say CDC has been doing a series of
3607 tracking the health issues in rural America and there are a number
3608 of disparities. The opioid overdose problem has now started to
3609 be worse in rural areas than urban or metropolitan areas and there
3610 are a number of other chronic conditions that are worse off.
3611 The solutions are probably going to be different. And one of
3612 the things that we do is support states to get better data that
3613 is locally granular and to track interventions into the hot spots,

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3614 if they are rural, or urban, or suburban.

3615 Mr. Loeb sack. So that is great. We have got to have good
3616 data. There is no question about it.

3617 Yes, anyone else?

3618 Dr. Volkow. So and we are planning also pilot trials to
3619 actually address the unique needs of the rural communities in
3620 places that have been hard hit by the epidemic to try to understand
3621 why the interventions are the most effective.

3622 Mr. Loeb sack. Right. And when meth was -- and meth is still
3623 a problem but when that was a real problem, even greater than
3624 it is now, it hit rural areas big time. There was a lot of cooking
3625 of meth that was going on at that time, too. We cracked down
3626 on some of that through some state laws but you know, again, we
3627 can't leave out the rural areas. I think that is the important
3628 thing to keep in mind. We don't hear much about them but it is
3629 important for someone like me to continue to voice those concerns.

3630 So thanks to the panel. Thank you, Mr. Chair, I really
3631 appreciate it. Thanks, everyone.

3632 The Chairman. Thank you, Mr. Loeb sack, I appreciate it.

3633 The chair now recognizes the gentleman from Ohio, Mr. Johnson
3634 for 5 minutes.

3635 Mr. Johnson. Thank you, Mr. Chairman and I thank the
3636 panelists for being here today. This is a critical, critical
3637 issue that we are talking about.

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3638 In my district, as in so many communities around the country,
3639 the opioid and drug abuse epidemic is a blight that is infecting
3640 and engulfing entire communities.

3641 We here on the Energy and Commerce Committee did some
3642 important work when we passed the 21st Century Cures Act and CARA
3643 on a bipartisan basis last year but we can't rest on our laurels.

3644 There is a lot more work to do. We must ensure that our efforts
3645 empower communities, healthcare providers, patients, and
3646 families to fight back against this vicious cycle of substance
3647 abuse.

3648 I recently visited an organization called Field of Hope.
3649 It is a facility, a faith-based, nonprofit treatment facility
3650 in my district. It is founded by a father whose daughter
3651 struggled with and eventually overcame addiction herself and now
3652 she works in the facility there.

3653 And in hearing the stories of the dozens of men, women, and
3654 children impacted by the work done by organizations like the Field
3655 of Hope, it becomes glaringly apparent that we are in danger of
3656 losing an entire generation. I mean hundreds of Americans are
3657 dying every day as a result of this epidemic and many of those
3658 people are in some of the most impoverished, low-income, high
3659 unemployment places around our country.

3660 Too many people began their slide into addiction as young
3661 people, as young as 12 years old, through prescription drugs for

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3662 a sports injury, or getting in with the wrong crowd, or even taking
3663 what parents think are safe medications over the counter for
3664 common cough and cold. We see that happening, too.

3665 So many of the testimonies document years of unrealized
3666 potential, frayed or destroyed relationships, and physical,
3667 emotional, and spiritual suffering but the testimonies also speak
3668 to the hope and the joy of recovery, if only people have access
3669 to the resources and the support that they need.

3670 And I am proud of the work that we have done on this committee
3671 and I am grateful, Mr. Chairman, for the continued focus that
3672 our committee is putting on it.

3673 So Dr. Gottlieb and Dr. Volkow, innovative non-opioid
3674 treatments for pain are being developed that can prevent addiction
3675 before it starts. How can we better align the approval process
3676 with Federal reimbursement policies for approved medications and
3677 devices so that, once new treatments are approved, patients are
3678 not barred from accessing them because they are not covered by
3679 Medicare, for example?

3680 Dr. Gottlieb. I can start, Congressman. I echo your
3681 sentiment. I think the Nation has weathered epidemics before
3682 but the current affliction is very different and very pervasive.

3683 We don't speak specifically to issues of reimbursement but
3684 it is the case that a lot of the drugs that are most commonly
3685 used are now generic drugs and they are very inexpensive. So

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3686 you do see preferential treatments on formularies for some of
3687 the drugs that are more addictive, or lack the abuse-deterrent
3688 formulations.

3689 We have taken steps recently, we will be issuing a final
3690 guidance document to delineate a more efficient pathway to bring
3691 generic versions of abuse-deterrent formulations to the market.

3692 And we have also taken steps to try to facilitate non-addictive
3693 forms of pain relievers. But it will be the case that some of
3694 those newer drugs will be more expensive than the older
3695 formulations and I think we need to think about how we provide
3696 incentives for those to be used, perhaps preferentially, if we
3697 think the public health outcome is going to be better.

3698 Mr. Johnson. Okay, my time has actually expired but can
3699 Dr. Volkow respond as well?

3700 The Chairman. Yes.

3701 Dr. Volkow. Yes, and I will just echo what Dr. Gottlieb
3702 said. And that is why in this public-private partnership not
3703 only are we working very closely with the FDA but it is important
3704 that we work with CMS. Because it is not just in terms of the
3705 patients being prescribed but in order to incentivize
3706 pharmaceuticals to develop products to invest, they need to have
3707 assurance that there will be a mechanism by which they are going
3708 to be able to recover their investments.

3709 Because if we are going to develop an opioid that has much

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3710 less vulnerability for abuse, diversion, and addiction, this is
3711 going to be more expensive but no one is going to cover for it,
3712 then they don't even start there. So it is also at the essence
3713 of being successful in getting them engaged in development of
3714 other medications.

3715 The Chairman. The gentleman's time has expired.

3716 Mr. Johnson. Thank you, Mr. Chairman.

3717 The Chairman. I recognize the gentleman from Maryland, Mr.
3718 Sarbanes, for 5 minutes.

3719 Mr. Sarbanes. Thank you, Mr. Chairman. I want to thank
3720 the panel.

3721 Dr. Volkow, I want to thank you for your terrific work.
3722 I had the opportunity, as you know, to come out to Bayview and
3723 see some of the research that is being done there, particularly
3724 with respect to kind of the brain response to these various
3725 medications and opioids and so forth and how we can use that
3726 research to develop effective responses to it.

3727 I also want to thank you, Ms. McCance-Katz in terms of your
3728 describing the importance of making naloxone available. I was
3729 proud that we were able to have included in one of the bills that
3730 we passed here on the Hill, a demonstration program to look at
3731 the co-prescribing of naloxone. And that is an important best
3732 practice, I think, for physicians to take up. And as more
3733 physicians are examining their practices, we can, hopefully, make

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3734 some progress in addressing this crisis.

3735 So thank you for referring to that. And that was a very
3736 bipartisan approach I wanted to add.

3737 I wanted to focus a little bit on the issue of workforce
3738 because I have been very focused for many years now on the kind
3739 of workforce side of our healthcare system and whether we have
3740 adequate people to provide whatever the particular care needs
3741 are but in this context, it is around the issue of treatment.

3742 And certainly we heard from Commissioner Gottlieb about some
3743 of the important medication responses that can be undertaken in
3744 response to this crisis and that is a critical component of it.

3745 But I am interested in hearing from you about what we need to
3746 do with some of these other treatment elements.

3747 I mean who are the kinds of professionals that need to be
3748 deployed as part of robust, meaningful treatment programs that
3749 can make a difference? I think, Dr. Volkow, you talked about
3750 key elements, being addressing the stigma, the lack of treatment
3751 slots in a lot of these programs, the lack of reimbursement for
3752 certain kinds of things.

3753 So let me ask -- why don't I start here? And then any others
3754 who want to come, I invite your perspective on the workforce side
3755 of this. Are there gaps? Are there shortages? Which of the
3756 kinds of professionals along the care continuum that we need to
3757 respond to this crisis where we have got put more resources,

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3758 recruit people into this?

3759 Dr. McCance-Katz. Well there definitely are gaps. We
3760 have, I don't have the exact number but I will guess around 10,000
3761 physicians who are addiction specialists in this country. We
3762 graduate only 1200 psychiatric residents a year to go into
3763 psychiatry, a very high-need area, where a lot of addiction work
3764 is done. We don't have enough advance practice clinicians.

3765 But what we need to do, one of the ways we can address this,
3766 is to integrate better addiction curriculum into the pre-graduate
3767 training. I actually wrote about a model that my colleagues and
3768 I at Brown University developed for our medical school, where
3769 every medical student will graduate qualified for a DATA waiver.

3770 And we do that through the addiction curriculum that we have
3771 put into our medical school. This not only makes people eligible
3772 to practice, once they become residents that are fully licensed
3773 with the DEA registration, but it also legitimizes addiction
3774 treatment. It makes addiction treatment a regular part of
3775 medical care, regardless of specialty. We need to do that in
3776 all medical schools, in all advance practice clinician programs,
3777 and we also need more psychologists, more counselors, more peer
3778 professionals. We lack all of these and it is one of the reasons-

3779 Mr. Sarbanes. I would love to get more information from
3780 you on that initiative.

3781 Dr. Volkow, I am going to run out of time so maybe I will

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3782 just come to you. You talked about sort of the psycho-social
3783 services component of the treatment response.

3784 Can you speak to the needs we have there in terms of the
3785 workforce?

3786 Dr. Volkow. One of the issues that has been brought up in
3787 the opioid crisis is yes, we over-prescribe opioids in our
3788 country. But the question is, What allowed it to disseminate
3789 so rapidly? And there is this concept of addiction being a
3790 disease of distress, and the fact that we have addiction is very,
3791 very frequently comorbid with mental illnesses, and there is some
3792 diseases that relate to adverse conditions that make you
3793 vulnerable.

3794 So as we are discussing the opioid crisis, we need to be
3795 mindful that we are going to need to have interventions that
3796 address those behavioral needs and psychological and psychiatric
3797 needs that many of these patients have.

3798 Mr. Sarbanes. Thank you. I yield back.

3799 The Chairman. The gentleman yields back.

3800 Just for the committee and for our witnesses, who I am sure
3801 would appreciate a break here at some point, we are going to go
3802 to Mr. Bucshon for 5 minutes.

3803 We have votes on the House floor that have been scheduled.

3804 So we will take a break. I think we have got three or four votes;
3805 probably 1/2 an hour, 45 minutes before we would we would

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3806 reconvene. Dr. Burgess will take over as subcommittee chair and
3807 run the remainder of the hearing.

3808 So there are members I know who want to ask some additional
3809 questions. So Mr. Bucshon, we will go with you, then we will
3810 recess, then we will return after the votes.

3811 Mr. Bucshon. Thank you, Chairman.

3812 The question is for Dr. McCance-Katz. Section 303 of the
3813 CARA Act, which I co-authored, requires that all office-based
3814 providers of addiction treatment have, and I quote, "the capacity
3815 to provide directly, by referral, or in such other manner as
3816 determined by the Secretary," all drugs approved by the FDA for
3817 the treatment of opioid use disorder and appropriate counseling
3818 and appropriate ancillary services.

3819 What has been SAMHSA's role in implementing this particular
3820 statute in CARA?

3821 Dr. McCance-Katz. Yes, so SAMHSA has implemented the
3822 required 24 hours of continuing education for nurse practitioners
3823 and physician assistants who wish to obtain a waiver for
3824 office-based treatment of opioid use disorder and we manage these.

3825 We keep the certifications. We provide that certification to
3826 the practitioners. And we continue to provide ongoing education
3827 through our provider clinical support system for
3828 medication-assisted treatment.

3829 Mr. Bucshon. Okay, that is not specifically what I asked

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3830 but so what is the current status of fully implementing Section
3831 303?

3832 Because you described expanding providers that are available
3833 but you haven't implemented what the providers actually have to
3834 do. I mean because -- is that true or not true? The capacity
3835 to provide direct, by referral, or such other manner determined
3836 by the Secretary for all treatment options. Does that make sense?

3837 Dr. McCance-Katz. Yes, so the education, the waiver
3838 education requires that all forms of approved medication-assisted
3839 treatment be taught.

3840 Mr. Bucshon. Okay because I am just being told that you
3841 haven't implemented a lot of Section 303.

3842 Dr. McCance-Katz. We have implemented all of Section 303.

3843 Mr. Bucshon. Okay, then I stand corrected.

3844 Within 18 months of enactment, HHS is required to update
3845 the practice guidelines for office-based treatment settings so
3846 as to conform with Section 303. What is the status of the practice
3847 guidelines?

3848 Dr. McCance-Katz. I got to SAMHSA 2 months ago. I will
3849 tell you that I have reviewed that document. That document, in
3850 my opinion, needs additional work but it is in the clearance
3851 process and we will get that done.

3852 Mr. Bucshon. Very good to hear that. Thank you very much.

3853 Mr. Doherty, what percentage of illicit drugs that are in

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3854 the United States come across our southern border, do you have
3855 any idea?

3856 Mr. Doherty. Sir, I could not give you an exact percentage
3857 but we determined that the Sinaloa Cartel, who currently has the
3858 control of the U.S. market share for heroin and now, alarmingly,
3859 fentanyl, they control a predominately large portion of the
3860 southwest border in terms of importation routes and
3861 transportation routes.

3862 Mr. Bucshon. So at least for them, it is 100 percent?

3863 Mr. Doherty. Yes, sir.

3864 Mr. Bucshon. And so do you think we are doing enough to
3865 stop it?

3866 Mr. Doherty. Sir --

3867 Mr. Bucshon. That is not a criticism, by the way. I mean
3868 overall, as a country, do you think we doing enough to stop it?

3869 Mr. Doherty. Sir, as a DEA agent for 28 years and someone
3870 that worked in Arizona and knows the border area, I would say
3871 that a comprehensive strategy, one that involves technology and
3872 power, boots on the ground, as well as intelligence is crucial
3873 to stopping the, for lack of a better term, poly-criminal
3874 organizations, ones that traffic in drugs, humans, contraband,
3875 weapons along our southwest border.

3876 So we would stand with all of our Federal, State, and local
3877 partners in coming up with new innovative solutions; however,

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3878 it has to be a comprehensive approach, sir.

3879 Mr. Bucshon. Yes, I don't want to cause you too much grief
3880 but is a physical barrier part of that?

3881 Mr. Doherty. Sir, again, it would have to be a comprehensive
3882 strategy and any measure that would lend itself to stop drug
3883 trafficking and other means of illegal activity from entering
3884 the United States, fold into an overall approach. As I said,
3885 technology, manpower, and intelligence I think would be
3886 beneficial.

3887 Mr. Bucshon. Great. Thanks for that.

3888 So I don't think we can overstate the importance of
3889 decreasing the demand for the product but also it is very important
3890 to prevent the supply. And I would encourage all my colleagues
3891 across Congress to work with the administration to secure the
3892 southern border using, as described, a multi-pronged approach,
3893 which may or may not include a physical barrier, and to quit
3894 actively preventing the administration from trying to secure the
3895 southern border.

3896 With that, Mr. Chairman, I yield back.

3897 The Chairman. The gentleman yields back.

3898 I recognize the gentleman from New York.

3899 Mr. Tonko. Mr. Chair, I asked that three letters be included
3900 in the record. They include the American Hospital Association,
3901 a second from Protecting Access to Pain Relief Coalition, and

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3902 finally, the American Society of Addiction Medicine.

3903 The Chairman. Without objection, they will be entered into
3904 the record.

3905 [The information follows:]

3906

3907 *****COMMITTEE INSERT 8*****

3908 The Chairman. For our witnesses, we probably won't be back
3909 for 1/2 an hour. So if you want to grab something to eat and
3910 whatever else, probably at least a 1/2 an hour before the committee
3911 starts, probably closer to 2:30.

3912 And Dr. Burgess will take over there because I know we still
3913 have members that want to ask questions.

3914 So with that, we will stand in recess.

3915 [Whereupon, at 1:43 p.m., the subcommittee recessed, to
3916 reconvene at 2:27 p.m., the same day.]

3917 Mr. Burgess. [Presiding.] Very well, I will ask everyone
3918 to take their seats and I will call the subcommittee back to order.

3919 When the subcommittee adjourned for votes, pending for
3920 questions was Dr. Raul Ruiz. So we will recognize Dr. Ruiz for
3921 5 minutes for questions, please.

3922 Mr. Ruiz. Thank you, Mr. Chairman. Welcome back,
3923 everybody. I hope you had a little nice break. I would like
3924 to thank all the witnesses for joining us.

3925 Many of you know I am an emergency physician. I have taken
3926 care hundreds of patients who have come in respiratory arrest
3927 from opioid overdose. I have taken care of toddlers who
3928 accidentally got into the cabinet. I have taken care of adolescents
3929 and young adults who took it for the high, while they were
3930 partying. And I have taken care of seniors who have gotten
3931 addicted throughout the time because of chronic pain usage of

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3932 opioids and took that extra sedative to help them sleep, you know
3933 the sleep pill, and also maybe a little cocktail, two cocktails
3934 at night. The next thing you know, they stop breathing during
3935 the night, and their spouses wake up, and they are blue, and they
3936 bring them into the emergency department.

3937 And most of the time, we are able to resuscitate and put
3938 them on mechanical ventilation, give them the appropriate
3939 medication soon enough to reverse it but sometimes, it is
3940 unfortunate, they are pronounced dead on the field or, after an
3941 incredible amount of resuscitation, their hearts don't come back,
3942 and so we can't get a beat, and we have to pronounce them dead.

3943 So this is something that I know firsthand in the community
3944 and in emergency departments that we are faced with. And I am
3945 extremely proud of our first responders who, in the patient's
3946 home, in the streets, at the clubs, at the bars, like are the
3947 first people on scene and provide the first live-saving
3948 resuscitation, anywhere from paramedics, EMTs, the firemen and
3949 women, men and women who wear the badge in our law enforcement.

3950 You know they are there. And they oftentimes then come to us
3951 in the emergency department with the handoff and we take over.

3952 We know that last Congress and during the Obama
3953 administration, we took some steps to expand the workforce and
3954 efforts to ease the access due to buprenorphine so that these
3955 first responders and healthcare providers can provide a

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3956 treatment.

3957 I want to revisit the workforce effort because we know there
3958 is folks in prevention that oftentimes we don't really think of.

3959 These are the high school counselors and teachers, the public
3960 health educators, the community health workers, the primary care
3961 docs, family medicine, internal medicines that can identify risks
3962 and education. Then we have the acute crisis, right, the
3963 emergency medicine, the first responders, the law enforcement,
3964 the nurses in the emergency departments. And then we have the
3965 detox and treatments, the addiction services for adolescents,
3966 adults, emergency physician nurses, psychiatrists,
3967 psychologists, mental health. And then we have the long-term
3968 rehabilitation services.

3969 So in your opinion, are we working in a coordinated mechanism
3970 with a strategic vision to provide enough training to all these
3971 different workforce healthcare providers with a clear set of
3972 priorities and understandings or is it scattered from here and
3973 there?

3974 I will ask Dr. Schuchat.

3975 Dr. Schuchat. Yes, I can begin and then I think my
3976 colleagues will probably expand.

3977 Our piece is the prevention piece, prevention for
3978 prescribing, and then supporting state and local public health,
3979 who have a role in the data to speed up the information so we

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3980 know where the hot spots are, and a role in evaluating the
3981 policies.

3982 Mr. Ruiz. Is it coordinated in curriculum and outreach to
3983 these individuals?

3984 Dr. Schuchat. Yes, so what I can say is that the guidelines
3985 for treatment of chronic pain have been adopted by dozens of
3986 states, and medical societies, and are now being taken up by the
3987 medical schools, the pharmacy schools, and the nursing schools.

3988 Mr. Ruiz. So your answer is no because every different
3989 groups are working in silos and what we need is a coordinated
3990 response with leadership from the top.

3991 Let me ask another question. I have a minute left.

3992 We know what the public health motto is. We do have a plan.
3993 There is a framework. You are trained in it. I am trained in
3994 it. You know the framework to come to the answer to identify
3995 high risk, to institute programs catering to high risk, and then
3996 measuring the outcomes of those and expanding those to the
3997 population.

3998 So what are the highest risk individuals, and what are the
3999 programs out there where we are addressing them to prevent them
4000 from being evicted, and also the highest risk for relapse, and
4001 what are we doing for them, Dr. McCance-Katz?

4002 Dr. McCance-Katz. So we have training programs that one
4003 is our Providers' Clinical Support System for Medication Assisted

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4004 Treatment and that provides structured training and mentoring
4005 --

4006 Mr. Ruiz. What is the population base most at risk of
4007 starting an addictive addiction and what are you doing to combat
4008 those in the public?

4009 Dr. McCance-Katz. So we know from a lot of research studies
4010 that people who are at highest risk are people who have a history
4011 of substance use disorder, a history of previous opiate addiction,
4012 a history of mental illness. We know that. And that is
4013 curriculum that is taught within our Providers' Clinical Support
4014 System, which is a consortium of a large number of different types
4015 of professional health organizations that do outreach to their
4016 members so that we can train them.

4017 We also have the Addiction Technology Transfer Centers that
4018 have the Nation divided into ten regions and we have one that
4019 also focuses on Native American issues. And those provide
4020 training to other types of practitioners, counselors, nurses,
4021 et cetera.

4022 Mr. Ruiz. Thank you.

4023 Mr. Burgess. The gentleman's time has expired. The
4024 gentleman yields back.

4025 The chair recognizes the gentleman from Michigan, Mr.
4026 Walberg, for 5 minutes for questions please.

4027 Mr. Walberg. Thank you, Chairman, for that opportunity and

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4028 thank you for being here today. As has been noted on numerous
4029 occasions -- I am having a hard time working with one wing here,
4030 Doctor, but we will get it working right -- we all share the
4031 concerns together. It is how we meet the needs, and how we can
4032 be an assist to all the things that you do, and have the
4033 communications that make us a resource and a partner alongside.

4034 Dr. McCance-Katz, PDNPs normally include a patient's history
4035 of prescriptions for controlled substances using data submitted
4036 by pharmacies and dispensing practitioners. Under Jessie's Law,
4037 a bill that I have introduced with Representative Dingle, HHS
4038 would be required to develop best practices for including a
4039 patient's history of addiction treatment with patient consent,
4040 of course, in their electronic health records. This information
4041 helps to better inform, I believe, a provider and avoids risk
4042 for relapse or dangerous side effects when a patient seeks
4043 treatment for a condition or illness separate from their
4044 addiction. And that was the genesis for this piece of legislation
4045 because of a very unfortunate outcome where things were missed.

4046 For similar reasons, should this same information be made
4047 available in PDNPs across the country as a way to better inform
4048 providers?

4049 Dr. McCance-Katz. So those kinds of questions I think are
4050 best left to Congress and the administration. The
4051 administration, to my knowledge, does not have a position on that

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4052 but we would be happy to work with you and provide any technical
4053 assistance to move that forward.

4054 Mr. Walberg. I appreciate that and I understand that a
4055 position has to be taken when the administration takes a position
4056 but this is something that would be of great help so that we don't
4057 run amuck of a lot of things that you have to consider in the
4058 day-to-day practice in meeting the needs. And while we want to
4059 make sure those needs are met, we provide resources, we need the
4060 support. So we will take you up on that.

4061 Dr. McCance-Katz. Thank you.

4062 Mr. Walberg. Mr. Doherty, drug diversion remains a serious
4063 problem and I have become aware of a particular challenge that
4064 exists in circumstances of in-home hospice care. DEA regulations
4065 issued in 2014 specifically forbid hospice staff from destroying
4066 leftover controlled substances, unless allowed for by state law.
4067 As a result, leftover pills belong to the family, which has no
4068 legal obligation to destroy them or give them up.

4069 I believe hospice staff could play a very meaningful role
4070 in helping to prevent instances of diversion but those regulations
4071 prohibit hospice personnel from taking a more active role in
4072 disposing or removing medications from the home.

4073 And so for the first question, I would ask is your agency
4074 willing to work with me and this committee to help establish a
4075 uniform set of practices that will allow hospice professionals

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4076 better to assist families to dispose of leftover drugs?

4077 Mr. Doherty. Congressman, thank you for that issue. And
4078 of course we can all look to all of our resources to do better
4079 and do more. We will be happy to work with Congress and the
4080 Department of Justice on that issue.

4081 Mr. Walberg. Well along that line, in addition to
4082 prescription takebacks, what other opportunities exist for
4083 families in this situation to properly dispose of opioids?

4084 Mr. Doherty. Sir, DEA has been a leader in the proper
4085 disposal, safe and effective disposal of unwanted and unused
4086 prescription drugs through our Take Back Initiative. As you
4087 mentioned, sir, we have run that program since 2011. We have
4088 had 13 iterations of that program and, collectively, we have taken
4089 in 8.1 million pounds of unused and unwanted prescription pain
4090 medication. And we feel it is terribly important due to the fact
4091 that we need to keep these things out of the medicine cabinet.

4092 Another issue I would point to, sir, is under CARA we have
4093 a provision that we worked on in conjunction with our partners
4094 that allows the option to not fill a complete prescription when
4095 you are going to get your medication. We think that is certainly
4096 important for, for example, teenagers that have their wisdom teeth
4097 out and you have a parent caring for them. It is certainly ethical
4098 and reasonable to take only take 5 out of 30 oxycodone if you
4099 are caring for a teenager with that procedure.

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4100 So we think that is another important factor. DEA has worked
4101 hard with HHS on that issue. Thank you for your concern, sir.

4102 Mr. Walberg. We appreciate that and we will be looking
4103 forward to working with you.

4104 I yield back.

4105 Mr. Burgess. The chair thanks the gentleman. The
4106 gentleman yields back.

4107 The chair recognizes the gentlelady from Florida, Ms.
4108 Castor, for 5 minutes for questions, please.

4109 Ms. Castor. Thank you. I would like to focus on an issue
4110 that this committee has been investigating and that I raised in
4111 committee last spring after the reports in the Charleston Gazette
4112 Mail that drug distributors shipped 780 million hydrocodone and
4113 oxycodone pills to West Virginia over 6 years, which amounted
4114 to 433 pills for every man, woman, and child in the state. And
4115 another news network further reported that one pharmacy in the
4116 small town of Kermit, with just 392 residents received nine
4117 million hydrocodone pills in just 2 years.

4118 So after our previous hearing in March, the committee asked
4119 the DEA what actions it took in response to the reported oversupply
4120 of opioids in West Virginia over the course of the 6 years. In
4121 DEA's response that we just received last night, DEA noted that
4122 it established a tactical diversion squad in Clarksburg, West
4123 Virginia in December 2016. But DEA's own data would suggest that

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4124 the distributors began sending large shipments of opioids to West
4125 Virginia well before that date.

4126 Mr. Doherty, please refer to the committee's October 13th
4127 letter to DEA. The charts in this letter, which utilized DEA's
4128 ARCOS data, showed that these massive shipments began taking place
4129 as early as 2007 and 2008.

4130 I am glad that DEA has now established a greater presence
4131 in West Virginia but, in hindsight, should DEA have spotted these
4132 trends earlier?

4133 Mr. Doherty. Ma'am, thank you for that question. And DEA
4134 agrees the amount of pills going into that area was excessive
4135 in looking back. At the time that you referenced, ma'am, and
4136 to your point, we had another phenomenon going on in this country.

4137 It was the proliferation of rogue pain clinics and pill mills
4138 in Florida. Florida was the epicenter of the beginning, in some
4139 ways, of the opioid crisis that we face today.

4140 DEA devoted a tremendous amount of resources and then we
4141 shifted our resources. We shifted our resources to areas like
4142 West Virginia when we realized this problem.

4143 Ms. Castor. So that tells me, though, that maybe DEA did
4144 not have the information on the flood of opioids going into West
4145 Virginia because certainly if you knew 780 million
4146 hydrocodone/oxycodone pills -- I mean that is your own, the data
4147 of the pills flooding in there.

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4148 How were you monitoring the flood of opioids into a
4149 particular community at that time?

4150 Mr. Doherty. Ma'am, I was not assigned to the Diversion
4151 Control Division at that time. I could tell you --

4152 Ms. Castor. How as the agency?

4153 Mr. Doherty. I could not speak to that, ma'am.

4154 Ms. Castor. Don't they have the tools to monitor shipments,
4155 a flood of opioids into a particular community? Weren't you able
4156 to monitor that?

4157 Mr. Doherty. Ma'am, the way these are monitored in
4158 conjunction with distributors, they are monitored through the
4159 submission of suspicious orders. And the distributors have an
4160 obligation to report that to DEA and that was a flaw and that
4161 is why --

4162 Ms. Castor. Are you saying they did not report it and DEA
4163 had to rely on news reports? That can't be the case.

4164 Mr. Doherty. No, ma'am, that is not what I am saying. What
4165 I am saying is in combined with the suspicious orders that are
4166 reported in oversight of our regulatory registrant community,
4167 specifically the distributors, as you mentioned, we realized that
4168 some were not reporting as required. And then we shifted
4169 resources to those areas and we became more stringent with our
4170 distributors by initiating a --

4171 Ms. Castor. So besides some suspicious, besides the

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4172 distributors reporting and some suspicious filing, DEA didn't
4173 have any other tools at its disposal to understand the flood of
4174 opioids into a community?

4175 Mr. Doherty. Ma'am, we do have, as you mentioned, in these
4176 charts, ARCOS data, which is not real-time data. And we use data
4177 analytics and we are getting better at data analytics to prevent
4178 this from happening again.

4179 Ms. Castor. What is the lag time in the ARCOS data?

4180 Mr. Doherty. I do not have that information, ma'am.

4181 Ms. Castor. So clearly, there is a breakdown here.

4182 What can you say to other communities across the country
4183 that maybe experiencing something similar right now, a flood of
4184 opioids, some new epidemic, some hot spot? What is DEA able to
4185 do to monitor that situation so it is not too late?

4186 Mr. Doherty. Ma'am, as I mentioned earlier, we are
4187 providing threat assessments to our 21 Domestic Field Divisions,
4188 with respect to ARCOS data specifically, and we are conducting
4189 a long-term overhaul of our SORS system, Suspicious Order Report
4190 System, to keep distributors in line and to prevent this from
4191 ever happening again.

4192 Ms. Castor. And then what other tools do you need from the
4193 Congress?

4194 Mr. Doherty. Ma'am, we would be happy to work with Members
4195 of Congress through the Department of Justice and we would also

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4196 advocate for full support of the President's budget.

4197 Ms. Castor. Well, we need to get to the bottom of this to
4198 protect communities that have been damaged by opioids and to
4199 ensure that other communities do not suffer the same fate.

4200 And people are relying on DEA to be the safeguard. And I
4201 hope the agency can be more proactive and use all the data at
4202 its disposal.

4203 Thank you very much.

4204 Mr. Burgess. The gentlelady yields back. The chair thanks
4205 the gentlelady.

4206 The chair recognizes the gentleman from Pennsylvania, Mr.
4207 Costello, for 5 minutes, please.

4208 Mr. Costello. Thank you.

4209 Mr. Doherty, what is your title with DEA?

4210 Mr. Doherty. Deputy Assistant Administrator Office of
4211 Diversion Control Operations.

4212 Mr. Costello. Amongst your duties is to stem the flow or
4213 ensure that the excessive illegal distribution of opiates around
4214 this country does not occur. Is that correct?

4215 Mr. Doherty. Yes, sir.

4216 Mr. Costello. If we could refer to the chart, if you could
4217 put that chart up, I am going to reference the bill that passed
4218 last year that is the subject of some journalistic inspection
4219 right now.

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4220 Clearly, between 2011 and 2016, prior to this bill being
4221 passed, the number of immediate suspension orders has reduced
4222 substantially, correct?

4223 Mr. Doherty. Yes.

4224 Mr. Costello. And an immediate suspension order is an order
4225 that, without prior notice, terminates a distributor's ability
4226 to distribute controlled substances. It is an extraordinary
4227 measure intended to supplement standard agency procedures in
4228 cases of imminent danger. Is that correct?

4229 Mr. Doherty. Yes, sir.

4230 Mr. Costello. And the legislation sought to define the term
4231 imminent danger because there was litigation and concern raised
4232 by many patient advocate groups, local pharmacies, et cetera,
4233 that that standard was unclear. Is that correct?

4234 Mr. Doherty. That is my understanding, sir.

4235 Mr. Costello. Is it true that since passage of the bill
4236 the number of ISOs has actually increased?

4237 Mr. Doherty. That is not true, sir.

4238 Mr. Costello. I believe that eight orders have been issued
4239 subsequent to the passage of the bill. Isn't that correct?

4240 Mr. Doherty. I stand corrected, sir. Since the passage
4241 of the bill, yes, sir.

4242 Mr. Costello. It has increased. Has the amount of opiates
4243 distributed decreased since passage of the bill?

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4244 Mr. Doherty. I would have to confer with my diversion staff
4245 and get back to you on that.

4246 Mr. Costello. If I read data points that indicated that
4247 amount of opiates manufactured and distributed in 2017 is less
4248 than 2016, would that be accurate?

4249 Mr. Doherty. That would be accurate, sir.

4250 Mr. Costello. So is it fair to say that since passage of
4251 the bill, the number of opiates manufactured and distributed has
4252 been less than before it was passed?

4253 Mr. Doherty. Yes, sir, and that would be directly in line
4254 with the reduction in the APQ, the aggregate production quota
4255 --

4256 Mr. Costello. Yes.

4257 Mr. Doherty. -- that DEA oversees.

4258 Mr. Costello. So if someone says the law has helped fuel
4259 the opiate epidemic, would that have any basis in fact, given
4260 the fact that the number of ISOs has increased since passage of
4261 the bill and then the number of opiates manufactured and
4262 distributed has decreased since the passage of the bill?

4263 Mr. Doherty. No, sir, I don't believe the data shows that.

4264 Mr. Costello. Okay, thank you.

4265 DEA and DOJ contributed significantly to the language of
4266 the bill that was passed. This has been generally represented
4267 by Senator Hatch and Senator Whitehouse, a Republican and a

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4268 Democrat, in the Senate. Do you agree that the DEA and the
4269 Department of Justice provided technical assistance to the bill
4270 that was ultimately passed and signed into law?

4271 Mr. Doherty. Yes, sir, that is my understanding.

4272 Mr. Costello. And if DEA had opposed the bill, they would
4273 have provided testimony, or correspondence, or done some level
4274 of advocacy with Members of Congress. Is that correct?

4275 Mr. Doherty. Yes, sir, I believe there was a technical
4276 advisement period and then, ultimately, the bill moved forward
4277 and was signed into law last April.

4278 Mr. Costello. And it is fair to say that there were previous
4279 iterations of the bill that the DEA took issue with and they did
4280 object to it. Is that correct?

4281 Mr. Doherty. That is my understanding, yes, sir.

4282 Mr. Costello. Is it further true, based upon reports that
4283 the Obama administration actually requested of the DEA whether
4284 or not they recommend that the President sign it and the DEA must
4285 have said, in some form or fashion, yes, this bill is appropriate
4286 to sign. Is that correct?

4287 Mr. Doherty. That is correct, sir.

4288 Mr. Costello. Let's talk about this. Do you think that
4289 the law should be repealed?

4290 Mr. Doherty. Sir, in terms of the bill that affects, as
4291 you say, the ISOs that we use in our administrative toolbox, we

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4292 also use criminal tools.

4293 Mr. Costello. Absolutely.

4294 Mr. Doherty. We also use investigative tools.

4295 Mr. Costello. There is a lot of other things you do.

4296 Mr. Doherty. Right.

4297 Mr. Costello. And you do it effectively in very many
4298 measures. But on this specific bill, which deals with ISOs, do
4299 you think it should be repealed or do you think that it is doing
4300 what it what it was intended to do, which was provide clarity
4301 so that you can actually go out and issue ISOs without having
4302 to deal with litigation that might actually call into question
4303 your enforcement powers in the first instance?

4304 Mr. Doherty. Sir, let me say that the bill -- the law changed
4305 the way that we looked at ISOs. It did not stop DEA from doing
4306 its job in the diversion space and we would be happy to work with
4307 Congress and DOJ, who is looking at this issue, as I said earlier,
4308 currently, to make sure that DEA has all the appropriate and
4309 updated tools.

4310 Mr. Costello. Do you agree that if we did repeal this law,
4311 and didn't supplement it with something else, then the same
4312 vagueness that caused litigation to occur, that raised concerns
4313 from a whole host of constituencies would come to bear once again?

4314 Mr. Doherty. Yes, sir, I believe we do need a mechanism
4315 at that level with respect to that tool.

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4316 Mr. Costello. One final question I am going to try and sneak
4317 in.

4318 Was there an internal policy change why the DEA so
4319 dramatically reduced ISOs between 2011 and 2016?

4320 Mr. Doherty. Not to my knowledge, sir.

4321 Mr. Costello. Thank you. I yield back.

4322 Mr. Burgess. The gentleman yields back. The chair thanks
4323 the gentleman.

4324 The chair recognizes the gentleman from Georgia, Mr. Carter,
4325 5 minutes for questions, please.

4326 Mr. Carter. Thank you, Mr. Chairman and thank you for this
4327 most important hearing.

4328 Mr. Chairman, I would ask unanimous consent to add into the
4329 record the written testimony from the International Chiropractors
4330 Association about non-pharmacological treatment of pain. Mr.
4331 Chairman?

4332 Mr. Chairman --

4333 Mr. Burgess. Is that your unanimous consent request?

4334 Mr. Carter. Yes.

4335 Mr. Burgess. Would you restate it, please?

4336 Mr. Carter. Yes, sir. Mr. Chairman, I would ask unanimous
4337 consent to add into the record the written testimony by the
4338 International Chiropractors Association on non-pharmaceutical
4339 treatment of pain.

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4340 Mr. Burgess. Without objection, so ordered.

4341 [The information follows:]

4342

4343 *****COMMITTEE INSERT 9*****

4344 Mr. Carter. Thank you.

4345 Dr. Schuchat, last year there was a study done that I believe
4346 was done in collaboration with the CDC and John Hopkins, and HHS,
4347 and NIH, and CMS that was called examining insurance coverage
4348 for acute and chronic back pain treatment pilots. Now are you
4349 familiar with this, dealing with insurance companies and how they
4350 can actually not approve non-pharmaceutical treatments and
4351 actually push more opioid use by what they cover and what they
4352 don't cover?

4353 Dr. Schuchat. I am not familiar with the specific study
4354 but I am familiar with that issue of what is reimbursed and what
4355 isn't and that there has been a problem with opioids being easily
4356 reimbursed and the alternative approaches were recommended not
4357 to be paid.

4358 Mr. Carter. Okay, well this is the study that I am speaking
4359 of. Because I want to make sure because CMS has actually cited
4360 this as being a problem.

4361 Also, in the New York Times, there was an article last week
4362 that addressed this well that I want to bring to your attention.

4363 And essentially what it says, it gave very many examples about
4364 how pharmacy benefit managers, PBMs, if you will, and insurance
4365 companies are actually pushing more opioid use by the fact that
4366 they are not approving the use of non-pharmaceutical or
4367 non-opioids.

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4368 Whereas, I agree with Dr. Gottlieb that there is a gap there
4369 between ibuprofen and the NSAIDs and then we go to opioids and
4370 we need to fill in that gap but there are some things can be used.

4371 You can use gabapentin. You can use Neurontin, Lyrica, those
4372 type of things but, in many cases, the insurance companies don't
4373 cover them. The PBMs don't cover them. The copay is higher,
4374 or you have to get a prior approval, or it is another tier, a
4375 higher tier so that you have to go through more hoops in order
4376 to get it approved which, of course, is leaning to more opioid
4377 use.

4378 Do you care to comment on that? Is that something you see?

4379 Dr. Schuchat. Yes, our incentives have been going the wrong
4380 way to get better practice, better paying management, and avoiding
4381 the harms of opioids.

4382 Mr. Carter. What can you do? What can CDC do? I mean is
4383 there anything you can do to encourage -- I have not had any success
4384 in dealing with the PBMs, I can tell you that, but perhaps you
4385 will.

4386 Dr. Schuchat. You know CDC's guidelines for the treatment
4387 of chronic pain are now being taken up by a number of health plans,
4388 insurers, medical societies and the defaults in the electronic
4389 medical records --

4390 Mr. Carter. Okay.

4391 Dr. Schuchat. -- and the ordering are better in many

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4392 places.

4393 But I wanted to say something about the pharmacy benefit
4394 managers and the --

4395 Mr. Carter. Please hurry.

4396 Dr. Schuchat. Sorry. Just that they have actually been
4397 helpful in spotting the problematic providers.

4398 Mr. Carter. They have been helpful to a certain extent but
4399 also they have been part of the problem because they have been
4400 not approving some of the drugs that could have been used and,
4401 instead, have been approving the cheaper opioids; therefore,
4402 increasing the amount of opioid use. So that is the point that
4403 I am trying to make here.

4404 Dr. Schuchat. Yes, absolutely.

4405 Mr. Carter. Okay.

4406 Dr. Schuchat. We need better prescribing.

4407 Mr. Carter. Okay, Dr. Gottlieb, I want to first of all
4408 applaud you. In July you made an announcement that you were
4409 expanding, that FDA was expanding prescriber educational
4410 opportunities for instant release opioids. And this is a step
4411 in the right direction. There is no question about that. As
4412 a practicing pharmacist for many years, I can tell you we need
4413 more physician education.

4414 And you also said at that time that you were exploring making
4415 prescription training mandatory. Has FDA addressed that in any

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4416 way at all?

4417 Dr. Gottlieb. We also expanded that education for
4418 pharmacists as well, Congressman Carter.

4419 Mr. Carter. And thank you for doing that. That needs to
4420 be done.

4421 Dr. Gottlieb. Right. We are still working -- we have a
4422 task force, a working group that is looking at different ways
4423 that we would operationalize a potential mandatory requirement
4424 for education, some of which could be contemplated by working
4425 in close concert, which we have been doing, with our partners
4426 at DEA. But we are looking at alternatives for how we could make
4427 education mandatory.

4428 Mr. Carter. One other thing I want to get in before my time
4429 is up and that is this. Dr. Gottlieb, I thought you made a great
4430 point in your opening statement when you made the point that there
4431 really are two problems we are facing here.

4432 First of all, we are facing the prevention of this happening
4433 and trying to prevent people from being addicted. But another
4434 problem that we have is that we have got over 11 million people
4435 that are addicted now. We have got to deal with that and that
4436 is a big, big problem.

4437 My question is -- you know last week I was in the treatment
4438 centers -- what will work? It is going to take more than just
4439 throwing money at it. This is not a situation where we can say

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4440 okay, we have hit \$50 billion; therefore, we have done our job.
4441 That is not what I am looking for at all. I am looking for
4442 effective treatments that are going to work.

4443 And I can tell you from personal experience I have seen opioid
4444 abuse firsthand. I have seen it ruin lives. I have seen it ruin
4445 families and careers. It is tough.

4446 What do you know, Dr. Volkow -- I have served on many panels
4447 with you and you do a great job. What works? What works in the
4448 way of rehabilitation?

4449 Dr. Volkow. First of all, I want to thank you for bringing
4450 up the issue that it is not just throwing money at something.

4451 You have to actually throw money at a solution that is going
4452 to be effective. And I think that what we are demanding. That
4453 is why one of the things that we are demanding is that the treatment
4454 that is provided for individuals with opioid use disorder with
4455 quality care treatment for which there is evidence of benefit
4456 and that we need to actually change the way that we provide that
4457 treatment so that we have a means to monitor the outcomes of the
4458 patients such that we can learn from what leads to a good response
4459 in a given patient and what in another one.

4460 We know, in general, that medication-assisted treatment
4461 significantly improved the outcomes and it prevents overdoses
4462 but we also know that not every patient responds and there is
4463 still significant relapse.

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4464 Mr. Carter. And thank you for that.

4465 And I am way over my time but one thing I want to warn all
4466 of us is that let's don't become too dependent on naloxone because
4467 it becomes a crutch and that is just not good.

4468 We have had problems already in Jacksonville, Florida, south
4469 of my district, where they can't even carry it on the ambulances
4470 anymore because of the high cost and people getting it three or
4471 four times a week. It does not need to become a crutch for these
4472 people as well, although I understand fully the value of it.

4473 Thank you, Mr. Chairman.

4474 Mr. Burgess. The gentleman's time has expired.

4475 The chair recognizes the gentleman from South Carolina, Mr.
4476 Duncan, the newest member of the committee, 5 minutes for
4477 questions, please.

4478 Mr. Duncan. Thank you, Mr. Chairman. And I have waited
4479 a long time to be on this committee. It is an honor to be part
4480 of Energy and Commerce.

4481 I would be remiss if I didn't mention the work of a good
4482 friend of mine, State Representative Eric Bedingfield in South
4483 Carolina, who lost his son a year ago after a decade-long battle
4484 with opioids. And Eric and his family are very much in my thoughts
4485 as we have this hearing today. So I want to honor his continuing
4486 work and the state legislature on this issue.

4487 As we have seen today, this is an issue that transcends

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4488 partisanship. It affects Americans in all 50 states. The opioid
4489 epidemic is real.

4490 Mr. Doherty, you mentioned tools that you had in your tool
4491 box for combatting the opioid epidemic. Could you tell me what
4492 some of those tools are, if not all of them? And then what would
4493 you say is the most valuable tools you have in this fight?

4494 Mr. Doherty. Congressman, thank you for that question.
4495 And I would say that from a law enforcement perspective and a
4496 DEA perspective, first of all, the scope of the problem is enormous
4497 and we need, literally, all hands on deck across the Federal,
4498 State, and local level, the medical community, the scientific
4499 community, and the law enforcement community.

4500 In terms of addressing the problem, we need to attack supply
4501 with the overseas suppliers with respect to heroin and fentanyl.
4502 We need to work to take the gang element out.

4503 Mr. Duncan. How do you do that without cooperation of the
4504 foreign governments? Are they cooperating, I guess is what I
4505 am asking?

4506 Mr. Doherty. Yes, sir, we have had great cooperation at
4507 the international level, the bilateral level, and the
4508 multilateral level. Yes, sir.

4509 Additionally, I would add that domestically we are
4510 initiating additional 360 Program cities for fiscal year 2018
4511 and the 360 Program has been a crucial part of having, as I said,

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4512 three distinct pillars of law enforcement attack this problem.

4513 We are also very much into the prevention space with the
4514 360 Prevention and also with Operation Prevention, which is a
4515 web-based curriculum that is cutting edge and designed to teach
4516 young adults the dangers of opioid use. And it is free. It is
4517 distributed to educators throughout the country and it has been
4518 viewed by hundreds of thousands of individuals so far.

4519 And we feel that partnership across government is key to
4520 establishing a dialogue, number one, about new and innovative
4521 ways to attack the opioid crisis. And I think that no idea facing
4522 all of us is off the table with respect to this problem.

4523 Mr. Duncan. All right. It is an immense challenge.

4524 I came to this committee from Homeland Security Committee
4525 and also the Foreign Affairs Committee, where I chaired the
4526 Western Hemisphere Subcommittee. Opioids is the focus of this
4527 today but let me just let the committee know that due to
4528 circumstances in Colombia and Peru, the cocoa production has been
4529 up over the last year, 18 months. Coca production has been up.

4530 As a result, there is a lot of cocaine out there ready to come
4531 north. They are not flooding the market with it. That is going
4532 to be our next issue to deal with with regard to drugs.

4533 I appreciate the work you guys do, your men and women around
4534 the globe. And I have dealt with them in South America, so I
4535 know the challenges they face.

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4536 Mr. Chairman, thank you so much and I yield back.

4537 Mr. Burgess. The chair thanks the gentleman.

4538 The chair recognizes the gentlelady from Indiana, Mrs.

4539 Brooks, 5 minutes for questions.

4540 Mrs. Brooks. Thank you, Mr. Chairman and I appreciate the
4541 fact that you all got a break. I want to thank you all so very
4542 much for your work because each of your agencies is so critically
4543 important.

4544 And I want to start out because in the CARA effort the first
4545 section of that bill was a section that my colleague from
4546 Massachusetts, Representative Kennedy and I worked on, and it
4547 was to establish an interagency and medical professional task
4548 force to review and, when necessary, update and modify the CDC
4549 best practices guidelines for pain management.

4550 And so, Dr. Schuchat, can you tell me did you know about
4551 this formation and that it needs to be formed by the end of December
4552 of 2018 and report? And you are looking at Dr. McCance-Katz.

4553 So I am curious. I just want to know. Is it happening? Is
4554 it in formation and will we get a report without great detail?

4555 I just want to know. You know we have had a change in
4556 administration. So I want to know that it is on people's radars.

4557 Dr. McCance-Katz. Yes, it is. And so we have members of
4558 the public that the application process closed. They are in the
4559 process of being selected now. And that committee is definitely

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4560 going to be in place and you will get the report.

4561 Mrs. Brooks. Okay, outstanding. Thank you.

4562 Dr. Gottlieb, building on what Representative Carter talked
4563 about with respect to prescriber education, you talked about we
4564 are at a point, in your opening remarks you said, where we might
4565 be doing some hard things, things we are not really comfortable
4566 with. And you talked about prescriber education and that we have
4567 a generation of prescribers that need more education.

4568 Can you -- and I am interested in the entire panel's very
4569 quick answer because I have like so many things I would like to
4570 ask all of you. Do you believe that mandatory prescriber
4571 education for either renewal, or for the first DEA licensure of
4572 someone who gets a DEA license or for renewal, that should come
4573 up with some mandatory prescriber education?

4574 Dr. Gottlieb. I would certainly support that goal and I
4575 have said as much.

4576 One caveat I would add is I don't think it needs to be a
4577 3-day course. I think it is more efficient if it a short course
4578 and we hit doctors with some key principles. I think there is
4579 ways to do that.

4580 Mrs. Brooks. Okay, where does a 3-day course come in?

4581 Dr. Gottlieb. I just threw it out there because there some
4582 states that have these long courses.

4583 Mrs. Brooks. Okay.

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4584 Dr. Gottlieb. But I think something short, and targeted,
4585 and focused would be the most effective way to try to
4586 operationalize this.

4587 Mrs. Brooks. Do you agree with that, Dr. McCance-Katz?

4588 Dr. McCance-Katz. I agree with it in general. I think that
4589 any prescriber who wants to prescribe controlled substances needs
4590 to have that education.

4591 Mrs. Brooks. Needs to have that education.

4592 Dr. McCance-Katz. Absolutely.

4593 Mrs. Brooks. Does anyone disagree with that?

4594 [No response.]

4595 Mrs. Brooks. Okay, thank you.

4596 Mr. Doherty, you may not know but I am a former U.S. Attorney
4597 and I did an OxyContin case against a physician that distributed
4598 to a community in southern Indiana and where people died, an
4599 OxyContin mill that was happening.

4600 So this type of challenge has been with us for a long time
4601 but when I met with IMPD last week, our Indianapolis Metropolitan
4602 Police Department, they said they took off a 55-gallon drum of
4603 pills in our community, full of pills laced with fentanyl. And
4604 can you tell me do you need any additional authorities that would
4605 help DEA improve its enforcement actions that have to do with
4606 pill presses?

4607 Mr. Doherty. Ma'am, DEA has been very active in leaning

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4608 forward on issues with respect to pill presses. We have
4609 formalized a rule that requires the import/export of pill presses
4610 to be electronically sent to DEA. We work very closely with CBP.

4611 That said, we would certainly welcome a dialogue with
4612 Congress and with the Department of Justice to look at --

4613 Mrs. Brooks. Do you need more teeth? Do you need anything?

4614 And if you would please give some thought to that, whether or
4615 not legislation needs to happen. Because as I understand, some
4616 of these pills that are coming in our police department believes
4617 that the traffickers don't even know what is in them. They don't
4618 even know that they are dealing fentanyl, necessarily.

4619 Is that something that you have seen?

4620 Mr. Doherty. Yes, ma'am, we have seen the fact that
4621 certainly the end user doesn't know what they are getting and
4622 some individuals in the supply chain are also unwitting, to a
4623 certain extent in terms of what they are trafficking.

4624 So I would be happy to take that back, ma'am, and have a
4625 dialogue on that and reengage with Congress and the Department.

4626 Mrs. Brooks. And then finally, Dr. McCance-Katz, in the
4627 context of the opioid crisis, do you believe it is important that
4628 a patient's provider, their primary care or their main doctor,
4629 has access to his or her substance use disorder records? Because
4630 I understand there is not a connection between the behavioral
4631 specialists -- and I am seeing nodding here from Dr. Volkow and

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4632 Dr. Schuchat.

4633 And so why is that a problem and how do we fix that, that
4634 a primary care provider or another physician cannot have access
4635 to the mental health provider record?

4636 Dr. McCance-Katz. So there are several laws in place that
4637 prevent certain types of communications and the 42 CFR prevents
4638 organizations or treatment providers, if you will, that hold
4639 themselves out as substance abuse treatment providers from
4640 sharing records without specific permission from the patient.

4641 I will tell you that this is something that the Trump
4642 administration has been looking at since before I got here. We
4643 will be coming out in a couple of months with some revisions to
4644 communication that could be allowed under 42 CFR to better serve
4645 communication with physicians who are not substance abuse
4646 treatment providers but may be treating a patient with a substance
4647 use disorder.

4648 Why is this important? Because very often, somebody has
4649 got a co-occurring illness which will require them to be on a
4650 medication and could have a significant drug-drug interaction
4651 that could place a person's life at risk, even on standard doses
4652 of medication. So it becomes a very important issue clinically.

4653 Mrs. Brooks. Thank you.

4654 And if I could just close with, and I know I am over time,
4655 but I think what hopefully you have seen is that if there is

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4656 legislation that anyone on either side of the aisle of this hearing
4657 we want to either resolve issues that occur either in statute
4658 or in regulation and please make sure we know what those are.

4659 Thank you. I yield back.

4660 Mr. Burgess. The chair thanks the gentlelady. The
4661 gentlelady yields back.

4662 I recognize the gentlelady from California, Mrs. Walters,
4663 5 minutes for questions.

4664 Mrs. Walters. Thank you, Mr. Chairman. And I have a letter
4665 from the Peace Officers Research Association of California that
4666 I would like to submit for the record.

4667 Mr. Burgess. Without objection, so ordered.

4668 [The information follows:]

4669

4670 *****COMMITTEE INSERT 10*****

4671 Mrs. Walters. Thank you, Mr. Chairman.

4672 An increasing number of reports have revealed problems
4673 resulting from the dramatic surge of addiction facilities in sober
4674 homes. My home of Orange County, California has a significant
4675 number of these facilities.

4676 These reports detail how individuals, as patient brokers,
4677 are recruiting patients and, in many cases, are flying them to
4678 a treatment facility across state lines, California being a very
4679 common destination. These patient brokers receive a generous
4680 financial kickback, amounts reportedly ranging from \$500 to
4681 \$5,000 for each patient who has successfully entered into a
4682 treatment facility or sober home.

4683 It is appalling that there are individuals treating those
4684 fighting addiction as a commodity and prioritizing profit over
4685 the well-being and sobriety of these vulnerable individuals.

4686 In light of these disturbing reports, the committee has sent
4687 HHS a letter on this very issue on July 13th. HHS provided a
4688 response last month and I have some questions for Dr. McCance-Katz
4689 following up on that response.

4690 Dr. McCance-Katz, in response, HHS noted that 80 percent
4691 of treatment facilities are licensed or certified by state bodies.

4692 First question: Who licenses and certifies these facilities?

4693 Dr. McCance-Katz. The states do and some of these
4694 facilities are not licensed or regulated within states.

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4695 So the Federal Government -- SAMHSA regulates opioid
4696 treatment programs and certain types of credentialing of
4697 providers but we do not have purview over what goes on in the
4698 states regarding other types of substance abuse treatment
4699 programs or recovery housing.

4700 Mrs. Walters. Okay so if you flip that 80 percent figure,
4701 that means that 20 percent of the facilities are not licensed
4702 or certified.

4703 Okay, so why aren't all facilities licensed or certified?

4704 Dr. McCance-Katz. Different states take different
4705 approaches to this. I would recommend that one of the things
4706 that states consider is requiring that these types of facilities
4707 get credentialed. There are national accreditation bodies that
4708 could do this. States would need to require it and then states
4709 would charge a licensing fee.

4710 The other thing that happens at these facilities is that
4711 they often use practitioners, or what they call practitioners,
4712 who have no certification or qualifications in the field. That
4713 can also be addressed by state regulatory bodies.

4714 Mrs. Walters. So do you know which states do require
4715 certifications and licenses and which don't?

4716 Dr. McCance-Katz. I don't have that information at my
4717 fingertips.

4718 Mrs. Walters. Okay. HHS also noted in its response that

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4719 SAMHSA is working with states to share best practices on how to
4720 address patient brokering with provider associations. And what
4721 are those best practices and who developed them?

4722 Dr. McCance-Katz. So SAMHSA does have a work group on this
4723 and that work group met over the summer. There is a report that
4724 is being put together right now.

4725 But I can tell you that some of the best practices that will
4726 come out will be, as I mentioned, requiring the licensure of
4727 practitioners in these programs, requiring accreditation of the
4728 programs themselves.

4729 We are going to make a bigger effort than we already do to
4730 put families in touch with our treatment locator system. We
4731 actually have a treatment locator system on our SAMHSA website
4732 that is linked to by other HHS agencies as well that has
4733 investigation that goes on. All of the programs on our system
4734 are approved by the SSAs in the different states. So they have
4735 a certain quality indicator if they are on that treatment locator.

4736 We also think it is important for families to be able to
4737 ask specific questions. So if I am a family member looking for
4738 a provider, I need to ask, What are your credentials? Are you
4739 accredited by a national organization? Have you been inspected?

4740 And if you have been inspected, were there any citations of your
4741 facility and what did you do about them? Those questions right
4742 there can tell families whether that is a facility that they would

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4743 want their loved one at.

4744 Mrs. Walters. Okay, just shifting gears a bit to focus on
4745 sober homes, which, based on the aforementioned reports, are equal
4746 offenders in the patient broker scheme.

4747 It is the committee's understanding that sober homes are
4748 regulated much differently than treatment facilities. Is that
4749 correct?

4750 Dr. McCance-Katz. That is my understanding.

4751 Mrs. Walters. Okay and what is SAMHSA's role in overseeing
4752 or regulating sober homes?

4753 Dr. McCance-Katz. We have no authority over sober homes.

4754 Mrs. Walters. Okay. Well, I will yield the balance of my
4755 time.

4756 Mr. Burgess. The chair thanks the gentlelady. The
4757 gentlelady yields back.

4758 And I believe that concludes members' questions. I was
4759 going to yield 5 minutes for questions to Mr. Green because he
4760 has been sitting her so patiently, if you have a follow-up or
4761 redirect.

4762 Mr. Green. Thank you, Mr. Chairman.

4763 Mr. Doherty, among the things the Controlled Substances Act
4764 establishes is a quota system that controls the qualities of basic
4765 ingredients needed to manufacture controlled substances. These
4766 quotas serve to try and reduce diversion, while also providing

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4767 the adequate supply of controlled substance for legitimate
4768 medical need.

4769 DEA sets these quotas using data regarding manufacturing
4770 history, forecasts, prescriptions dispensed, past quota
4771 histories, and internal DEA data on controlled substance
4772 transactions.

4773 Deputy Assistant Administrative Doherty, I would like to
4774 ask about DEA's process on establishing these quotas. In
4775 reviewing the aggregate production quota history of oxycodone,
4776 hydrocodone, and morphine, and fentanyl, the quotas from 2007
4777 to 2015 show dramatic increase.

4778 For example, the quota for oxycodone doubled from 70,000
4779 kilograms in 2007 to 149,000 in 2014. This is true for
4780 hydrocodone, which increased from 46,000 kilograms in 2007 to
4781 99,000 kilograms in 2014.

4782 Can you explain to the committee the process DEA undertakes
4783 in setting these quotas?

4784 Mr. Doherty. Sir, thank you for that question. Sir, my
4785 oversight responsibilities with respect to the Diversion Control
4786 Division are over the criminal investigative side of the house,
4787 the law enforcement side of the house.

4788 Last year, the DEA Diversion Control Division was
4789 reorganized in such that we are now a complete division. We were
4790 formally an office, an Office of Diversion Control under the

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4791 Operations Division of DEA. We are now a standalone division
4792 and we have two offices, the Office of Diversion Control
4793 Operations, which I oversee, as the law enforcement arm, running
4794 the criminal investigations and technology aspect. And then we
4795 have a regulatory compliance oversight arm, which is the Office
4796 of Diversion Control Regulatory.

4797 So, sir, I am generally aware of the quota system, in terms
4798 of the points you mentioned. And I can state that last year the
4799 APQ, the aggregate production quota, was reduced 25 percent across
4800 the board and additional reductions are proposed for, as you
4801 mentioned, certain drugs, hydrocodone, oxycodone, and fentanyl
4802 for an additional 20 percent.

4803 I would be happy to take that back and get you a complete
4804 answer, sir.

4805 Mr. Green. Yes, if you could, just to share with the
4806 committee, to the chair of how that decision is made. Because
4807 again, from 2007 to 2015, the quotas were double and I wanted
4808 to see why DEA decided to do that, if they felt like that was
4809 needed.

4810 According to DEA's history, quota history, it is not until
4811 2016 and 2017 that DEA announced that the quotas for oxycodone,
4812 hydrocodone, and morphine, and fentanyl would be reduced. And
4813 if you don't know that question, if you could get it back to us
4814 why all of a sudden they waited until 2016 and 2017 to do that.

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4815 And I understand the DEA has the authority to revise their
4816 quota at any during the year in response to change in sales, new
4817 manufacturers entering the market, new product development, or
4818 product recalls.

4819 Does DEA have the authority to revise the quota of controlled
4820 substance in response to patterns of abuse, or misuse, or increase
4821 diversion?

4822 Mr. Doherty. Again, sir, not under my direct purview but
4823 I do know, generally speaking, that that authority does rest with
4824 DEA, as well as decreasing quota when requested by a registrant.

4825 Mr. Green. Okay. Well, Mr. Chairman, I would hope we could
4826 get -- if you could have somebody who has that information to
4827 get to the committee. And if we have to send a letter, hopefully
4828 the committee would send that.

4829 Mr. Chairman, before I yield back, when we did the Affordable
4830 Care Act, it is crucial to address the opioid crisis. And what
4831 we did with the Affordable Care Act, prior to the ACA there was
4832 34 percent of individual market policies did not cover substance
4833 use treatment. Now all health care policies that are sold in
4834 marketplaces must include these services for substance use
4835 disorders. And repealing the mental health and substance use
4836 disorder coverage provisions of the ACA will remove at least \$5.5
4837 billion annually from the treatment of low-income people with
4838 mental and substance use disorders.

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4839 In my early days as a probate lawyer, I also did mental
4840 health. And so often, back in the 1980s and even the 1990s, we
4841 did not have a place where people would go. And most insurance
4842 policies in Texas, in their State, did not cover mental health,
4843 unless you were very wealthy.

4844 And so that is why the ACA was changed, to do that. And
4845 as I recall, for mental health and substance abuse, Medicaid is
4846 probably still the biggest provider in the country. And so by
4847 cutting Medicaid, it is making it even more of a problem.

4848 And I know I am running 17 minutes -- 17 seconds over my
4849 time but I run through the 3 minutes. So, I yield back.

4850 Mr. Burgess. The chair thanks the gentleman. The
4851 gentleman is correct to observe the chair has been very indulgent
4852 with letting people go over because this is an important topic.

4853 And I am also going to yield myself a time for redirect.

4854 I want to ask a couple of additional questions on the PDMD
4855 programs.

4856 This committee authorized NASPER, probably in 2005. It has
4857 been funded. In this year's Labor/HHS appropriations bill as
4858 passed by the house in September, there was an amendment offered
4859 and accepted by your chairman that funded, for the first time,
4860 the NASPER program, which I think is terribly important.

4861 In my home community, an obituary in the paper the other
4862 day of a young man in the mid-20s was the child of a woman who

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4863 was my daughter's best friend -- my sister's best friend in high
4864 school. And it was quite a shock to the community. And you ask
4865 questions and it comes out that it probably was opiate-related
4866 and probably was a rather substantial number of pills that this
4867 young man was given his last physician visit.

4868 So it bothers me that we have the data and Mr. Doherty, this
4869 probably for you. I realize it is not law enforcement data but
4870 I will even broaden it for anyone. The information is now there.

4871 It is being collected in a prescription drug monitoring program.

4872 There has to be some sort of algorithm and a red flag go up,
4873 even de-identified patient data, to help identify a hot spot,
4874 either a pharmacy -- so much of the PDMP program is
4875 provider-directed but it seems like it could also be
4876 pharmacy-directed as well.

4877 You identify a hot spot. Here is one prescriber where more
4878 pills are going out the door than any other prescriber in town
4879 or here is a pharmacy where more are filled. Is there any way
4880 to create that nexus so that at least there is the reason to do
4881 a little bit more investigation?

4882 De-identify the patient data. I am not trying to out the
4883 patient who has a problem but where are these facilities where
4884 the difficulty is occurring?

4885 Mr. Doherty. Sir, thank you for that question. And in
4886 terms of data analytics, such as a PDMP, DEA supports them and

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4887 DEA supports law enforcement access to them.

4888 Unfortunately, sir, the 49 states that currently have PDMPs
4889 have a varying degree of access. Some require a court order.

4890 DEA advocates for law enforcement access, obviously with the
4891 PII, personal identification information, in mind and we feel
4892 it is a vital tool for law enforcement to do as you said, sir,
4893 to identify hot spots and to further our criminal investigations
4894 and take action against registrants operating outside the law.

4895 As I said, 49 states have them; 41, to my knowledge, re
4896 connected through a program called InterConnect. We think that
4897 is a positive step as well. However, as I stated before, the
4898 degree of access varies. It varies quite a bit, sir.

4899 Mr. Burgess. I think going forward that is something that
4900 we do have to keep in mind. There has to be a way to identify
4901 these places where problems are occurring and at least have a
4902 chance for intervention.

4903 Dr. McCance-Katz, you and I talked briefly before the hearing
4904 started. You know I am not a fan of needle exchange programs
4905 but let me just ask you this.

4906 There is technology where a syringe and needle can only be
4907 used one time. Retractable Technologies, in my district, has
4908 developed such a syringe. You push the plunger all the way in
4909 and the needle retracts up into the barrel and you cannot retrieve
4910 the needle without destroying the device.

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4911 I don't know whether that is something that SAMHSA has looked
4912 at but in the needle exchange programs, as they exist, I would
4913 at least like the assurance that it is a true single-use device
4914 that is being dispensed in a needle exchange program.

4915 Dr. McCance-Katz. Well, what I believe to be the case, sir,
4916 is that the Federal Government, our funds do not go to purchase
4917 syringe equipment of any kind. What funds can be used for are
4918 things like support staff within a program that does syringe
4919 exchange, mainly to help people get to treatment.

4920 So we do not have any authority over that and are not involved
4921 in that.

4922 Mr. Burgess. To get the continuing medical education I
4923 required for my license this year, I took your online
4924 SAMHSA-sponsored opioid abuse. I took two of the three modules.

4925 And thank you for having it online. Thank you for having it
4926 at a price I could afford.

4927 But one of the harm-reduction strategies that they talk about
4928 in this SAMHSA-authorized product out of Harvard Medical School
4929 is our needle exchange programs. And again, I am not a fan of
4930 that. But if we are involved in that, I really think the effort
4931 should be that they be a single-use device and this retractable
4932 technology is FDA approved. It has been around for a while.
4933 It has never been widely used because they are a little bit more
4934 expensive. But if we are going to the trouble to do harm

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4935 reduction, I think that is a type of harm reduction I would like
4936 to see.

4937 Dr. McCance-Katz. I think that is a very good suggestion.
4938 And I actually, since you bring that up, I will take it back
4939 to our staff at SAMHSA and we will look at that course you are
4940 talking about.

4941 Mr. Burgess. Thank you. I am not trying to be the Chamber
4942 of Commerce guy for Retractable Technologies, but they do have
4943 a good product.

4944 I want to thank all of you. This has been a lengthy but
4945 I think important and informative hearing. I know I have gotten
4946 a lot of information. This coupled with the 50 members that we
4947 heard from 2 weeks' ago with the individual opiate problems they
4948 have in their district, I hope will form the nidus of the ability
4949 to come together on some things. We obviously have a problem
4950 that needs to be fixed. We have heard it expressed passionately
4951 several times today.

4952 Dr. Gottlieb, I do have one question for the record that
4953 I am going to submit to you in writing because it was so technically
4954 complicated, I didn't think I could do it justice by reading it
4955 to you. But it is an important question and it deals with
4956 distribution of counterfeit products. And again, I will submit
4957 that in writing because we have gone significantly overtime.

4958 Seeing that there are no further members wishing to ask

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4959 questions, I do want to thank all of our witnesses for being here
4960 today.

4961 We have received outside feedback from a number of
4962 organizations and I would like to submit statements from the
4963 following for the record: The American Medical Association, the
4964 Academy of Integrated Pain Management, the American Dental
4965 Association, the American Society of Addiction Medicine,
4966 Medication Assisted Treatment Coalition, International
4967 Chiropractors Association, Oxford Housing Incorporated, American
4968 Association of Nurse Anesthetists, Protecting Access to Pain
4969 Relief, and America's Health Insurance Plans.

4970 Without objection, so ordered.

4971 [The information follows:]

4972

4973 *****COMMITTEE INSERT 11*****

4974 Mr. Burgess. Pursuant to committee rules, I remind members
4975 they have 10 business days to submit additional questions for
4976 the record and I ask the witnesses to submit their response within
4977 10 business days upon receipt of the questions.

4978 Without objection, the subcommittee is adjourned.

4979 [Whereupon, at 3:26 p.m., the subcommittee was adjourned.]