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MARKUP OF ENERGY AND COMMERCE COMMITTEE VOTE

ON OPIOIDS LEGISLATION AND H.R. 4606, H.R.

5174, H.R. 5175, H.R. 5239, AND H.R. 5240

WEDNESDAY, MAY 9, 2018

House of Representatives

Committee on Energy and Commerce

Washington, D.C.

The committee met, pursuant to call, at 9:00 a.m., in Room 2123 Rayburn House Office Building, Hon. Greg Walden [chairman of the committee] presiding.

Members present: Representatives Walden, Barton, Upton, Shimkus, Burgess, Blackburn, Scalise, Latta, McMorris Rodgers, Harper, Lance, Guthrie, Olson, McKinley, Kinzinger, Griffith, Bilirakis, Johnson, Long, Bucshon, Flores, Brooks, Mullin, Hudson, Collins, Cramer, Walberg, Walters, Costello, Carter, Duncan, Pallone, Rush, Eshoo, Engel, Green, DeGette, Doyle, Schakowsky, Butterfield, Matsui, Castor, Sarbanes, McNerney,

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26 Welch, Lujan, Tonko, Clarke, Loeb sack, Schrader, Kennedy,
27 Cardenas, Ruiz, Peters, and Dingell.

28 Staff present: Mike Bloomquist, Deputy Staff Director; Adam
29 Buckalew, Professional Staff Member, Health; Karen Christian,
30 General Counsel; Kelly Collins, Staff Assistant; Zachary
31 Dareshori, Staff Assistant; Jordan Davis, Director of Policy and
32 External Affairs; Paul Eddatel, Chief Counsel, Health; Margaret
33 Tucker Fogarty, Staff Assistant; Melissa Froelich, Chief Counsel,
34 Digital Commerce and Consumer Protection; Adam Fromm, Director
35 of Outreach and Coalitions; Ali Fulling, Legislative Clerk,
36 Oversight & Investigations, Digital Commerce and Consumer
37 Protection; Theresa Gambo, Human Resources/Office Administrator;
38 Jay Gulshen, Legislative Clerk, Health; Peter Kielty, Deputy
39 General Counsel; Ed Kim, Policy Coordinator, Health; Caprice
40 Knapp, Fellow, Health; Ryan Long, Deputy Staff Director; Mary
41 Martin, Deputy Chief Counsel, Energy & Environment; Drew
42 McDowell, Executive Assistant; Brandon Mooney, Deputy Chief
43 Energy Advisor; Mark Ratner, Policy Coordinator; Annelise
44 Rickert, Counsel, Energy; Kristen Shatynski, Professional Staff
45 Member, Health; Jennifer Sherman, Press Secretary; Danielle
46 Steele, Counsel, Health; Austin Stonebraker, Press Assistant;
47 Evan Viau, Legislative Clerk, Communications & Technology; Hamlin
48 Wade, Special Advisor, External Affairs; Everett Winnick,
49 Director of Information Technology; Jacquelyn Bolen, Minority
50 Professional Staff; Jeff Carroll, Minority Staff Director;

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Elizabeth Ertel, Minority Deputy Clerk; Waverly Gordon, Minority Health Counsel; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Caitlin Haberman, Minority Professional Staff Member; Rick Kessler, Minority Senior Advisor and Staff Director, Energy and Environment; Una Lee, Minority Senior Health Counsel; John Marshall, Minority Policy Coordinator; Dan Miller, Minority Policy Analyst; Alexander Ratner, Minority Policy Analyst; Tim Robinson, Minority Chief Counsel; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Minority Senior Health Policy Advisor; and C.J. Young, Minority Press Secretary.

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63 The Chairman. All right. I'll call to order the Energy
64 and Commerce Committee and recognize myself for an opening
65 statement.

66 Today marks an important step in this committee's effort
67 to combat the opioid crisis which continues to wreak havoc on
68 communities all across our nation.

69 From our legislative and investigative hearings to the round
70 table where we heard from families impacted by this deadly crisis,
71 it is clear that Americans across the country are asking for more
72 solutions from their elected leaders.

73 Today, we will consider 26 pieces of legislation to combat
74 the opioid crisis and I hope these bills will receive bipartisan
75 support just as they did at the subcommittee level two weeks ago.

76 We know there is no silver bullet. We know there is no
77 one-size-fits-all approach that will remedy the catastrophic
78 effects of this crisis over the last decade.

79 But much can be done to help vulnerable patients get the
80 treatments they want and that they need and to ensure those
81 powerful drugs are not getting into the wrong hands.

82 These bills will help protect our communities and bolster
83 enforcement efforts, strengthen our prevention and public health
84 efforts, and address coverage and payment issues in Medicare.

85 These targeted solutions as well as additional bills the
86 full committee will consider next week represent months of work
87 that the committee had undertaken, to listen to families,

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88 providers, patients, law enforcement, state and federal officials
89 on how we can best assist them to take on this epidemic.

90 Upon completion of our markups this week and next, we will
91 have fulfilled our commitment to report a package of bills to
92 combat the opioid crisis to the floor by Memorial Day.

93 So I look forward to working with leadership to schedule
94 floor action soon.

95 Today, we will also be considering bipartisan FDA
96 legislation to advance a timely reauthorization of the Animal
97 Drug and Animal Generic Drug User Fee Act, which is authored by
98 Mr. Mullin, as well as bipartisan legislation from Mr. Latta to
99 modernize how we regulate over-the-counter drugs.

100 Last, but certainly not least, we will consider five
101 important bills from our Energy Subcommittee today. In today's
102 highly interconnected world we are facing rapidly-evolving and
103 persistent cybersecurity threats.

104 As the sector-specific agency for energy, the Department
105 of Energy plays a critical role in making the nation's electric
106 grid and oil and gas and natural gas infrastructure resilient
107 to cyber attacks.

108 But DOE needs Congress to provide them with new tools to
109 get the job done. Four of the bills before us today will do just
110 that. They will help DOE strengthen Cybersecurity preparedness,
111 coordinate cyber incident response and recovery, and accelerate
112 research and development on advanced Cybersecurity tools and

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113 technologies.

114 I am really proud of the members of the committee on both
115 sides of the aisle. You've put in an incredible amount of work
116 both through the O&I investigative side of our House as well as
117 on the legislative side to produce these bipartisan and really
118 important pieces of legislation.

119 With that, I yield back the balance of my time and recognize
120 my friend from New Jersey, the ranking member, Mr. Pallone, for
121 purposes of an opening statement.

122 Mr. Pallone. Thank you, Mr. Chairman.

123 Today, the committee will consider a large number of bills
124 reported out of our Energy and Health Subcommittees. The four
125 cybersecurity bills before us will enhance the Department of
126 Energy's efforts to strengthen the cybersecurity of our nation's
127 electricity grid and pipeline network and I support these four
128 bipartisan bills and commend my colleagues who have taken
129 leadership on the issue.

130 While I commend Representative Green's effort to improve
131 Representative Johnson's LNG licensing bill, I cannot support
132 even an improved version.

133 I believe an unrestricted export policy would significantly
134 impact domestic natural gas prices and adversely affect American
135 consumers and manufacturers.

136 We will also consider two user fee agreements dealing with
137 animal drugs and over-the-counter -- OTC -- drugs. Both have

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138 had extensive debate and deliberation aimed to give the FDA
139 important resources and authority to ensure the safety and
140 effectiveness of these products.

141 In addition to these bills, today's markup mainly focuses
142 on proposals to address the opioid epidemic. This complex public
143 health crisis facing our nation requires thoughtful measured
144 solutions.

145 As I noted during the subcommittee markup, I will evaluate
146 the opioid bills in this committee based on two principles --
147 one, whether the proposal meaningfully improves access to
148 treatment for opioid use disorders, and two, whether the proposal
149 helps to prevent people from getting addicted to opioids in the
150 first place.

151 There are 25 small bills before us that make incremental
152 changes around prevention and recovery. I support them all and
153 commend the sponsors who have found ways to strengthen our laws
154 within the drug supply chain and our public health system.

155 I am concerned, however, that many of these proposals that
156 most meaningfully improve or expand treatment for opioid use
157 disorders will not be discussed today.

158 For instance, I support the legislation that my colleague,
159 Ms. DeGette, is working on to exempt the short supply of
160 medication-assisted treatment from prior authorization
161 requirements.

162 I think this bill could have an immediate and meaningful

163 impact on access to medication-assisted treatment. But that bill
164 was not included in this process.

165 I also ask the chairman to include a bill that I have
166 introduced with Representative Richie Neal, the ranking member
167 of the Ways and Means Committee, that would extend Medicare
168 coverage to methadone clinics.

169 Currently, seniors with opioid use disorders do not have
170 access to treatment at methadone clinics, which has been a
171 longstanding gap in the Medicare benefit.

172 Failure to close this gap would be a missed opportunity and
173 a serious shortcoming in any final legislative package.

174 There are also a number of substantial bills during the
175 subcommittee process that were left off the table that could have
176 made an immediately impact.

177 Most notable is Mr. Tonko's TREAT Act that would have an
178 immediate effect on the number of providers treating opioid
179 addiction.

180 Also missing from today's markup is the Rural DOCS Act, which
181 would have increased the treatment capacity for substance use
182 disorder treatment and there is still significant uncertainty
183 about what Medicaid and Medicare policies will eventually be
184 marked up next week.

185 So Mr. Chairman, as we move forward, we need to be
186 deliberative and thoughtful and we need to address the evolving
187 nature of the epidemic which includes the shift away from

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188 prescription medications to extremely deadly opioid analogs like
189 fentanyl. The shift exacerbates the need to expand access to
190 lifesaving evidence-based treatment in addition to focusing in
191 prevention.

192 So I hope to continue work with my colleagues today on a
193 list of opioid bills in addition to the others, moving forward,
194 Mr. Chairman.

195 The Chairman. Thank you. The gentleman yields back the
196 balance of his time.

197 The chair recognizes former chairman of the committee, Mr.
198 Upton, for purposes of an opening statement.

199 Mr. Upton. Thank you, Mr. Chairman.

200 Today's full committee markup is going to include several
201 bills from both the Health and Energy Subcommittees and I am
202 pleased to see that the ACE Research Act, bipartisan bill that
203 I've worked on with my colleague, Debbie Dingell, is included
204 as part of this markup.

205 This bill gives other transaction authority to the NIH,
206 allowing them to better partner with innovative companies doing
207 cutting-edge research to address the opioid epidemic and get
208 nonaddictive pain medication to those in need.

209 We also have five bipartisan energy bills that address
210 cybersecurity, emergency preparedness, and energy security. We
211 have to address the constant and ever-evolving threat of cyber
212 attack.

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213 Every minute of every day hackers are trying to penetrate
214 our electric grid and pipeline systems. The DOE could do more
215 to address these threats. But they need the authority to do so.

216

217 So these bills, including H.R. 5175, the Pipeline and LNG
218 Facilities Cybersecurity Preparedness Act, will in fact allow
219 us to be better prepared to confront these threats.

220 Taken together, these bills are going to build a more
221 reliable resilient system. So I would urge all my colleagues
222 to vote yes.

223 Thank you, Mr. Chairman.

224 The Chairman. And the gentleman yields back the balance
225 of time.

226 Other members seeking recognition?

227 Mr. Green is recognized for one minute for purposes of an
228 opening statement.

229 Mr. Green. I want to thank the chair and ranking member
230 for holding today's markup.

231 There are several health bills that I wish to highlight and
232 ask for everyone's support. I ask for the members' support for
233 the Comprehensive Opioid Recovery Centers Act, which I was proud
234 to introduce with Representatives Guthrie, Lujan, and Bucshon.

235 This legislation will fund designated treatment centers
236 where individuals will receive comprehensive patient center care
237 for opioid addiction.

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238 I also act for my colleagues to join in support of
239 Over-The-Counter Monograph Safety, Innovation, and Reform Act
240 and the amendment that will be considered.

241 This bill will reform the currently inefficient and
242 burdensome OTC drug monograph system that prevents the FDA from
243 quickly updating the monographs to respond to safety concerns.

244
245 This legislation has bipartisan support and the support of
246 public health organizations like the March of Dimes and the Pew
247 Charitable Trust.

248 I also ask my colleagues to support H.R. 5554, the Animal
249 Drug and Animal Generic Drug User Fee Amendments. This
250 legislation reauthorizes ADUFA and AGDUFA.

251 It's the product of intensive negotiations between FDA,
252 stakeholders, and members on this committee and I sense has strong
253 bipartisan support.

254 I thank the chairman. I yield back my time.

255 The Chairman. I thank the gentleman from Texas. He yields
256 back.

257 The chair recognizes the gentlelady from Tennessee, Mrs.
258 Blackburn, for one minute.

259 Mrs. Blackburn. Thank you, Mr. Chairman.

260 I appreciate the work that you and Dr. Burgess and the
261 committee have done on the bills that are moving forward today
262 and also what we will see next week.

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263 As I have worked in my district with law enforcement, those
264 that are in treatment and recovery and with treatment facilities,
265 one of the things they mention regularly is that they want to
266 see partnerships between the federal and the state level and they
267 want to see research take place on the nonaddictive pain killers
268 and to have these bills come before us that are going to meet
269 some of these requests that will encourage the research into the
270 nonopioid painkillers.

271 And these are things that are timely. I appreciate the
272 efforts and I look forward to their passage. Yield back.

273 The Chairman. Thank the gentlelady.

274 The chair recognizes the gentlelady from Colorado, Ms.
275 DeGette, for one minute.

276 Ms. DeGette. Thank you, Mr. Chairman. Thank you for this
277 markup today.

278 I am supportive of all of the opioid bills and, obviously,
279 the monograph bill, which I am the Democratically sponsor of.

280 But I think that what we need to do in this committee, and
281 I've talked to you, Mr. Chairman, and others, we need to make
282 sure we are not nibbling around the edges of this opioid crisis.

283 We need to make sure that we are addressing the crisis head
284 on, similarly to how we did with the AIDS crisis with Ryan White.

285 Some of the issues we need to look at are research and
286 development alternatives for pain treatment, how we are
287 distributing opioids, physician education and prescription

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288 coordination so that we don't have over prescription,
289 availability of MAT and other treatment programs for people,
290 availability of health professionals to work with these folks,
291 aid to the states so that they can combat this, and help with
292 law enforcement as people shift away from legal opioids.

293 These are just some of the things I thought up from the top
294 of my head that we need to work on in a comprehensive way, and
295 I am hoping we can go on from today and do this in a bipartisan
296 way.

297 Otherwise, we are just really nibbling around the edges.

298 The Chairman. Gentlelady's time has expired. We look
299 forward to working continuously with you on those issues as we
300 move forward.

301 The chair recognizes the gentleman from Ohio, Mr. Latta,
302 for one minute.

303 Mr. Latta. Thank you, Mr. Chairman, and thank you very much
304 for holding today's markup. I am pleased that we are taking up
305 several of my bills that would help modernize the Department of
306 Energy to prevent -- to address cyber threats, promote federal
307 coordination on opioid abuse reduction, and reform the
308 over-the-counter monograph system towards a more flexible
309 framework.

310 H.R. 5239, the CyberSense Act, would direct the secretary
311 of energy to establish a voluntary cybersense program to test
312 the cybersecurity of products and technologies intended for use

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313 in the block power system.

314 Last month, during two Energy Subcommittee hearings, both
315 the DOE secretary and the FERC commissioners expressed support
316 for this policy as a way to help improve the grid's resiliency.

317 H.R. 4284, the INFO Act, would help to unravel and work to
318 solve the opioid epidemic by allowing advocates and health care
319 providers better access to information and data on the nationwide
320 efforts to combat opioid abuse and more easily search for
321 available funding.

322 H.R. 5333, the Over-The-Counter Monograph Safety Innovation
323 Reform Act, would affect products that Americans use every single
324 day.

325 This bipartisan bill would modernize an outdated regulatory
326 system and allow for timely safety updates for the two products
327 and create a pathway for innovation in over-the-counter
328 marketplace.

329 I urge my colleagues' support of these three measures and
330 with that, Mr. Chairman, I yield back.

331 The Chairman. Gentleman's time has expired. Gentleman
332 yields back.

333 The chair recognizes the gentlelady from Illinois, Ms.
334 Schakowsky, for one minute.

335 Ms. Schakowsky. Thank you, Mr. Chairman. I want to
336 highlight one program that we know works for those with substance
337 abuse disorder.

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338 It's called Medicaid. It provides coverage for 40 percent
339 of those with opioid use disorder. But yet the Trump
340 administration has waged war on this lifeline.

341 The most recent Trump budget cut Medicaid by hundreds of
342 billions of dollars. The Trump administration is encouraging
343 work requirements for Medicaid enrollees and a Price Waterhouse
344 Cooper study found that 1.7 million people would lose coverage
345 in the 10 states that are considering work requirements right
346 now.

347 Republican attempts to repeal the Affordable Care Act would
348 have cut Medicaid by \$800 billion. We should be talking about
349 expanding Medicaid, not cutting it.

350 Plain and simple, cutting Medicaid hurts people suffering
351 from substance abuse disorder.

352 Thank you, and I yield back.

353 The Chairman. Gentlelady yields back.

354 Are there members on the Republican side seeking
355 recognition? The chair recognizes the gentleman from Florida,
356 Mr. Bilirakis, for one minute.

357 Mr. Bilirakis. Thank you, Mr. Chairman. Appreciate it.

358 There is no silver bullet solution to the opioid crisis.

359 We must use a comprehensive approach, taking into consideration
360 the health system we have presented -- we presently have while
361 also lay the groundwork for the health system of the future.

362 I am proud of the work this committee has done in relentlessly

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363 attacking this challenging issue. I am glad we are marking up
364 my bill today, co-led by my good friend, Ben Ray Lujan.

365 H.R. 5675 builds off the Comprehensive Addiction Recovery
366 Act Reforms and requires prescription drug plan sponsors under
367 the Medicare program to establish drug management programs for
368 at-risk beneficiaries.

369 In addition, I am pleased to see we are marking up measures
370 aimed at strengthening security and resiliency of America's
371 energy assets, both physically and digitally.

372 I look forward to continuing again the great work of this
373 committee in advancing these bipartisan solutions to the House
374 floor.

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

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

377 The chair recognizes the gentlelady from California, Ms.
378 Matsui, for one minute.

379 Ms. Matsui. Thank you, Mr. Chairman.

380 Mr. Chairman, while I am pleased to work on a few targeted
381 bipartisan bills that have been a part of this process to
382 legislatively address the opioid epidemic, I'd like to point out
383 that even if we passed all of these bills on the House floor,
384 the sum benefit of all of that effort would be completely
385 overshadowed by the harm that would be caused if we made large
386 scale cuts to the Medicaid program.

387 The president's budget efforts to repeal the Affordable Care

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388 Act and other proposals for Speaker Ryan have all called for
389 billions of dollars in cuts to Medicaid.

390 Medicaid is the primary payer of mental health treatment
391 in this country including substance use disorder treatment.
392 Without out, we would take many steps backward in our efforts
393 to address the opioid epidemic.

394 I am hopeful we can make policy changes here that would have
395 a positive impact on people's lives. But I just want us to
396 remember the big picture when we talk about the opioid epidemic.

397 Thank you, and I yield back.

398 The Chairman. Gentlelady yields back.

399 Any members on the Republican side seeking recognition for
400 an opening statement?

401 Any on the Democrat -- Mr. Welch is recognized for one minute.

402 Mr. Welch. I thank you, Mr. Chairman, and look forward to
403 passing these bills that will help.

404 But two things -- one, I've been having opioid round tables
405 all around Vermont and it's inspiring on one level. So many
406 people who are suffering from addiction are plunging into trying
407 to help others.

408 But second, we have to do two things. One, we have to
409 preserve Medicaid. That's essentially the lifeline. We can't
410 have these bills as a substitute.

411 And second, we have got to invest in rural America. What
412 I am seeing as the common denominator is the economies of these

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413 small towns are collapsing, and unless we have rural broadband
414 as just one example, built out to our entire rural America, we
415 are not going to give these folks the shot that hope brings to
416 deal with this epidemic.

417 I yield back.

418 The Chairman. Gentleman yields back.

419 Other members on the Republican side seeking recognition?

420 Seeing none, the chair recognizes the gentlelady from Florida,
421 Ms. Castor, for one minute.

422 Ms. Castor. Well, thank you very much, Mr. Chairman, and
423 thank you, colleagues, for coming together on these bipartisan
424 bills today.

425 But I think what is plain now, as with the opioid public
426 health epidemic, we need to be doing much more.

427 We need to meet the scale of this crisis, and the AIDS
428 epidemic of decades ago provides a model because Congress was
429 criticized at that time for not acting fast enough or boldly enough
430 and finally got their act together with the Ryan White Act, and
431 we need to be looking at something similar that's meaningful.

432 Secondly, I think my colleagues -- my Democratic colleagues
433 are absolutely right, you cannot on one hand say oh, we are
434 addressing this public health crisis and then on the other say
435 we are going to undermine Medicaid, like the Trump administration
436 and many on the other side of the aisle are doing. You simply
437 cannot do that.

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438 If you listen to the testimony of experts here and folks
439 at home, they need something dependable and consistent, whether
440 it's funding, whether it's more robust treatment, a comprehensive
441 approach like Ms. DeGette mentioned. But those are the
442 overriding issues, even as we move these bills forward today.

443 Thank you. I yield back.

444 The Chairman. Gentlelady's time has expired and yields
445 back.

446 Other members seeking recognition on the Republican side?

447 Seeing none, others on the Democratic side?

448 All right. Oh, Dr. Ruiz, recognized for one minute.

449 Mr. Ruiz. Thank you, Mr. Chairman.

450 I really do, as a physician and just a human being really
451 want to provide some comprehensive treatment and prevention for
452 the opioid epidemic and I really do sincerely say that this is
453 a step forward.

454 I really do want to express my thanks for even having these
455 conversations and these bills, and I also really want to sincerely
456 and genuinely raise caution, because if we do roll back Medicaid
457 expansion, which 40 percent of patients rely on to get the
458 treatment, if we eliminate mental health and emergency care as
459 essential health benefits, then we are taking one step forward,
460 10 steps back and we are actually hurting patients, because the
461 money you're putting in this bill to build health treatment
462 facilities, yet you don't let your patients have the insurance

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463 or remove their insurance, then they won't be able to afford the
464 services.

465 So I just really raise caution for all of you to rethink
466 the efforts in repealing the Medicaid and essential health
467 benefits.

468 I yield back.

469 The Chairman. Gentleman yields back.

470 Other members seeking recognition on the Republican side?

471 Seeing none, our final speaker this morning is the gentlelady
472 from Michigan. Mrs. Dingell is recognized for one minute.

473 Mrs. Dingell. Thank you, Mr. Chairman.

474 The opioid epidemic is ravaging every corner of this country
475 and as many of you know, I've lived on all sides of it.

476 My father was addicted to opioids at a time no one knew what
477 it was and my sister ultimately died of a drug overdose after
478 years of hell in trying to get her help that we could not make
479 work.

480 I know the pain, the fear, the desperation, the frustration
481 of living with family members with addiction and the sadness when
482 you don't win the battle.

483 But I also live with a man who's in intense pain who has
484 to use opioids because there are no other alternatives. What
485 we are talking about today here is not an academic exercise.
486 It has real impact on people's lives across this country.

487 Thank you, Mr. Chairman, for doing this markup. But we have

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488 to keep going. We must commit to keep working, to take a
489 comprehensive approach. This means protecting safety net
490 programs like Medicare, Medicaid, and CHIP while also emphasizing
491 the importance of getting people into treatment quickly and
492 putting real money behind it.

493 Lastly, we have got to work on the -- we cannot forget that
494 we have decimated the mental health system. People are taking
495 these drugs because they are suffering from anxiety and depression
496 --

497 The Chairman. The gentlelady's time --

498 Mrs. Dingell. My time has expired. Let's be committed to
499 working together to really fix this.

500 The Chairman. And we are.

501 The chair recognizes the gentlelady from Washington, Mrs.
502 McMorris Rodgers for one minute.

503 Mrs. McMorris Rodgers. Thank you, Mr. Chairman.

504 I want to thank the Health Subcommittee, Dr. Burgess, the
505 full committee chairman, Chairman Walden, for focusing this
506 committee on combating America's opioid crisis.

507 This committee has worked for years to prevent opioid abuse
508 by investigating the causes of this epidemic and identifying
509 legislative solutions.

510 Chairman Walden has made stemming the tide of this scourge
511 a top priority and has worked diligently and deliberately with
512 members of both parties both on and off the committee to advance

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513 collaborative bipartisan legislative solutions to counter the
514 growing epidemic.

515 The Republican Congress has led on this issue, most recently
516 by providing the largest investment to date, nearly \$4 billion,
517 in the recently enacted omnibus to support treatment and
518 prevention, improve law enforcement, and stop the flow of illegal
519 drugs into our country.

520 This committee has advanced a number of bipartisan
521 initiatives that are now law to help address the opioid crisis.

522

523 For instance, the 21st Century CURES Act provided a billion
524 in funding to help states and territories combat addiction and
525 there is so much more.

526 But I will -- I've run out of time so I will yield.

527 The Chairman. I thank the gentlelady for her comments and
528 a good reminder for the American people.

529 I recognize the gentleman from California, Mr. McNerney,
530 for one minute.

531 Mr. McNerney. Well, I thank the chairman and ranking
532 members for the markup today. Congressman Bob Latta and I are
533 co-sponsoring two bills that will enhance our grid security.

534 As co-chairs of the Grid Innovation Caucus, we are focused
535 on advocating for grid investment. H.R. 5230, the CyberSense Act
536 of 2018, creates a program to identify cyber secure products for
537 the bulk power grid through a testing and verification program.

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538 The bulk power system is the backbone of the American industry
539 and this bill will strengthen our system against cyber attacks.

540 H.R. 5240, Enhancing Grid Security Through Public-Private
541 Partnership Act, creates a program to enhance the physical and
542 cybersecurity of electric utilities through assessing security
543 vulnerabilities, increase cybersecurity training, and data
544 collection.

545 These two bipartisan bills will help put us on a path to
546 better securing our electric system. I ask the committee for
547 the full support of this bill and I yield back.

548 The Chairman. I thank the gentleman for his comments. Are
549 there any other members seeking recognition?

550 Seeing none, the chair now calls up H.R. 449 and in your
551 list that's probably number ten, as forwarded by the Subcommittee
552 on Health on April 25th, 2018, and ask the clerk to report.

553 The Clerk. H.R. 449, to require the surgeon general of the
554 Public Health Service to submit to Congress a report on the effects
555 on public health of the increased rate of the use of synthetic
556 drugs.

557 [The Bill H.R. 449 follows:]

558

559 *****INSERT 1*****

560 The Chairman. Without objection, the first reading of this
561 bill is dispensed with and the bill will be open at any point.

562 Are there bipartisan amendments to the bill?

563 Mr. Collins. Mr. Chair, I move to strike the last word.

564 The Chairman. For what purpose does the gentleman from New
565 York seek recognition?

566 Mr. Collins. Move to strike the last word.

567 The Chairman. The gentleman is recognized to strike the
568 last word.

569 Mr. Collins. I would like to recognize my fellow New Yorker,
570 Mr. Jeffries, for his leadership in the Synthetic Drug Awareness
571 Act.

572 Synthetic drugs present an evolving threat. We have already
573 seen far too many young men and women die from synthetic drug
574 addiction.

575 In order to continue to combat this crisis, we need more
576 information. To this end, H.R. 449 will require the surgeon
577 general to report to Congress the public health effects of
578 increased use of synthetics by 12- to 18-year-olds.

579 While Mr. Jeffries is not a member of this committee, I would
580 like to read a statement on his behalf, as follows: "The opioid
581 crisis is ravaging families across the nation without regard to
582 zip code, income, race, religion, or gender.

583 It is laying waste to young people in urban, rural, and
584 suburban America, and just like we saw during the crack epidemic,

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585 it is putting a strain on community services and creating a
586 generation of parentless children.

587 In order to properly address these tough issues, Congress
588 must learn from the mistakes of the past. We must act
589 collaboratively, quickly, and creatively to attack the scourge
590 of drug abuse from all sides.

591 That is why I am so appreciative that this committee is
592 advancing the Synthetic Drug Awareness Act to address teen drug
593 use.

594 With the information the study will provide, Congress can
595 work to prevent substance abuse by younger Americans through an
596 enhanced and enlightened lens."

597 Mr. Chair, I yield back.

598 The Chairman. Gentleman yields back.

599 Are there any bipartisan amendments to this bill?

600 Are there any amendments to this bill? Are there any other
601 members seeking recognition on this bill?

602 Seeing none, the question now occurs on favorably reporting
603 H.R. 449 as amended to the House.

604 All those in favor will signify by saying aye.

605 Those opposed, no.

606 The ayes have it. This bill is favorably reported.

607 The chair calls up H.R. 4284. This would be number 11 on
608 your list. As forwarded by the Subcommittee on Health on April
609 25th, 2018 and ask the clerk to report.

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610 The Clerk. H.R. 4284, to establish a federal coordinator
611 within the Department of Health and Human Services and for other
612 purposes.

613 [The Bill H.R. 4284 follows:]

614

615 *****INSERT 2*****

616 The Chairman. Without objection, the first reading of the
617 bill is dispensed with and the bill will be open for amendment
618 at any point.

619 Are there any bipartisan amendments to this bill?

620 Mr. Latta. Mr. Chairman?

621 The Chairman. For what purpose does the gentleman from Ohio
622 seek recognition?

623 Mr. Latta. Thank you very much, Mr. Chairman.

624 I have an amendment at the desk.

625 The Chairman. The clerk will report the amendment.

626 The Clerk. H.R. 4284 offered by Mr. Latta.

627 The Chairman. Without objection the reading of the
628 amendment of is dispensed with. The gentleman is now recognized
629 for up to five minutes to discuss his amendment.

630 Mr. Latta. Thank you very much, Mr. Chairman.

631 My amendment to H.R. 4284 is forwarded by the Subcommittee
632 on Health. It accepts technical assistance by FDA in the
633 following ways: extending the deadline to create a substance use
634 disorder information dashboard for 16 days -- that is six months,
635 redrafting the dashboard provision to be an amendment to the
636 Public Health Service Act, changing minimal wording on the
637 formation of interagency substance abuse disorder coordinating
638 committee and ordering how the committee reviews federal SUD
639 grants and programs from evaluating the effectiveness to
640 providing recommendations for improving SUD grants and programs.

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641 And, again, INFO Act is one of these pieces of legislation
642 that came to me from being out in my district.

643 We had a lot of small towns and communities out there that
644 don't have grant writers, that don't have the ability to have
645 people looking at the things all day long. It gives them the
646 ability to go online to find the help that they need and where
647 the fund are.

648 And with that, Mr. Chairman, I yield back.

649 The Chairman. Mr. Chairman, would you yield to me?

650 Mr. Latta. I yield.

651 The Chairman. I want to thank you for your leadership and
652 work on this effort. As I've done multiple round tables and
653 meetings around my district, the themes you've identified and
654 the effort to help get a simpler way to access federal programs
655 is something I've heard time and time again -- didn't know it
656 was out there -- don't know how to reach it -- don't know how
657 to do this.

658 And so thank you for your leadership on this. I know I am
659 not alone. And I would yield back.

660 Mr. Latta. Well, thank you, Mr. Chairman. I yield back.

661 The Chairman. Gentleman yields back.

662 Other members seeking recognition? Seeing none, are there
663 any bipartisan amendments or amendments on this bill?

664 I guess we have the Latta amendment before us. So is there
665 any objection? Those in favor of the Latta amendment will say

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666 aye.

667 Those opposed, nay.

668 The ayes appear to have it. The ayes have it.

669 The amendment is adopted.

670 Further discussion on the bill? Further amendments?

671 Seeing none, if there is no further discussion, the vote
672 occurs on final passage of the legislation as amended to the House
673 floor.

674 All those in favor will signify by saying aye.

675 All opposed, no.

676 The ayes appear to have it. The ayes have it, and the bill
677 is favorably reported to the House floor.

678 The chair now calls up H.R. 5002, number 12 on your program,
679 and asks the clerk to report.

680 The Clerk. H.R. 5002, to expand the unique research
681 initiatives authority of the National Institutes of Health.

682 [The Bill H.R. 5002 follows:]

683

684 *****INSERT 3*****

685 The Chairman. Without objection, the first reading of the
686 bill is dispenses with. The bill will be open for amendment at
687 any point.

688 Are there any bipartisan amendments to the bill? Are there
689 any amendments? For what purpose the gentleman from Michigan
690 seek recognition?

691 Mr. Upton. Strike the last word.

692 The Chairman. So recognized. Five minutes.

693 Mr. Upton. And I won't use the five minutes, that's for
694 sure.

695 We know that the opioid epidemic is a dangerous scourge --
696 that it affects millions of folks across the country regardless
697 of age, race, economic background.

698 I would note that between 2000 and 2016, 600,000 folks have
699 died from drug overdoses. According to the CDC, opioid overdoses
700 claim, as we know, 115 people every day.

701 In Michigan, there were over 1,700 opioid deaths last year
702 alone. That's up from only 455 total drug related deaths in 1999.

703 So using better science to understand the biology of pain
704 and addiction is the first step in combating this devastating
705 crisis.

706 With the help of our colleagues in Congress, we do have an
707 opportunity to collaborate with some of the best minds in the
708 world. But we have to tap those tools and resources to overcome
709 the challenge.

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710 That's why Debbie Dingell and I have introduced bipartisan
711 legislation, H.R. 5002, this bill, Advancing Cutting-Edge
712 Research Act, ACE.

713 This bill provides the NIH with new flexible authorities
714 to conduct innovative research on ways to prevent, treat, and
715 cure diseases including vital research to respond to public health
716 threats such as the opioid epidemic.

717 This forward-looking bipartisan legislation will spur
718 urgently needed research on new nonaddictive pain medications
719 much along the same lines as what we did with 21st Century CURES.

720 Twenty-five million Americans suffer from pain every day
721 and it's essential that nonaddictive medications are available
722 to them.

723 We can innovate our way out of this crisis but we have to
724 face the challenges that stand in the way. That's what this bill
725 does. I would urge all my colleagues to support it, and yield
726 back my time.

727 The Chairman. Gentleman yields back the balance of time.

728 Chair recognizes the co-sponsor of the bill, gentlelady from
729 Michigan, my friend, Mrs. Dingell, for five minutes.

730 Mrs. Dingell. I move to strike the last word.

731 The Chairman. So recognized.

732 Mrs. Dingell. Thank you, Chairman Walden and Ranking Member
733 Pallone.

734 Thank you for advancing this legislation. As I've said in

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735 my opening statement, I've lived on all sides of this issue.

736 I live with a man who is in chronic pain and the only hope
737 for him right now is opioids to live life comfortably.

738 The doctor says he's not addicted because he needs it, but
739 he becomes afraid that he will be addicted. We got to be careful
740 to not let the pendulum swing too far in either direction and
741 we cannot deny medication to those who need it.

742 As Fred said, my colleague, Mr. Upton, 25 million Americans
743 suffer from pain every single day, and while pain may not be the
744 fifth vital sign, it's a major issue that needs to be addressed
745 in modern medicine.

746 We cannot stigmatize people who legitimately suffer from
747 chronic pain. It's only going to make the opioid epidemic worse.

748 One thing we can all agree on is that we need more
749 alternatives or opioids in this country. This way, we can give
750 people the relief they need from crippling pain while not
751 subjecting them to the risk of addiction.

752 It's going to require a lot of work and a lot of research
753 to accomplish it, which is why it is so essential that we start
754 this work now.

755 The ACE Research Act accomplishes this goal by spurring
756 innovative research into nonopioid pain medications at NIH which
757 will ultimately lead to the next big breakthrough which will
758 benefit patients.

759 This bill gives the NIH director what is known as the other

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760 transaction authority so that the NIH will be able to move more
761 easily, to partner with innovative companies who are working with
762 cutting-edge technology to address the opioid crisis and other
763 public health interests.

764 In congressional testimony earlier this year, NIH Director
765 Dr. Collins said that giving this agency the authority would
766 improve their ability to do the research we need desperately into
767 nonopioid pain alternatives.

768 Well, we listened to that suggestion and we are delivering
769 that in this bill. There are so many people focused on the opioid
770 epidemic these days.

771 But many small startup companies are hesitant to partner
772 with the federal government on research because the terms of a
773 grant or a contract are just too rigid and no other options are
774 available.

775 The ACE Research Act will ensure that NIH is able to partner
776 with real innovators on research. You never know where that next
777 breakthrough might be coming from and this bill ensures that we
778 will leave no stones uncovered.

779 By funding research on new treatments quicker, we are
780 ensuring that we are going to reach patients fast. In a future
781 with more effective nonopioid pain medications is a future with
782 fewer opportunities for addiction. That's something we all agree
783 on.

784 I am pleased that the legislation has the support of the

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785 American Medical Association, the American Academy of Neurology,
786 and the Coalition to Stop Opioid Overdose, among many others.

787 I want to thank my friend and my colleague, Congressman Fred
788 Upton, for working on this legislation with me and getting it
789 to where we are. This is the first step towards ensuring we are
790 doing the best research in this country on alternatives to opioids
791 for pain medication.

792 I urge my colleagues to join me in supporting H.R. 5002,
793 and I yield back the balance of my time.

794 The Chairman. I thank the gentlelady.

795 Are there other members seeking recognition on this topic?

796 Yes, the gentleman from California is recognized for
797 purposes of striking the last word.

798 Mr. McNerney. Well, I was going to ask to strike the last
799 word.

800 The Chairman. You're recognized five minutes.

801 Mr. McNerney. I appreciate the majority's empathy on this
802 for the pain that people suffer for addiction and their
803 willingness to work across the aisle. I just wish they would
804 extend that pain to the people that suffer from violence of gun
805 deaths and work with us to conduct research on the causes of gun
806 violence and ways to stop it.

807 With that, I yield back.

808 The Chairman. The gentleman yields back.

809 Are there other members seeking recognition on H.R. 5002?

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810 Seeing none, the question now occurs on favorably reporting H.R.
811 5002 to the House.

812 All those in favor shall signify by saying aye.

813 Those opposed, no.

814 The ayes have it and the bill is favorably reported.

815 The chair now calls up H.R. 5102. This is number 14 on the
816 list, and ask the clerk to report.

817 The Clerk. H.R. 5102, to amend the Public Health Service
818 Act to authorize a loan repayment program for substance use
819 disorder treatment employees and for other purposes.

820 [The Bill H.R. 5102 follows:]

821

822 *****INSERT 4*****

823 The Chairman. Without objection, the first reading of the
824 bill is dispensed with. The bill will be open for amendment at
825 any point.

826 Are there any bipartisan amendments to the bill? Are there
827 any amendments to the bill?

828 Mr. Guthrie is recognized. Did you want to speak on the
829 bill? No? Okay.

830 Are there any members wishing to speak on this bill?

831 If not, then the question now occurs on favorably reporting
832 H.R. 5102 to the House.

833 All those in favor will signify by saying aye.

834 Those opposed, no.

835 The ayes have it. The bill is favorably reported.

836 The chair now calls up H.R. 5009. That's number 13, and
837 asks the clerk to report.

838 The Clerk. H.R. 5009, to include information concerning
839 a patient's opioid addiction in certain medical records.

840 [The Bill H.R. 5009 follows:]

841

842 *****INSERT 5*****

843 The Chairman. Without objection, the first reading of the
844 bill is dispensed with. The bill will be open for amendment at
845 any point.

846 Are there bipartisan amendments to this bill? For what
847 purpose does the gentleman from West Virginia seek recognition?

848 Mr. McKinley. For a bipartisan amendment.

849 The Chairman. The clerk will report the McKinley amendment.

850 The Clerk. Amendment to H.R. 5009, offered by Mr. McKinley.

851 The Chairman. Without objection, the reading of the
852 amendment is dispensed with. The gentleman is recognized for
853 five minutes in support of his amendment.

854 Mr. McKinley. Thank you, Mr. Chairman.

855 Last month, our committee held a round table discussion with
856 families whose loved ones were lost due to this scourge of the
857 opioid epidemic.

858 During that discussion, we heard a moving story -- a
859 particularly moving story from a woman named Amy whose son,
860 Emmett, had passed away from an overdose.

861 She shared their family was surprised to learn that her son
862 had overdosed on multiple previous times but they were never
863 notified due to a misinterpretation of the HIPAA law by hospital
864 staff.

865 Amy shared that had they only known they might have been
866 able to intervene and prevent that final overdose that claimed
867 Emmett's life.

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868 That story is why I am offering this amendment to the Jessie's
869 Law legislation. This amendment simply requires the secretary
870 of Health of and Human Services to annually develop and
871 disseminate materials to health care providers with a clear
872 explanation of the permitted disclosures under HIPAA and other
873 federal privacy laws in emergency situations including an
874 overdose. The bill does not make any further changes to HIPAA.

875 I am grateful to have the support of the sponsors of this
876 bill with Mr. Walberg and Mrs. Dingell and urge the adoption of
877 this bipartisan amendment.

878 I yield back.

879 The Chairman. Gentleman yields back.

880 Are there other members seeking recognition?

881 What purposes does the gentleman from Michigan seek
882 recognition?

883 Mr. Walberg. Thank you, Mr. Chairman, for slowing down the
884 pace.

885 The Chairman. Yes. For what purpose do you seek
886 recognition to speak on the amendment?

887 The gentleman is recognized for five minutes on this
888 amendment.

889 Mr. Walberg. Thank you. Before I discuss the amendment,
890 I'd first like to speak generally on H.R. 5041, the Safe Disposal
891 of Unused Medication Act.

892 Bipartisan legislation that I introduced with my good friend

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893 and colleague, Jessie's Law -- I rise to speak in support of H.R.
894 5009, Jesse's Law, a bipartisan bill that I introduced with
895 Congresswoman Debbie Dingell.

896 The bill is named in memory of Michigan resident, Jessie
897 Grubb who, tragically, died of an opioid overdose in 2016. Jessie
898 had battled a heroin addiction for nearly seven years but had
899 been clean for six months.

900 She had made a new life for herself in Michigan and was
901 training for a marathon when an infection related to running
902 injury required her to have surgery.

903 Jessie's parents informed the hospital that she was a
904 recovering addict. However, despite informing the hospital of
905 her history with addiction, the information never made it to her
906 discharging physician.

907 As a result, Jessie was unknowingly discharged from the
908 hospital with a prescription for oxycodone, which ultimately lead
909 to her death the following day.

910 If Jesse's past history of addiction had been noted on her
911 chart in a manner similar to other potentially lethal medical
912 concerns, like a drug allergy, Jessie might still be here today.

913 Jessie's tragic story was entirely preventable and is an
914 example of why we need common sense legislation like Jessie's
915 Law. Jessie's Law will require the Department of Health and Human
916 Services to establish best practices for hospitals and physicians
917 for sharing information about a patient's past opioid addiction

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918 when that information is willingly shared by the patient with
919 their doctor.

920 By ensuring medical professionals are equipped with the
921 right processes and tool to treat their patients, we can prevent
922 future overdose tragedies like Jessie's and, ultimately, save
923 lives.

924 I urge adoption. I strongly support Representative
925 McKinley's amendment and I thank my friend from West Virginia
926 for working with me and Representative Dingell in offering this
927 bipartisan amendment.

928 The amendment will strengthen the underlying bill by
929 ensuring emergency room physicians receive yearly guidance on
930 how to appropriately notify patients' family members after there
931 has been an overdose.

932 Family members play a pivotal role in helping their loved
933 ones get the treatment they need. However, if family is never
934 notified after their loved one experiences a potentially fatal
935 overdose because of a misunderstanding of federal HIPAA privacy
936 rules, then they may never have the opportunity to help their
937 loved ones before it's too late.

938 This is a common sense amendment and I urge its adoption
939 to the underlying bill. I thank the chairman. I yield back.

940 The Chairman. Gentleman yields back the balance of his
941 time.

942 Other members seeking recognition? The chair recognizes

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943 the gentlelady from Michigan, Mrs. Dingell, for five minutes.

944 Mrs. Dingell. Thank you, Mr. Chairman.

945 I move to strike the last word. Thank you.

946 I support this amendment and I thank my colleague from
947 Michigan for working with all of us on this.

948 I really -- I have to say this. I don't think you can know
949 what it's like to be a family member that's trying to help somebody
950 that doesn't know where they are, where they are looking for them
951 -- the desperateness -- and HIPAA making it impossible for you
952 to get information you need.

953 This amendment is needed. This bill is needed. Jessie was
954 -- this family -- Tim and I have gotten to know this family.
955 Their daughter -- they were open. The doctor knew she had been
956 an addict. They gave her 50 pills when she was discharged and
957 she was dead the next day.

958 This death was preventable. We need to make sure medical
959 providers have the information we need. I urge my colleagues
960 to support this bill. And I yield back.

961 The Chairman. The gentlelady yields. The gentlelady
962 yields back the balance of her time. Are there other members
963 seeking recognition?

964 Seeing none, the committee will now vote on the amendment
965 from Mr. McKinley.

966 Those in favor of adopting the amendment will vote aye.

967 Those opposed, nay.

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968 The ayes appear to have it. The ayes have it and the
969 amendment is adopted.

970 Are there other amendments to this legislation? Seeing
971 none, anyone else seeking to strike the last word?

972 Seeing none, the question now occurs on favorably reporting
973 H.R. 5009 as amended to the House.

974 All those in favor shall signify by saying aye.

975 Those opposed, no.

976 The ayes appear to have it. The ayes have it and the bill
977 is favorably reported as amended.

978 The chair now calls up H.R. 5176. This would be number 15
979 on your list, as forwarded by the Subcommittee on Health on April
980 25th, 2018 and ask the clerk to report.

981 The Clerk. H.R. 5176, to require the secretary of Health
982 and Human Services to provide coordinated care to patients who
983 have experienced a nonfatal overdose after emergency room
984 discharge and for other purposes.

985 [The Bill H.R. 5176 follows:]

986

987 *****INSERT 6*****

988 The Chairman. Without objection, the first reading of the
989 bill is dispensed with. The bill will be open for amendment at
990 any point.

991 Are there any bipartisan amendments?

992 Mr. McKinley. Strike the -- strike the last --

993 The Chairman. For what purpose does the gentleman from West
994 Virginia seek recognition?

995 Mr. McKinley. Strike the word -- strike the last word.

996 The Chairman. The gentleman is recognized for five minutes.

997 Mr. McKinley. Mr. Chairman, when patients come into the
998 emergency rooms with a substance use disorder, hospitals offer
999 treatment or referrals to other providers.

1000 But the demand for these services far exceed availability.
1001 Treatment is particular scarce in rural communities despite
1002 having an average overdose death rate that is 45 percent higher
1003 than metropolitan areas.

1004 In March, Center for Disease Control reported that emergency
1005 room visits for opioid overdoses had risen 30 percent since July
1006 of 2016.

1007 This is why I joined with Congressman Doyle to introduce
1008 his bipartisan Preventing Overdoses While in the Emergency Room
1009 Act, also known as the POWER Act.

1010 This legislation will provide competitive grants to
1011 emergency rooms, especially those in high overdose areas, in the
1012 rural areas, to establish procedures for providing

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1013 medication-assisted treatment in the ER and engage in what might
1014 be known as a warm handoff of patients to qualified treatment
1015 providers; to hire coaches, counselors and social workers and
1016 other professionals to treat the patients' substance abuse
1017 disorder there at the beginning in the emergency room; and
1018 establish an integrated care model for implementation in other
1019 emergency rooms across America.

1020 This bill would ensure that overdose patients receive the
1021 treatment they need in the emergency room, giving them a better
1022 shot at recovery.

1023 This legislation is supported by the Addiction Policy Forum,
1024 the National Council of Alcoholism and Drug Dependence, the
1025 National Rural Health Association, and the American College of
1026 American Physicians.

1027 I urge my colleagues to support this legislation and ask
1028 unanimous consent to enter letters of support in the record.

1029 The Chairman. Without objection. Does the gentleman yield
1030 back?

1031 The gentleman yields back the balance of his time. The chair
1032 recognizes the gentleman from --

1033 Mr. Doyle. Mr. Chairman. Mr. Chairman.

1034 The Chairman. Okay. Did you have an amendment?

1035 Mr. Doyle. No, I am a cosponsor of the bill.

1036 The Chairman. Okay. Yes. The chair -- I am sorry. I
1037 didn't --

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1038 The chair recognizes the gentleman from Pennsylvania for
1039 what purpose?

1040 Mr. Doyle. Thank you, Mr. Chairman.

1041 The Chairman. Strike the last word. So recognized, five
1042 minutes.

1043 Mr. Doyle. I move to strike the last word in support of
1044 H.R. 5176, the Preventing Overdoses While in Emergency Rooms Act.

1045 First responders in emergency departments are doing a great
1046 job of administering naloxone and saving lives of a lot of people
1047 who suffer from an overdose. Yet, we are missing a critical piece
1048 of the puzzle.

1049 Those people are often not being connected in time or in
1050 a meaningful way to evidence-based treatment. In fact,
1051 nationally only one in five individuals who need treatment for
1052 opioid addiction received treatment in the past year.

1053 This means that those same patients are ending up in the
1054 ER again with the same problem, or worse. Researchers have found
1055 that starting medication-assisted treatment in the hospital
1056 followed by a referral for ongoing treatment results in more
1057 effective and less costly treatment for the patients.

1058 This bill will help hospitals do just that. The bill will
1059 provide grants for hospitals to begin administering
1060 medication-assisted treatment and coordinating continuing care
1061 after a patient is seen and discharged from the ER.

1062 By starting treatment right away in the emergency room and

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1063 then handing those patients right off to longer-term substance
1064 abuse treatment providers -- what we call a warm handoff -- we
1065 can dramatically increase the likelihood that they will quit using
1066 and have a successful recovery.

1067 This bill gives patients a much greater chance of finding
1068 and completing treatment and ultimately getting their lives back.

1069 I want to thank my friend and colleague, Mr. McKinley, and
1070 his staff for their hard work on this bill as well as the support
1071 of the American College of Emergency Physicians and the Addiction
1072 Policy Forum.

1073 Mr. Chairman, without objection, I would also like to submit
1074 a letter of support from the American Hospital Association for
1075 the record.

1076 The Chairman. Without objection.

1077 [The information follows:]

1078

1079 *****COMMITTEE INSERT 7*****

1080 Mr. Doyle. I look forward to continuing to work together
1081 on this important effort. Mr. Chairman, I thank you and I yield
1082 back the balance of my time.

1083 The Chairman. I thank the gentleman and he yields back the
1084 balance of his time.

1085 Just for our members, we are having a little difficulty with
1086 the clock and so I am keeping a timer here on my alternative clock
1087 device, shall we say.

1088 Other members seeking recognition? I recognize the
1089 gentleman from California for purposes of offering an amendment,
1090 I understand.

1091 Mr. Ruiz. Yes, Mr. Chairman.

1092 First, I want to applaud Representative --

1093 The Chairman. Let -- we will have the clerk report the
1094 amendment.

1095 The Clerk. Amendment to H.R. 5176, offered by Mr. Ruiz.

1096 The Chairman. Without objection, further reading of the
1097 amendment is dispensed with. The chair now recognizes Mr. Ruiz
1098 and his amendment.

1099 Mr. Ruiz. Thank you. I want to applaud Representative
1100 McKinley and Representative Doyle. This is music to my ears as
1101 an emergency physician and I know these kind of projects work.

1102 I have often times wished I had these type of resources when
1103 I took care of patients in a busy emergency department.

1104 I have an amendment at the desk that I am actually going

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1105 to withdraw. But I believe one -- I want to add to the
1106 conversation on this bill and this problem that I am going to
1107 address.

1108 The grants created by this bill will fill in a gap in current
1109 coverage by ensuring that patients presenting to the emergency
1110 department can get on the path toward recovery seamlessly and
1111 easily.

1112 I've seen countless patients in the emergency department
1113 who I was unable to help into long-term treatment due to lack
1114 of funding. But it isn't just funding that can be the problem.

1115
1116 There are well-intentioned regulatory barriers that prevent
1117 physicians from doing their jobs and getting patients the
1118 treatment they need for opioid and substance misuse disorders.

1119 My amendment is simple and will eliminate one of these
1120 barriers. It will remove a rule that restricts doctors from
1121 giving a patient more than one day's worth of buprenorphine or
1122 other medicated -- medication-assisted treatment at a time.

1123 Instead, they will be allowed to provide three days' worth
1124 at once. Currently, if a patient goes to see a doctor and needs
1125 longer term care, the physician can administer only one day's
1126 worth of the medication for three consecutive days while securing
1127 long-term treatment.

1128 But that means, if you think about it, for those three days
1129 the patient has to make a separate visit to the doctor or emergency

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1130 department no matter how far they have to travel, no matter how
1131 long they have to wait in a busy and crowded emergency room, every
1132 24 hours, which, as we all know, rarely occurs.

1133 This is the same three days of treatment currently authorized
1134 under DEA regulation. If a patient comes into the emergency room
1135 on a Tuesday morning, this may not be a problem, since the
1136 long-term treatment facility and providers may be ready on
1137 Wednesday to see the patient.

1138 But the opioid epidemic is not a Monday to Friday 9:00 to
1139 5:00 kind of problem. It strikes at night or on the weekend and
1140 providing some flexibility to physicians can help get more
1141 patients into treatment. This will save time for patients.

1142 It will increase the chances that a patient will remain on
1143 medication-assisted treatment and off of illegal and illicit
1144 drugs while they are waiting for long-term treatment.

1145 It will save money for the health care system by requiring
1146 fewer visits and it will maintain all of the other safeguards
1147 currently in place under DEA regulation.

1148 Most importantly, it will save lives. Let me say that again.
1149 It will save lives.

1150 We know that no one measure will fix the opioid epidemic
1151 but this underlying bill and this amendment are a step in the
1152 right direction. So I will introduce this amendment as a bill
1153 and hope to work with Republicans and Democrats to help improve
1154 and save lives.

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1155 The Chairman. Dr. Ruiz, if you would yield to me.

1156 Mr. Ruiz. Sure.

1157 The Chairman. I get where you're coming from. I think you
1158 make a lot of sense on this and we want to work with you perhaps
1159 in getting this included in something on the way to the floor.

1160 Representing a district that's bigger than any state east
1161 of the Mississippi makes no sense to me that my constituents would
1162 have to drive back to the doctor, which could be an hours long
1163 drive on day two of detoxing and then day three of detoxing until
1164 they can get in somewhere. So we are interested in working with
1165 you on this.

1166 Mr. Ruiz. Thank you very much. I look forward to that.

1167 The Chairman. Do you withdraw your amendment at this time?

1168 Mr. Ruiz. I do withdraw my amendment.

1169 The Chairman. The gentleman withdraws his amendment.

1170 The chair recognizes the gentleman from Pennsylvania, Mr.
1171 Doyle.

1172 Mr. Doyle. Move to strike the last word.

1173 The Chairman. Strike the last word.

1174 Mr. Doyle. I just want to speak briefly in support of Dr.
1175 Ruiz's amendment. While I was working on this bill with Mr.
1176 McKinley, I was contacted by the governor of Pennsylvania as well
1177 as doctors on the ground that this change could really be helpful
1178 for patients to bridge the gap between the ER and long-term
1179 treatment.

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1180 So, Mr. Chairman, I look forward to continuing to work with
1181 the committee staff to try to incorporate this amendment into
1182 the underlying bill and without objection I'd like to submit a
1183 letter of support from Governor Wolf of Pennsylvania for the
1184 underlying bill and the amendment, for the record.

1185 The Chairman. Yes. Without objection, we look forward to
1186 working with you on this.

1187 [The information follows:]

1188

1189 *****COMMITTEE INSERT 8*****

1190 Mr. Doyle. Thank you. I yield back.

1191 The Chairman. The gentleman yields back.

1192 Are there other members seeking recognition on this
1193 legislation?

1194 If not, a question now arises on favorably reporting H.R.
1195 5176 as amended to the House.

1196 All those in favor will signify by saying aye.

1197 Those opposed, no.

1198 The ayes appear to have it. The ayes have it, and this bill
1199 is favorably reported to the House.

1200 The chair now calls up H.R. 5197. This would be number 16
1201 on your program, as forwarded by the Subcommittee on Health on
1202 April 25th, 2018 and ask the clerk to report.

1203 The Clerk. H.R. 5197, to direct the secretary of Health
1204 and Human Services to conduct a demonstration program to test
1205 alternative pain management protocols to limit the use of opioids
1206 in emergency departments.

1207 [The Bill H.R. 5197 follows:]

1208

1209 *****INSERT 9*****

1210 The Chairman. Without objection, the first reading of the
1211 bill is dispensed with. The bill will be open for amendment at
1212 any point.

1213 Are there any bipartisan amendments to this bill?

1214 Mr. McKinley. Strike the last word.

1215 The Chairman. The chair recognizes the gentleman from West
1216 Virginia for purposes of striking the last word, for five minutes.

1217 Mr. McKinley. Thank you, Mr. Chairman.

1218 Mr. Chairman, developing alternatives to opioids for pain
1219 treatment is an issue our office has been working on for years.

1220

1221 We successfully increased funding for the National Institute
1222 of Health to achieve this objective. But we must do more to find
1223 alternatives in the emergency room where many patients first come
1224 into contact with opioids.

1225 Emergency rooms in several states have been developing new
1226 and innovative programs to reduce their over prescription of
1227 opioids. One emergency room in particular, St. Joseph's Medical
1228 Center in Patterson, New Jersey, has reduced opioid prescriptions
1229 by 82 percent in the last two years.

1230 They've achieved this by targeting nonopioid therapies
1231 instead of relying on opioid painkillers as has been the normal
1232 procedure over the past 10 years.

1233 This bipartisan legislation that we are co-sponsoring with
1234 Congressman Pascrell from New Jersey would establish a

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1235 demonstration project and provide grant funding -- grant funding
1236 -- to test alternative pain management protocols.

1237 At the completion of the demonstration period, the secretary
1238 of HHS would report to Congress the results along with
1239 recommendations for broader implementation.

1240 The legislation is supported by the American College of
1241 Emergency Physicians, America's essential hospitals, the
1242 American Hospital Association, and the American Psychological
1243 Association.

1244 Mr. Chairman, I urge my colleagues to support this bipartisan
1245 legislation.

1246 Ms. DeGette. Will the gentleman yield?

1247 Mr. McKinley. I yield back my time.

1248 Ms. DeGette. No, will the gentleman yield?

1249 Mr. McKinley. I yield back. No, I'll -- yes, I'll yield.

1250 Ms. DeGette. Thank you very much.

1251 Mr. Chairman, I want to thank the gentleman for yielding
1252 and I want to thank him for his tireless work on this bill along
1253 with our colleagues, Pascrell and Tipton, who are also original
1254 co-sponsors of the bill.

1255 As the gentleman from West Virginia said, the bill addresses
1256 an important part of this committee's response to the opioid
1257 epidemic, which is prevention.

1258 The ALTO bill would help hospital emergency rooms test
1259 alternative pain management protocols because the emergency rooms

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1260 are especially susceptible to drug diversion behaviors due to
1261 time and resource combinations.

1262 This combination of factors increases the risk for opioid
1263 disorders among emergency room patients. And so what this bill
1264 does is it helps limit opioid prescriptions in the emergency room,
1265 which creates fewer opportunities for drug diversion.

1266 In Colorado, we have one of these pilot projects like they
1267 do in New Jersey and it's at Swedish Medical Center, which is
1268 in my congressional district.

1269 They tested alternative pain management protocols in 10
1270 hospitals across the state of Colorado and in the first six months
1271 opioid prescriptions dropped by an average of 36 percent at these
1272 participating hospitals.

1273 And so this is a program that can work and I think it really
1274 can help us in our effort to have a overall prevention response
1275 to the opioid epidemic.

1276 With that, I'll yield back to the gentleman from West
1277 Virginia.

1278 Mr. Upton. [Presiding.] Gentleman yields back.

1279 Other members -- are there amendments to the bill? The
1280 gentleman from New Jersey has amendment at the -- at the desk?

1281 Mr. Pallone. Yes, Mr. Chairman.

1282 Mr. Upton. The clerk will read the title of the amendment.

1283 The Clerk. Amendment to H.R. 5197, offered by Mr. Pallone.

1284 Mr. Upton. The amendment will be considered as read. The

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1285 staff will distribute the amendment and the gentleman is
1286 recognized for five minutes in support of his amendment.

1287 Mr. Pallone. Thank you, Mr. Chairman.

1288 My amendment is labeled amendment in the nature of a
1289 substitute. It makes a small technical change to the underlying
1290 legislation. It would create a demonstration program to support
1291 emergency departments in developing, implementing, enhancing,
1292 or studying alternative pain management protocols and treatments
1293 that limit the use and prescription of opioids in emergency
1294 departments.

1295 Supporting the development of additional protocols for
1296 alternatives to opioid medications as proposed by this bill can
1297 help reduce the number of those put at risk of addiction and lead
1298 to fewer fatal and nonfatal overdoses and I encourage my
1299 colleagues to support the amendment as well as the underlying
1300 legislation.

1301 I yield back.

1302 Mr. Upton. Gentleman yields back.

1303 Other members wishing to speak on the amendment? Seeing
1304 none, the vote occurs on the amendment offered by the gentleman
1305 from New Jersey.

1306 All those in favor will say aye.

1307 Those opposed say no.

1308 In the opinion of the chair, the ayes have it. The amendment
1309 is agreed to.

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1310 Are there further amendments to the bill?

1311 Seeing none, the vote now occurs on H.R. 5197 as amended.

1312 All those in favor will say aye.

1313 Those opposed say no.

1314 In the opinion of the chair, the ayes have it. The bill
1315 is adopted and forwarded.

1316 The chair will now call up H.R. 5261, which is number 17
1317 on the list, as forwarded by the Subcommittee on Health on April
1318 25th and ask the clerk to report.

1319 The Clerk. H.R. 5261, to amend the Public Health Service
1320 Act to provide for regional centers of excellence in substance
1321 use disorder education and for other purposes.

1322 [The Bill H.R. 5261 follows:]

1323

1324 *****INSERT 10*****

1325 Mr. Upton. Without objection, the first reading of the bill
1326 is dispensed with. The bill will be open for amendment at any
1327 point.

1328 Are there any bipartisan amendments to the bill? Any
1329 amendments to the bill?

1330 The chair recognizes the gentleman from Ohio to strike to
1331 last word.

1332 Mr. Johnson. Yes, Mr. Chairman. I move to strike the last
1333 word and thank you for the recognition.

1334 The TEACH to Combat Addiction Act will increase the amount
1335 of education that health professional students get during their
1336 education on substance use disorder, pain management, and
1337 addiction.

1338 And I want to personally thank my colleague, Representative
1339 Tonko, for co-leading this bill with me. During the legislative
1340 hearing on this bill we heard testimony that only 8 percent of
1341 U.S. medical schools require dedicated courses on addiction and
1342 only a handful have robust curriculum on the diagnosis and
1343 treatment of substance use disorders.

1344 By recognizing institutions that have put a focus on these
1345 areas and sharing their strategies publicly, we hope to ensure
1346 that the next generation of health care professionals is fully
1347 prepared to address the opioid epidemic as well as other forms
1348 of addiction.

1349 The bill also includes a community outreach piece to ensure

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1350 that educational institutions are working with front line
1351 organizations in their communities to exchange expertise and
1352 strategies to address local needs.

1353 These partnerships can be with local mental health or
1354 substance use disorder treatment providers, law enforcement, the
1355 business community, or others working on this epidemic.

1356 A response to the opioid epidemic requires an
1357 all-hands-on-deck effort. Health care providers are in a unique
1358 position to recognize and start to address a patient suffering
1359 from addiction and it's important that their training fully
1360 prepares them to play that important role.

1361 And, Mr. Chairman, I would ask unanimous consent to enter
1362 two letters of support into the record, one from Addiction Policy
1363 Forum and one from numerous health profession schools, and with
1364 that, I yield back.

1365 Mr. Upton. Without objection, it will be entered as part
1366 of the record.

1367 [The information follows:]

1368

1369 *****COMMITTEE INSERT 11*****

1370 Mr. Upton. The chair will recognize the gentleman from New
1371 York, Mr. Tonko, to strike the last word. Recognized for five
1372 minutes.

1373 Mr. Tonko. Yes, Mr. Chair. I move to strike the last word.

1374 I rise in support of the TEACH to Combat Addiction Act, which
1375 I joined with my friend from Ohio, Representative Bill Johnson,
1376 in introducing.

1377 This legislation will invest in our addiction infrastructure
1378 by helping to develop and disseminate model curricula to train
1379 our next generation of medical professionals on the practice of
1380 addiction.

1381 Empowering our health care workforce to better understand
1382 and effectively prevent and treat substance use disorder will
1383 yield dividends in our fight against the opioid epidemic.

1384 I am proud to work with Representative Johnson on this
1385 critical legislation that will strengthen the tools and
1386 information we use to educate the next generation of health care
1387 professionals and I strongly urge the committee to favorably
1388 report this bill from committee.

1389 With that, Mr. Chair, I yield back.

1390 Mr. Upton. Gentleman yields back.

1391 Other members wishing to speak on the bill?

1392 Seeing none, the vote occurs on H.R. 5261.

1393 All those in favor will say aye.

1394 Those opposed say no.

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1395 In the opinion of the chair, the ayes have it. The bill
1396 is favorably reported.

1397 The chair now calls up H.R. 5272, which is number 18, as
1398 forwarded by the Subcommittee on Health on April 25th and ask
1399 the clerk to report.

1400 The Clerk. H.R. 5272, the ensure that programs and
1401 activities that are funded by a grant, cooperative agreement,
1402 loan, or loan guarantee from the Department of Health and Human
1403 Services and whose purpose is to prevent or treat a mental health
1404 or substance use disorder are evidence based.

1405 [The Bill H.R. 5272 follows:]

1406

1407 *****INSERT 12*****

1408 Mr. Upton. Without objection, the first reading of the bill
1409 is dispensed with. The bill will be open for amendment at any
1410 point. Are there any bipartisan amendments to the bill?

1411 Seeing none, the vote occurs on H.R. 5272.

1412 All those in favor will say aye.

1413 Those opposed say no.

1414 In the opinion of the chair, the ayes have it and the bill
1415 is favorably reported.

1416 The chair now calls up H.R. 5327, which is number 19 on your
1417 little schedule, as forwarded by the Subcommittee on Health on
1418 April 25th and ask the clerk to report.

1419 The Clerk. H.R. 5327, to amend Title 10 of the Public Health
1420 Service Act to establish a grant program to create comprehensive
1421 opioid recovery centers and for other purposes. [The Bill
1422 H.R. 5327 follows:]

1423

1424 *****INSERT 13*****

1425 Mr. Upton. Without objection, the first reading of the bill
1426 is dispensed with. The bill will be open for amendment at any
1427 point. Are there any bipartisan amendments to the bill?

1428 Mr. Guthrie. Mr. Chairman.

1429 Mr. Upton. Gentleman has a bipartisan amendment.

1430 Mr. Guthrie. I have a bipartisan amendment at the desk.

1431 Mr. Upton. The clerk will report the title of the amendment.

1432 The Clerk. Amendment to H.R. 5327 offered by Mr. Guthrie.

1433 Mr. Upton. And the clerk will -- the amendment will be
1434 considered as read. The staff will distribute the amendment and
1435 the gentleman is recognized for five minutes in support of his
1436 amendment.

1437 Mr. Guthrie. Thank you, Mr. Chairman.

1438 I offer this bipartisan amendment as a technical
1439 clarification to the comprehensive opioid recovery center
1440 requirements.

1441 This amendment clarifies that the service may be contracted
1442 out in order to provide patients with proper resources to combat
1443 their disease of addiction.

1444 The current addiction treatment system in America is
1445 fragmented and composed of many types of settings, providing
1446 varying degrees of treatment services.

1447 Oversight of these providers ranges from none to minimal
1448 to extensive, depending on the location, type of setting, and
1449 the treatment offered to patients.

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1450 I urge my colleagues to support this amendment and while
1451 I have the time I would like to also, if it's appropriate, to
1452 ask that a letter from the Addiction Policy Forum supporting this
1453 amendment and bill -- a letter of support be entered into the
1454 record --

1455 Mr. Upton. Without objection.

1456 [The information follows:]

1457

1458 *****COMMITTEE INSERT 14*****

1459 Mr. Upton. Gentleman yields back.

1460 Mr. Guthrie. I yield back.

1461 Mr. Upton. Other members wish to speak on the amendment?

1462 Seeing none, the vote occurs on the amendment offered by
1463 the gentleman from Kentucky.

1464 All those in favor will say aye.

1465 Those opposed say no.

1466 In the opinion of the chair the ayes have it. The amendment
1467 is adopted.

1468 Are there further amendments to the bill?

1469 The gentleman from New Mexico.

1470 Mr. Lujan. Mr. Chairman, I have an amendment at the desk.

1471 Mr. Upton. The clerk will report the title of the amendment.

1472 The Clerk. Amendment to H.R. 5327, offered by Mr. Lujan.

1473 Mr. Upton. And the amendment will be considered as read
1474 and the staff will distribute the amendment and the gentleman
1475 is recognized for five minutes in support of his amendment.

1476 Mr. Lujan. Thank you, Mr. Chairman, and thank you to Mr.
1477 Guthrie and Mr. Bucshon with working with myself and Mr. Green
1478 on this bill.

1479 This bill would fund at least 10 comprehensive opioid centers
1480 across the country. Now, we know 10 centers across 50 states
1481 will not solve this problem but we hope that these centers can
1482 stand as examples for what other substance use disorder facilities
1483 could strive to be.

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1484 Mr. Guthrie, I also want to personally thank you and your
1485 staff for working together to make sure prevention services are
1486 part of these centers.

1487 I think this amendment that we have here is a strong addition
1488 and, again, I want to recognize Mr. Guthrie and his staff for
1489 their leadership in their work.

1490 This amendment, which I truly believe we can all support,
1491 requires these centers to either provide directly or contract
1492 out prevention services for two specific and important groups.

1493 One, prevention services for family members of those
1494 diagnosed with substance use disorder; two, targeted intervention
1495 services for opioid-dependent chronic pain patients without a
1496 terminal illness.

1497 That's it. Prevention for people whose family members
1498 suffer from addiction and early intervention for people who suffer
1499 from chronic pain and are dependent upon their opioid
1500 prescription.

1501 Public health research shows us that intervening with these
1502 two groups can prevent thousands of people from suffering from
1503 substance use disorder down the line and that's really what we
1504 are trying to do here with this bill -- provide more families
1505 hope for a future without substance use disorder.

1506 I think this bill is a step in the right direction. Thank
1507 you very much, and I yield back, Mr. Chairman.

1508 Mr. Guthrie. Would the gentleman yield?

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1509 Mr. Lujan. I would yield.

1510 Mr. Guthrie. I just want to, to my colleagues, to say I
1511 support this amendment. I appreciate your staff working together
1512 with us and I urge my colleagues to vote for this amendment.

1513 Mr. Lujan. Thank you, Mr. Guthrie, and I would yield to
1514 Ms. Castor of Florida.

1515 Ms. Castor. I also want to thank you, Mr. Guthrie and Mr.
1516 Lujan, and the other co-sponsors here.

1517 This is a step in the right direction. But I want to make
1518 the point that these grants will not be enough. Over time, we
1519 really need -- what folks are saying at home and across the country
1520 they need the consistent dependable funding and resources to
1521 really tackle this crisis. And while this is a good step forward,
1522 we need to -- we need to think in more robust and bold terms,
1523 moving ahead.

1524 Thank you again and I yield back.

1525 Mr. Lujan. I yield back, Mr. Chair.

1526 Mr. Upton. Gentleman yields back.

1527 Other members wishing to speak on amendments?

1528 Seeing none, the vote occurs on the amendment offered by
1529 the gentleman from New Mexico, Mr. Lujan.

1530 All those in favor will say aye.

1531 Those opposed say no.

1532 In the opinion of the chair the ayes have it and the amendment
1533 is agreed to.

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1534 Further amendments to the bill?

1535 Mr. Green. Mr. Chairman, I move to strike the last word.

1536 Mr. Upton. The gentleman is recognized for five minutes.

1537 Mr. Green. Mr. Chairman, I speak in support of H.R. 5327

1538 as amended in the Comprehensive Opioid Recovery Centers Act.

1539 This legislation creates a unique model of patient-centered care
1540 designed to address the opioid crisis.

1541 The Comprehensive Opioid Recovery Centers Act when enacted
1542 will provide a full range of treatments for options for patients
1543 suffering from opioid addiction and other substance use
1544 disorders.

1545 Designated centers will receive grants and their designation
1546 through SAMHSA will be required to provide a wide range of
1547 evidence-based treatment services as well as recovery support
1548 programs.

1549 These services include but are not limited to all
1550 FDA-approved medications, detoxification, counseling,
1551 residential rehab, recovery housing, community-based and peer
1552 recovery support systems, and job training and placement
1553 assistance.

1554 I thank my colleagues, both Congressman Guthrie, Congressman
1555 Lucan, and Congressman Bucshon for their hard work and cooperation
1556 on this valuable legislation.

1557 I ask my colleagues to support this bill. It clarifies also
1558 that the methadone services could be conducted by referral if

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1559 needed.

1560 Our goal is to establish centers like this that would be
1561 the gold standard for treatment in all parts of the country and
1562 so we can get some kind of clarity on how we treat all these
1563 different illnesses.

1564 I urge my colleagues to support this valuable legislation
1565 and yield back the remainder of my time.

1566 Mr. Upton. Gentleman yields back.

1567 Other members wishing to speak on the bill? Further
1568 amendments to the bill?

1569 Seeing none, the vote occurs on H.R. 5327 as amended.

1570 All those in favor will say aye.

1571 Those opposed say no.

1572 In the opinion of the chair the ayes have it. The bill is
1573 favorably reported.

1574 The chair now calls up H.R. 5353, number 20, as forwarded
1575 by the Subcommittee on Health on April 25th and ask the clerk
1576 to report.

1577 The Clerk. H.R. 5353, to amend the Public Health Service
1578 Act to reauthorize and expand the program of surveillance and
1579 education carried out by the Centers for Disease Control and
1580 Prevention regarding infections associated with injection drug
1581 use. [The Bill H.R. 5353 follows:]

1582

1583 *****INSERT 15*****

1584 Mr. Upton. Without objection, the first reading of the bill
1585 is dispensed with. The bill will be open for amendment at any
1586 point.

1587 Are there any bipartisan amendments to the bill?

1588 Are there any amendments to the bill?

1589 Seeing none, the vote occurs on favorably reporting H.R.
1590 5353.

1591 All those in favor will say aye.

1592 Those opposed say no.

1593 In the opinion of the chair the ayes have it. The bill is
1594 favorably reported.

1595 The chair now calls up H.R. 3331, number 21 on your list,
1596 and ask the clerk to report.

1597 The Clerk. H.R. 3331, to amend Title 11 of the Social
1598 Security Act to promote testing of incentive payments for
1599 behavioral health providers for adoption and use of certified
1600 electronic health record technology. [The Bill H.R. 3331
1601 follows:]

1602

1603 *****INSERT 16*****

1604 Mr. Upton. Without objection, the first reading of the bill
1605 is dispensed with and the bill will be open for amendment at any
1606 point.

1607 Are there any bipartisan amendments to the bill?

1608 The chair recognizes the gentlelady from California, Ms.
1609 Matsui.

1610 Ms. Matsui. Thank you, Mr. Chairman.

1611 I have a bipartisan amendment at the desk, an amendment in
1612 the nature of a substitute to H.R. 3331.

1613 Mr. Upton. And the clerk will report the title of the
1614 amendment.

1615 The Clerk. Amendment in the nature of a substitute to H.R.
1616 3331, offered by Ms. Matsui.

1617 Mr. Upton. And the amendment will be considered as read.
1618 Staff will distribute the amendment and the gentlelady is
1619 recognized for five minutes.

1620 Ms. Matsui. Thank you, Mr. Chairman.

1621 Mr. Chairman, I am pleased to work on this legislation with
1622 my colleagues, Representative Lynn Jenkins from the Ways and Means
1623 Committee and Representative Mullin here as well as Ranking Member
1624 Pallone and Chairman Walden.

1625 Just yesterday, Senator Whitehouse and Portman championed
1626 this bill's passage in the Senate. The amendment at the desk
1627 makes some technical changes to the bill including conforming
1628 changes to the Senate version and updates based on feedback from

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1629 CMS.

1630 Additionally, we have added psychiatric nurse practitioners
1631 to the list of providers that may potentially qualify for a CMMI
1632 demonstration under this bill.

1633 We must continue to push for our health system to include
1634 behavior health treatment as a part of regular medical care.
1635 Ensuring that behavior health providers have electronic health
1636 records is one step in that direction.

1637 I thank my colleagues for working with me on this important
1638 legislation. I urge support on this bipartisan bill and yield
1639 back.

1640 Mr. Upton. The gentlelady yields back.

1641 Other members wish to speak on the amendment?

1642 Seeing none, the vote occurs on the amendment offered by
1643 the gentlelady from California.

1644 All those in favor will say aye.

1645 Those opposed say no.

1646 In the opinion of the chair the ayes have it and the amendment
1647 is agreed to.

1648 Are there further amendments to H.R. 3331?

1649 Seeing none, the vote occurs on H.R. 3331 as amended.

1650 All those in favor will say aye.

1651 Those opposed say no.

1652 In the opinion of the chair the ayes have it. The bill is
1653 favorably reported.

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1654 The chair now calls up H.R. 5685, number 22 on your list,
1655 and ask the clerk to report.

1656 The Clerk. H.R. 5685, to amend Title 18 of the Social
1657 Security Act to provide educational resources regarding opioid
1658 use and pain management as part of the Medicare and You Handbook.

1659 [The Bill H.R. 5685 follows:]

1660

1661 *****INSERT 17*****

1662 Mr. Upton. Without objection, the first reading of the bill
1663 is dispensed with. The bill will be open for amendment at any
1664 point.

1665 Are there are any bipartisan amendments to the bill?

1666 Are there any amendments to the bill?

1667 Seeing none, the vote occurs on favorably reporting H.R.
1668 5685.

1669 All those in favor will say aye.

1670 Those opposed say no.

1671 In the opinion of the chair the ayes have it. The bill is
1672 favorably reported.

1673 The chair now will call up H.R. 5603, number 23 on your list,
1674 and that --

1675 [Pause.]

1676 The chair will call up instead H.R. 3528, number 24 on your
1677 list, as forwarded by the Subcommittee on Health on April 25th
1678 and will ask the clerk to report on H.R. 3528.

1679 The Clerk. H.R. 3528, to amend Title 18 of the Social
1680 Security Act to require e-prescribing for coverage under Part
1681 D of the Medicare program of prescription drugs that are
1682 controlled substances. [The Bill H.R. 3528 follows:]

1683

1684 *****INSERT 18*****

1685 Mr. Upton. Without objection, the first reading of the bill
1686 is dispensed with and the bill will be open for amendment at any
1687 point.

1688 Are there any bipartisan amendments to the bill?

1689 Are there any amendments to the bill?

1690 Seeing none, the vote occurs on favorably reporting H.R.
1691 3528.

1692 [Pause.]

1693 I will call up the amendment. We have an amendment, number
1694 -- offered by Mr. Mullin. I am going to offer the Mullin
1695 amendment, number 36.

1696 The Clerk. Amendment to H.R. 3528, offered by Mr. Upton.

1697 Mr. Upton. The amendment will be considered as read. The
1698 staff will distribute the amendment and I will be recognized for
1699 five minutes in support of the Mullin amendment.

1700 It is told as a technical amendment. It's been cleared with
1701 both sides. It shouldn't be any problem. I would urge my
1702 colleagues to support it.

1703 In the absence of Mr. Mullin, who is -- yes, and I will yield
1704 to my friend and colleague to also speak in favor of the Mullin
1705 amendment as offered by Mr. Upton.

1706 The gentleman from New Jersey, Mr. Pallone.

1707 Mr. Pallone. Thank you, Mr. Chairman.

1708 I support the Mullin amendment but I really am speaking on
1709 the underlying bill. As I noted during our subcommittee markup,

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1710 I believe this legislation has the potential to reduce abuse and
1711 diversion of prescription opioid medications by requiring that
1712 prescriptions for controlled substances covered under Medicare
1713 Part D be electronically prescribed and transmitted securely for
1714 dispensing.

1715 As I've reiterated throughout the committee's consideration
1716 of these opioid proposals, I intend to support legislation that
1717 either directly impacts treatment or will meaningfully prevent
1718 the spread of opioid addiction and I believe that this bill is
1719 one of the proposals that can have a very real preventative impact
1720 by utilizing the technology we have to ensure legitimate
1721 prescriptions for controlled substances are not forged or
1722 tampered with but instead are delivered securely through an
1723 electronic means to the dispensing pharmacy.

1724 I am aware that some are concerned that this legislation
1725 may result in additional burdens on prescribers and I am
1726 sympathetic to those concerns but also believe that this bill
1727 could be a way to reduce diversion and fraud while also ensuring
1728 patients that need their covered prescriptions are still able
1729 to obtain them.

1730 So I am pleased that H.R. 3528 is bipartisan. I thank Ms.
1731 Clarke and Mr. Mullin for their leadership on this bill and I
1732 stand ready to continue to work with my colleagues on this
1733 legislation as needed.

1734 But the underlying bill is really, I think, important. I

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1735 urge my colleagues to support it.

1736 Mr. Upton. The gentleman yields back.

1737 Are there other members wishing to speak on the Mullin
1738 amendment as offered by Mr. Upton?

1739 Seeing none, the vote occurs on that amendment.

1740 Those in favor will say aye.

1741 Those opposed say no.

1742 In the opinion of the chair, the ayes have it. The amendment
1743 is agreed to.

1744 Are there further amendments to H.R. 3528?

1745 Seeing none, the vote occurs on H.R. 3528 as amended.

1746 All those in favor will say aye.

1747 Those opposed say no.

1748 In the opinion of the chair, the ayes of it. The bill is
1749 favorably reported.

1750 Now the chair calls up H.R. 4841, which is number 25 on your
1751 list, and ask the clerk to report.

1752 The Clerk. H.R. 4841, to amend Title 18 of the Social
1753 Security Act to provide for electronic prior authorization under
1754 Medicare Part D for covered Part D drugs and for other purposes.

1755 [The Bill H.R. 4841 follows:]

1756 *****INSERT 19*****

1757 Mr. Upton. And without objection the first reading of the
1758 bill is dispensed with. The bill will be open for amendment at
1759 any point.

1760 Are there any bipartisan amendments to the bill?

1761 Are there any amendments to the bill?

1762 The gentleman from New Mexico.

1763 Mr. Lujan. I was not sure if Mr. Johnson was going to offer.
1764 If not, I'd be happy to offer the amendment.

1765 Mr. Upton. Mr. Johnson has got an amendment at the desk.
1766 The clerk will report the title of the amendment.

1767 The Clerk. Amendment to H.R. 4841, offered by Mr. Johnson.

1768 Mr. Upton. And the amendment will be considered as read.
1769 The staff will distribute the amendment and the gentleman from
1770 Ohio is recognized for five minutes in support of his amendment.

1771 Mr. Johnson. Thank you, Mr. Chairman.

1772 This amendment makes a small clarifying change to the base
1773 text of the Standardizing Electronic Prior Authorization, or
1774 SAFE, Prescribing Act. This bill will improve efficiencies in
1775 Medicare and allow beneficiaries to begin doctor-prescribed
1776 therapies without delay.

1777 There are a number of medications that require approval by
1778 a health insurance plan prior to dispensing in order to ensure
1779 coverage, a process known as prior authorization, or PA.

1780 However, the traditional PA process uses outdated modes of
1781 communication such as phone and fax, which can be burdensome for

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1782 the provider and pharmacist and often causes undue delays for
1783 the patient.

1784 Electronic prior authorization, or EPA, has seen widespread
1785 and successful adoption in the commercial market and this
1786 legislation takes an important step to further encourage its
1787 adoption in Medicare Part D.

1788 EPA provides a pathway for a quick determination of clinical
1789 appropriateness, assisting in the prevention of prescription
1790 misuse while maintaining access to medication for those with
1791 legitimate needs, which is particularly impactful in the opioid
1792 prescription space.

1793 I urge my colleagues to support this technical amendment
1794 as well as the underlying legislation and I have -- Mr. Chairman,
1795 I would like to offer with unanimous consent -- enter into the
1796 record a letter from supporters.

1797 We have over a dozen supporters from companies -- American
1798 Academy of Ophthalmology, AstraZeneca, Athena Health, Global
1799 Healthy Living Foundation, IBM, Health Care Leadership Council,
1800 National Association for Mental Illness, Patients Rising Now,
1801 and Pharmaceutical Care Management Association, and I request
1802 that that letter of support be entered into the record, and with
1803 that I yield back.

1804 Mr. Upton. Without objection, it will entered and part of
1805 the record.

1806 [The information follows:]

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1807

1808

*****COMMITTEE INSERT 20*****

1809 Mr. Upton. The gentleman from New Mexico.

1810 Mr. Lujan. Strike the last word, Mr. Chairman.

1811 Mr. Upton. Gentleman is recognized for five minutes.

1812 Mr. Lujan. Thank you, Mr. Chairman, and thank you, Mr.

1813 Johnson, for your work and your leadership on this initiative as

1814 well.

1815 This legislation improves the prior authorization of
1816 medications to the Medicare program by streamlining the PA process
1817 and ensuring legitimate beneficiary access to prescribed
1818 medication under PA, such as many opioids.

1819 Most importantly, a more efficient PA process will help to
1820 improve health outcomes and reduce overall health costs.

1821 The amendment that Mr. Johnson and I are offering today are
1822 simply two technical fixes -- applying electronic prior
1823 authorization to the Medicare Part D program would reduce provider
1824 burdens, improve patient access and adherence, and decrease
1825 systems cost, and I think this is something we can all stand
1826 behind.

1827 And with that, Mr. Chairman, I yield back.

1828 The Chairman. [Presiding.] The gentleman yields back the
1829 balance of his time.

1830 Other members seeking recognition on the amendment?

1831 Seeing none, the question now arises on passing the
1832 amendment.

1833 All those in favor of the Johnson amendment will say aye.

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1834 Those opposed, nay.

1835 The ayes appear to have it. The ayes have it. The amendment
1836 is adopted.

1837 Any other members seeking recognition on this legislation
1838 or any other amendments?

1839 Seeing none, the vote now arises on approving and reporting
1840 H.R. 4841 as amended to the House floor favorably.

1841 All those in favor shall say aye.

1842 Those opposed, nay.

1843 The ayes appear to have it. The ayes have it and the bill
1844 is reported as amended.

1845 Next up the chair calls up H.R. 5675, number 26 on your
1846 program, and asks the clerk to report.

1847 The Clerk. H.R. 5675, to amend Title 18 of the Social
1848 Security Act to require prescription drug plan sponsors under
1849 the Medicare program to establish drug management programs for
1850 at-risk beneficiaries. [The Bill H.R. 5675 follows:]

1851

1852 *****INSERT 21*****

1853

1854

1855

1856

The Chairman. Without objection, the first reading of the bill is dispensed with. The bill is open for amendment at any point.

1857

Are there any bipartisan amendments to this legislation?

1858

Are there any amendments? Anyone seeking recognition?

1859

1860

The chair recognizes the gentleman from Florida for five minutes to strike the last word.

1861

Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it.

1862

Mr. Chairman, thanks for including H.R. 5675 in this markup.

1863

I appreciate it so much.

1864

1865

1866

This bill was introduced by myself and my good friend, Ben Ray Lujan, along with Peter Roskam and Sander Levin. So it's truly a bipartisan bill.

1867

1868

1869

1870

This bill is a simple tweak to the already existing Medicare lock-in program. Back in 2013, myself and Ben Ray Lujan introduced the Patient Safety and Drug Abuse Prevention Act which would create a pharmacy lock-in program in Medicare.

1871

1872

1873

1874

1875

This provision was ultimately included in CARE, the Comprehensive Addiction Recovery Act in 2016. Pharmacy lock-in is not a new concept. As you know, states have been using physician or pharmacy lock-in or some combination of both as part of Medicaid for year.

1876

1877

So the TRICARE uses it and so do commercial insurance. This law, as it stands, has a main authority. This bill will change

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1878 it to a shell authority.

1879 Right now, it is up to the discretion of the Part D plan
1880 that they may run a lock-in program or may not run a lock-in
1881 program. This legislation will require that all Part D plans
1882 have a pharmacy lock-in program in place for at-risk
1883 beneficiaries.

1884 This is a common sense tweak to the law. Beneficiaries have
1885 the ability to switch plans every year. At-risk beneficiaries
1886 would simply find prescription drugs plans that do not have a
1887 lock-in program in place and use those plans to continue their
1888 drug diversion habits inside Medicare. Under the current law,
1889 this plan -- this particular bill ensures that we have a uniform
1890 system in place across Part D and that all beneficiaries who are
1891 at-risk -- again, at-risk beneficiaries can be identified and
1892 ensured that they receive the assistance they need.

1893 In 2012, an estimated 336,000 seniors had misused or become
1894 dependent upon prescription pain relievers, according to SAMHSA.

1895 We need to do all we can to help our seniors in Medicare, Mr.
1896 Chairman.

1897 This bill makes the law better, and I ask swift passage,
1898 and I yield back the balance of my time.

1899 Thank you so much.

1900 Mr. Lujan. Will the gentleman yield?

1901 Mr. Bilirakis. Yes, please. I yield to my good friend,
1902 Ben Ray.

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1903 Mr. Lujan. I thank you, Mr. Bilirakis, and as my friend
1904 pointed out, this bill we are considering today will build off
1905 of work done in the Comprehensive Addiction Recovery Act.

1906 I want to quickly thank my partner and friend on this bill,
1907 Mr. Gus Bilirakis, and his staff for working on this issue
1908 together.

1909 This bill is an important step forward to help our seniors
1910 stay as safe as possible when it comes to prescription opioids.

1911 As we know, seniors represent a growing percentage of people
1912 with substance use disorder. I am proud to continue the
1913 bipartisan work we started last Congress and I hope all my
1914 colleagues can also support this important legislation.

1915 I would yield back to Mr. Bilirakis.

1916 Mr. Bilirakis. Yes, and I yield back the balance of my time,
1917 Mr. Chairman.

1918 The Chairman. Gentleman yields back the balance of his
1919 time.

1920 Are there other members seeking recognition?

1921 Seeing none, the question now arises on reporting favorably
1922 H.R. 5675 as amended to the House.

1923 All those in favor will signify by saying aye.

1924 Those opposed, nay.

1925 The ayes appear to have it. The ayes have it and the bill
1926 is reported favorably to the House.

1927 The chair now calls up H.R. 5686, number 27 on the list,

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1928 and asks the clerk to report.

1929 The Clerk. H.R. 5686, to amend --

1930 The Chairman. Without a -- sorry.

1931 The Clerk. To amend Title 18 of the Social Security Act
1932 to require prescription drug plans under Medicare Part D to
1933 include information on the adverse effects of opioid
1934 overutilization and of coverage of nonpharmacological therapies
1935 and nonopioid medications or devices used to treat pain.

1936 [The Bill H.R. 5686 follows:]

1937

1938 *****INSERT 22*****

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The Chairman. Without objection, the first reading of the bill is dispensed with. The bill will be open for amendment at any point. Are there any bipartisan amendments?

Mr. Collins. Chair, I move to strike the last word.

The Chairman. Gentleman is recognized for five minutes to strike the last word.

Mr. Collins. Thank you, Mr. Chairman.

When it comes to combating the opioid epidemic, education and awareness are core components. A lack of knowledge for consumers and prescribers has left many of our communities in crisis.

Years ago, we did not fully understand the neurobiology behind opioid use, especially when they are taken for a prolonged period.

Because of that, opioids were the gold standard in pain management and became a commonly prescribed drug. We also didn't realize that these drugs have different impacts on different demographics.

Take seniors, for example. According to the Substance Abuse and Mental Health Services Administration, opioid use can cause breathing complications, confusion, drug interaction problems, and increased risk of falls.

All of these side effects are already more dangerous in older populations, putting our seniors at greater risk.

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1964 In addition, a 2016 analysis by HHS inspector general found
1965 that over half a million Medicare Part D beneficiaries received
1966 what they would consider a high amount of opioids with the average
1967 dose far exceeding the manufacturers' recommended amount.

1968 It is estimated that, roughly, one in three beneficiaries
1969 receives a prescription for opioids. It's also estimated that
1970 nearly half of older Americans suffer from a chronic pain
1971 condition which typically becomes more common and severe as we
1972 age.

1973 Yet, despite the risks, opioids can be a valuable tool in
1974 pain management so long as they are being prescribed and used
1975 properly.

1976 We need to make sure that patients understand the risks of
1977 overutilization of these prescriptions as well as available
1978 treatment options.

1979 Ensuring that Americans are presented with the information
1980 to make their own decisions is important. That is why I was proud
1981 to join Representative Paulsen, Kind, and Lamb in introducing
1982 the Choice Act.

1983 This bipartisan legislation will help Medicare
1984 beneficiaries make informed decisions on pain management. The
1985 policy idea is simple. If a person is informed about the dangers
1986 that can come with taking prescription opioids, they are likely
1987 to discuss their prescriptions with their physicians.

1988 This will lead both the patient and the doctor to be more

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1989 cognizant of the early warning signs of addiction.

1990 The Choice Act will require Medicare Part D plans to annually
1991 inform patients about the adverse effects associated with
1992 prolonged opioid use.

1993 In addition, these notices will provide information on other
1994 options like nonpharmacological therapies, devices, and
1995 nonopioid medications.

1996 I am hopeful that this legislation will encourage more
1997 patients to talk to their doctors about the risk for addiction
1998 and other treatments available in order to prevent addiction from
1999 occurring.

2000 I yield back.

2001 The Chairman. Gentleman yields back the balance of his
2002 time.

2003 Are there other members seeking recognition on H.R. 5686?

2004 Are the other -- are there any offers of amendments?

2005 Hearing and seeing none, the question now arises on favorably
2006 reporting H.R. 5686 to the floor.

2007 All those in favor will signify saying aye.

2008 Those opposed, nay.

2009 The ayes appear to have it. The ayes have it and the measure
2010 is reported favorably to the House.

2011 The chair calls up H.R. 5582, number 28 on your list, and
2012 asks the clerk to report.

2013 The Clerk. H.R. 5582, to direct the secretary of Health

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2014 and Human Services to conduct a study and submit a report on
2015 barriers to accessing abuse-deterrent opioid formulations for
2016 individuals enrolled in a plan under Part C or D of the Medicare
2017 program. [The Bill H.R. 5582 follows:]

2018

2019 *****INSERT 23*****

2020 The Chairman. Without objection, the first reading of the
2021 bill is dispensed with. The bill will be open for amendment at
2022 any point.

2023 Are there bipartisan amendments to the bill?

2024 Mr. Carter. Mr. Chairman, I have an amendment.

2025 The Chairman. The gentleman is recognized. The clerk will
2026 report the amendment.

2027 The Clerk. Amendment to H.R. 5582, offered by Mr. Carter.

2028 The Chairman. The gentleman is -- without further
2029 objection, further reading of the amendment is dispensed with.

2030

2031 The chair recognizes the gentleman from Georgia, Mr. Carter,
2032 for five minutes to speak in support of his amendment.

2033 Mr. Carter. Thank you, Mr. Chairman.

2034 Mr. Chairman, this amendment makes three simple changes to
2035 the underlying legislation that was reported out of subcommittee.

2036 This amendment extends the deadline for CMS to conduct the
2037 study to one year. It includes the term "pro-drug" as an example
2038 of ADFs and it includes list prices, a potential barrier to
2039 accessing ADFs.

2040 Each year, approximately 4.5 million Americans use
2041 prescription pain medications for nonmedical purposes,
2042 contributing to 89 deaths per day.

2043 Of those that misuse prescription pain relievers, 53 percent
2044 reported obtaining them from friends or relatives.

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2045 Although past legislative efforts have encouraged
2046 innovation in prescription drug regulation law enforcement and
2047 education, there are still individuals who have severe legitimate
2048 chronic pain and need access to opioids.

2049 Abuse deterrent formations, or ADFs, represent a
2050 breakthrough technology for these individuals that helps prevent
2051 the crushing, snorting, and injection of pain killers.

2052 Currently, many prescription drug plans present barriers
2053 to ADFs including cost-sharing tiers, fail-first requirements,
2054 prior authorization requirements, and list price, all limiting
2055 patient access to abuse deterrent formulations.

2056 Instead of receiving ADFs, many patients are limited to using
2057 opioids that can be easily crushed, snorted, and injections.

2058 Solutions to this public health crisis must balance the need
2059 to preserve access to effective pain medications for legitimate
2060 patients living with pain while minimizing the risk of opioid
2061 misuse and abuse that occurs in our communities.

2062 ADF should be an integral component of a comprehensive
2063 prescription opioid misuse, abuse, and diversion prevention
2064 strategy designed to limit harm for patients, abusers, and the
2065 surrounding community.

2066 I am proud to introduce this with my colleague across the
2067 aisle, Representative Loeb sack, and my Ways and Means colleague,
2068 Representative Reed, and I urge your support.

2069 And I yield back.

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2070 The Chairman. The gentleman yields back the balance of his
2071 time.

2072 The chair recognizes the gentleman from Pennsylvania to
2073 strike the last word.

2074 Mr. Doyle. Thank you, Mr. Chairman.

2075 I want to speak in support of this bill. We all know that
2076 the opioid crisis can't be solved with one single bill, which
2077 is why we are here today, and I believe that none of us are under
2078 any delusion that we have a silver bullet solution, and I don't
2079 believe that abuse deterrent opioids are such a solution.

2080 However, I do believe they can be a small part of our approach
2081 to tackle this problem from many different directions.

2082 While these drugs are not less addictive, these medicines
2083 can be helpful to keep patients from taking pills inappropriately,
2084 whether through crushing, injecting, or snorting.

2085 We should be giving doctors and patients every tool possible
2086 to help mitigate this process. This bill will help us get a sense
2087 of how many patients have access to ADF drugs, which may help
2088 us address the increased need or demand, going forward.

2089 I am happy to see the bill included in this package. I look
2090 forward to working with the committee and Mr. Carter as we continue
2091 this process.

2092 I want to thank you and yield back the balance of my time.

2093 The Chairman. Gentleman yields back.

2094 Are there members on the majority side seeking recognition?

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2095 Seeing none, the chair recognizes the gentlelady from
2096 Illinois, Ms. Schakowsky, for five minutes to strike the last
2097 word.

2098 Ms. Schakowsky. Thank you, Mr. Chairman.

2099 I am very encouraged that this amendment includes the cost
2100 of abuse deterrent formulation drugs in the -- in the study and
2101 I am grateful to Representative Carter for working in a bipartisan
2102 manner to include a price study in this bill.

2103 I do still believe that we need to examine the price of
2104 naloxone products to see how the skyrocketing prices have impacted
2105 access to that lifesaving drug.

2106 Generic and brand formulations of naloxone have seen huge
2107 price increases within the last few years. The generic version
2108 now sells for double its price and Evzio has increased its price
2109 500 percent.

2110 With the increased demand on these drugs to equip police,
2111 emergency medical providers, schools, families, and friends, the
2112 burden on public programs has increased as well.

2113 We need to know how these price increases are affecting
2114 access. Additionally, we should give the secretary of HHS every
2115 tool he needs to address this public health emergency, especially
2116 the authority to negotiate the prices of naloxone.

2117 President Trump is announcing his plan to address rising
2118 drug prices on Friday and there are many things I hope he includes.

2119 But one area we should all be unified on is lowering the price

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2120 of naloxone through negotiation.

2121 We cannot allow pharmaceutical corporations to profit from
2122 this epidemic. It is unacceptable. I hope, as we move forward
2123 with next week's markup, we can continue to discuss how we can
2124 lower the barriers to accessing naloxone because we can't afford
2125 naloxone -- because when we can't afford naloxone and it is not
2126 available, people die.

2127 Thank you, and I yield back.

2128 The Chairman. Gentlelady yields back.

2129 Other members seeking recognition to speak on the
2130 legislation?

2131 The chair recognizes the gentleman from Iowa, Mr. Loeb sack,
2132 for five minutes to strike the last world.

2133 Mr. Loeb sack. Thank you, Mr. Chair.

2134 Just very quickly, I am really happy to work with my good
2135 friend, Buddy Carter, on this and colleague Buddy Carter.

2136 He's done a great job on this. We have worked together on
2137 a number of issues. I know we are going to continue to do so,
2138 especially on committee pharmacy issues but others well, and I
2139 think he's explained not only the underlying bill but the
2140 amendment very well and I appreciate the bipartisan support on
2141 this side of the aisle, too.

2142 So thank you, Mr. Carter, and thank you, Mr. Chair, and I
2143 yield back.

2144 The Chairman. Gentleman yields back. Are there other

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2145 members seeking recognition to speak on this amendment?

2146 Seeing none, the question now arises on approving the
2147 amendment.

2148 All those in favor will say aye.

2149 Those opposed, nay.

2150 The ayes appear to have it. The ayes have it.

2151 The amendment is adopted.

2152 Are there further amendments to H.R. 5582?

2153 Seeing none, the question now arises on approving --
2154 reporting to the full House as amended H.R. 5582 and doing so
2155 favorably.

2156 Those in favor will signify by saying aye.

2157 Those opposed, nay.

2158 The ayes appear to have it. The ayes have it and the bill
2159 is reported to the House favorably as amended.

2160 The chair calls up H.R. 5684 -- this would be number 29 on
2161 the list -- and ask the clerk to report.

2162 The Clerk. H.R. 5684, to amend Title 18 of the Social
2163 Security Act to expand eligibility for medication therapy
2164 management programs established under Part D of the Medicare
2165 program to include certain individuals who are at risk for
2166 prescription drug abuse. [The Bill H.R. 5684 follows:]

2167

2168 *****INSERT 24*****

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The Chairman. Without objection, the first reading of the bill is dispensed with. The bill will open for amendment at any point.

Are there any bipartisan amendments to the bill?

Are there any amendments to the bill?

For what purpose does the gentleman from Texas seek recognition?

Mr. Burgess. Move to strike the last word.

The Chairman. I recognize the chairman of the Subcommittee on Health to, for the next five minutes, strike the last word.

Mr. Burgess. I thank the chairman.

I do want to commend our colleague, Kathy McMorris Rodgers, and members on both sides of the dais on this committee and the Ways and Means Committee for working on this legislation.

Medication therapy management has been shown to improve patients outcomes and lower health care costs. This bill would expand medication therapy management by adding those at risk for prescription drug abuse to the list of targeted beneficiaries eligible for medication therapy management services under the Medicare Part D program.

Mr. Chairman, I have a letter from the American Medical Association actually detailing support for a number of the bills that we are working on today but this one in particular. So I'd ask unanimous consent to --

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2194 The Chairman. Without objection.

2195 [The information follows:]

2196

2197 *****COMMITTEE INSERT 25*****

2198 Mr. Burgess. -- place the AMA letter into the record, and
2199 I urge members on both sides of the dais to support this important
2200 legislation and, again, thank our colleagues on Ways and Means.
2201 I yield back.

2202 The Chairman. Gentleman yields back.

2203 Are there other members seeking recognition?

2204 The chair recognizes the gentleman from Pennsylvania for
2205 five minutes to strike the last word.

2206 Mr. Doyle. Thank you, Mr. Chairman.

2207 I want to speak in support of H.R. 5684. Again, I think
2208 this bill can be a small piece of the puzzle in addressing the
2209 opioid epidemic.

2210 Medicare currently offers medication therapy management for
2211 beneficiaries with complex health needs.

2212 This program helps both patients and doctors make sure that
2213 medications are working to improve their health.

2214 Under an MTM program, a pharmacist can give beneficiaries
2215 a comprehensive review of all of their medications and talk about
2216 how well they are working -- side effects, potential interactions
2217 between drugs, and any other problems that they may be having.

2218 Currently, this program is only available for certain
2219 Medicare beneficiaries with multiple chronic conditions or taking
2220 several medications.

2221 But the program could also be used to help prevent opioid
2222 abuse and at-risk beneficiaries. In fact, CMS encourages plans

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2223 to offer MTM services to beneficiaries who are at risk for
2224 substance use disorder.

2225 Our bill would expand edibility to medication therapy
2226 management programs for Medicare beneficiaries who are at risk
2227 for prescription drug abuse as determined by the secretary.

2228 I think that this type of service could really help people
2229 understand the drugs they are taking and help foster important
2230 conversations between patients and providers.

2231 Again, I appreciate the work of the committee. I look
2232 forward to seeing this bill move forward.

2233 I want to thank you, Mr. Chairman, and I yield back my time.

2234 The Chairman. Gentleman yields back.

2235 Other members seeking recognition on this legislation?

2236 Seeing none, the question now arises on favorably reporting
2237 H.R. 5684 to the House as amended.

2238 All those in favor -- no, I am sorry -- on favorably reporting
2239 H.R. 5684 to the House.

2240 All those in favor will signify by saying aye.

2241 Those opposed, nay.

2242 The ayes appear to have it. The ayes have it, and H.R. 5684
2243 is approved.

2244 The chair now calls up H.R. 5333. This is number 30 -- number
2245 30 on your list and ask the clerk to report.

2246 The Clerk. H.R. 5333, amend the Federal Food, Drug, and
2247 Cosmetic Act to clarify the regulatory framework with respect

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2248 to certain nonprescription drugs that are marketed without an
2249 approved new drug application and for other purposes. [The
2250 Bill H.R. 5333 follows:]

2251

2252 *****INSERT 26*****

2253 The Chairman. Without objection, the first reading of the
2254 bill is dispensed with and the bill will be open for amendment
2255 at any point. Are there any bipartisan amendments?

2256 Mr. Latta. Mr. Chairman, the bipartisan --

2257 The Chairman. For what purpose the gentleman from Ohio seek
2258 recognition?

2259 Mr. Latta. I have a bipartisan amendment at the desk.

2260 The Chairman. The clerk will report the amendment.

2261 The Clerk. Amendment to H.R. 5333, offered by Mr. Latta.

2262 The Chairman. Without objection, further reading of the
2263 amendment is dispensed with. The chair recognizes the gentleman
2264 from Ohio, Mr. Latta, to speak on the amendment for the next
2265 minutes.

2266 Mr. Latta. Move to strike the last word, Mr. Chairman.

2267 The Chairman. Without objection.

2268 Mr. Latta. Thank you, Mr. Chairman.

2269 My amendment to H.R. 5333 makes technical changes to the
2270 underlying bill to better articulate the true intent of Congress
2271 in modernizing the TOC monograph framework.

2272 These bipartisan changes reflect guidance we received from
2273 stakeholders and technical assistance provided by the FDA.

2274 The amendment also adds a provision from my friend, the
2275 gentlelady from Colorado, Ms. DeGette, that would require GAO
2276 to conduct a study to evaluate the impact of exclusivity on the
2277 OTC markets and consumers.

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2278 And also, Mr. Chairman, I'd ask unanimous consent to submit
2279 for the record a number of letters of support.

2280 The Chairman. Without objection.

2281 [The information follows:]

2282

2283 *****COMMITTEE INSERT 27*****

2284 Mr. Latta. Mr. Chairman, those letters of support come from
2285 the American Academy of Allergy, Asthma, and Immunology, the
2286 American Academy of Pediatrics, the American Public Health
2287 Association, the Consumer Health Care Products Association, the
2288 March of Dimes, the National Association of County and City Health
2289 Officials, the Pew Charitable Trust, the Society for Maternal
2290 Fetal Medicine, GSK Consumer Health Care, and the American Dental
2291 Association.

2292 And those are the letters I'd like to submit, Mr. Chairman.

2293 The Chairman. Yes, without objection.

2294 Mr. Latta. Thank you.

2295 The Chairman. Does the gentleman yield back or is he --
2296 the gentleman yield back the balance of his time?

2297 Mr. Latta. I yield back, Mr. Chairman.

2298 The Chairman. The gentleman yields back.

2299 The chair now recognizes the gentleman from Texas, Mr. Green,
2300 for five minutes to strike the last word.

2301 Mr. Green. Strike the last word and speak in support of
2302 both H.R. 5333, the Over The Counter Monograph Safety Innovation
2303 Reform Act, and also this amendment.

2304 The legislation was carefully drafted over several years
2305 and reflects the hard work of this Congress and the FDA and other
2306 stakeholders.

2307 I particularly want to thank my colleagues in the FDA who
2308 have spent countless hours on this legislation to strike the

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2309 appropriate balance to benefit consumers and provide FDA with
2310 the necessary resources to expedite safety, labeling changes,
2311 and accommodation innovation.

2312 It's important to note that until recently over the country
2313 drugs, which comprise 60 percent of all medicines sold in the
2314 United States, were overseen by only 18 full time employees at
2315 the FDA with a budget of just \$8 million a year.

2316 These user fee programs authorized by this legislation will
2317 enhance the FDA's ability to respond swiftly and effectively to
2318 safety concerns, review OTC ingredient applications in a timely
2319 manner, and encourage sponsors to submit OTC innovations.

2320 I know there is concerns about the length of time including
2321 in this legislation which is an innovative OTC product that would
2322 be on the shelves without store brand competition.

2323 It's important to remember that exclusivity in this
2324 legislation is not the same as exclusivity for new medications.

2325 Consumers will still have the same access to affordable store
2326 brand products.

2327 Additionally, the exclusivity provided under this
2328 legislation, which would just be 18 months -- six months less
2329 than the Senate bill -- I ask everyone in addition to support
2330 the amendment we will be considering.

2331 The amendment will add a GAO study at the recommendation
2332 of Congresswoman DeGette on the effectiveness and overall impact
2333 of exclusivity including its impact on consumer access.

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2334 I want to thank Representative Latta for leading the effort
2335 with me along with Congresswoman DeGette, Dingell, and
2336 Congressman Chair Burgess, and also Congressman Guthrie.

2337 I'd also like to thank Ranking Member Pallone who's been
2338 instrumental in this effort and Chair Walden for his work on this
2339 issue.

2340 And I yield back the balance of my time.

2341 Ms. DeGette. Will you yield to me?

2342 Mr. Green. I'll be glad to yield time to my colleague from
2343 Colorado.

2344 Ms. DeGette. Thank you. Thank you.

2345 I thank the gentleman for yielding and I thank him for his
2346 leadership on this bill. This is a really important piece of
2347 legislation and I know we are moving quickly.

2348 But we need to see why we are doing this bill. In 2015,
2349 the average U.S. household spent \$338 on OTC products like cough
2350 and cold medicine, but they are regulated through an antiquated
2351 40-year monograph system.

2352 This system struggles to effectively keep up with emerging
2353 safety issues, which can cause serious risks for consumers.

2354 For example, in 2006 the FDA learned that common cough
2355 medications tragically cost several toddlers to die. Then the
2356 agency spent a decade trying to update the monograph for cough
2357 medications to warn parents about the health risks.

2358 But the agency was unsuccessful in overcoming the burdensome

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2359 and time-consuming process. So this is really going to be a
2360 wonderful piece of legislation for family safety.

2361 I want to thank the FDA for their technical assistance and
2362 for working on this and I just want to say one thing about this
2363 amendment, which includes my language for a GAO study of the OTC
2364 bill's exclusivity language.

2365 Here's a situation where everybody agrees we need to have
2366 some exclusivity but nobody agrees what the amount should be in
2367 this context.

2368 As Mr. Green said, it's not the same type of exclusivity
2369 that we see with prescription drugs, and when we were having this
2370 debate it became clear to me that nobody really knows exactly
2371 what the number should be.

2372 The Senate bill has 24 months as does this underlying bill.
2373 Mr. Pallone feels quite strongly it should be 12 months and I
2374 know he has an amendment.

2375 And so we sort of compromised at 18 months but we don't even
2376 know if that's the sweet spot to both encourage innovation but
2377 also keep consumer costs low.

2378 And so that's why -- I don't usually like studies but that's
2379 why I suggested this particular GAO study and I am happy that
2380 it's included in the manager's amendment.

2381 I would urge everybody to support this amendment and then
2382 to support the underlying bill. It's really an important piece
2383 of legislation and I hope we can get it through both bodies and

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2384 signed by the president as soon as possible.

2385 With that, I yield back.

2386 Mr. Green. Mr. Chairman, reclaiming my time.

2387 I think this shows what the Energy and Commerce Committee
2388 can do as a whole when you work together across party lines.
2389 We come to compromises and that's why I am so proud of being on
2390 this committee, and I yield back my time.

2391 The Chairman. We appreciate that and that's our goal.
2392 Thank you, and the gentleman yields back the balance of his time.

2393 Are there other members seeking recognition on the
2394 amendment?

2395 If not -- oh, I am sorry. The gentlelady from Michigan is
2396 recognized for five minutes to speak on the amendment.

2397 Mrs. Dingell. Strike the last word.

2398 Mr. Chairman, I am proud to support H.R. 5333, the Over the
2399 County Monograph Safety Innovation and Reform Act and to support
2400 my colleague from Ohio's amendment.

2401 This committee has been focused on reforming the OTC
2402 monograph system for many years, before I ever got here. The work
2403 began with the passage of the Sunscreen Innovation Act in 2014,
2404 legislation which was written in this committee and championed
2405 by somebody I may know and love.

2406 Passage of the OTC bill today finishes the work that a lot
2407 of people have put a lot of blood, sweat, and tears into. As
2408 others have previously noted, the current rulemaking process had

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2409 prevented FDA from many OTC monographs, which is problematic for
2410 many reasons.

2411 Not only does it make it harder for innovative products like
2412 new sunscreens to come to market, but it also makes it nearly
2413 impossible for FDA to amend existing monographs if they see safety
2414 concerns in certain products.

2415 We need to make sure FDA has the ability to act quickly if
2416 they see unsafe products and protect the consumer.

2417 Pure and simple, the current system is broken. It doesn't
2418 work for patients, it doesn't work for companies, it doesn't work
2419 for FDA.

2420 From past experience, we know that user fee programs have
2421 been very successful at FDA and this bill extends that successful
2422 model.

2423 I do know that there has been a lot of discussion about the
2424 exclusivity provisions of this legislation. If it was up to me,
2425 I would lower the number and I will support Ranking Member Pallone
2426 in his efforts to do so.

2427 But, ultimately, it's a compromise, and compromise is a good
2428 word, not a dirty word. I support this legislation as drafted
2429 today with 18 months of exclusivity.

2430 I'll be the first to admit we could continue to make it
2431 better. But as my colleague, Representative Green said, this
2432 committee knows how to work together on balance and it's important
2433 the public health benefits outweigh any other concerns.

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2434 Americans deserve safe products on the market. They deserve
2435 innovative products on the market, and I am proud to say this
2436 legislation accomplishes both -- accomplishes these goals.

2437 I am proud to work with my colleagues Bob Latta, Diana
2438 DeGette, Brett Guthrie, Gene Green, and Dr. Burgess. A lot of
2439 people put a lot of hard work into this.

2440 I thank everybody and the staff for their tireless work on
2441 this. I urge support of this legislation and yield back the
2442 balance of my time.

2443 The Chairman. Gentlelady yields back the balance of her
2444 time.

2445 Other members seeking to speak on the amendment?

2446 Seeing none, we will now take up passage of the amendment.

2447 All those in favor will say aye.

2448 Those opposed, nay.

2449 The ayes appear to have it. The ayes have it. The amendment
2450 is adopted.

2451 Chair recognizes the gentleman from New Jersey for five
2452 minutes.

2453 Mr. Pallone. Thank you, Mr. Chairman.

2454 I move to strike the last word to discuss the underlying
2455 bill.

2456 The Chairman. The gentleman is recognized.

2457 Mr. Pallone. Thank you.

2458 This legislation would reform the current monograph system

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2459 that is used to legally market over-the-counter drugs and would
2460 create a user fee program to provide stable resources for the
2461 Food and Drug Administration to achieve such reform.

2462 And I want to thank Chairman Burgess as well as Ranking Member
2463 Green, Representatives DeGette, Latta, Guthrie, and Dingell for
2464 your work in crafting a proposal that will accomplish these goals.

2465 We have heard from FDA and industry that the current
2466 monograph system is woefully outdated and unwieldy, making it
2467 difficult for the agency to finalize, revise, or update monographs
2468 to reflect innovations or changes in science or to respond to
2469 safety issues.

2470 Industry has also expressed concerns that the current
2471 monograph process does not lend itself well to evolving science
2472 and technology and therefore discourages innovation.

2473 The case for regulatory reform is clear, but it can't be
2474 achieved without stable and reliable funding that reflects the
2475 growth and size of the over-counter industry.

2476 Today, the over-the-counter monograph program oversees more
2477 than 100,000 products with a staff of about 30 people and a budget
2478 of just over \$8 million.

2479 H.R. 5333 establishes an over-the-counter user fee program
2480 that will provide the agency with resources to transition the
2481 monograph program, provide for additional capacity, and enable
2482 innovation and safety changes in the current market.

2483 While I am supportive of monograph reform and the

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2484 establishment of a user fee program, I remain concerned about
2485 the inclusion of an exclusivity award in the bill.

2486 It's been made clear to me that industry sees such an award
2487 as the only way to support providing the agency with the resources
2488 needed to bring this program into the modern era.

2489 The expansion of exclusivity is not something I take lightly.

2490 I've in the past supported exclusivity when I have found that
2491 the current market or regulatory pathway is not working as it
2492 should.

2493 However, this was after the market or current regulatory
2494 pathway demonstrated a failing not before the pathway was even
2495 realized.

2496 To me, the more responsible policy approach would be to
2497 establish the administrative order procedure for
2498 industry-initiated innovation and examine how such a pathway is
2499 working first before considering whether or not to grant
2500 exclusivity.

2501 And I am also disappointed that we are not taking action
2502 today on cosmetics. Millions of Americans use cosmetic products
2503 every day.

2504 Yet, FDA's current regulatory authority in this area has
2505 not been updated for 30 years. In just the last year, millions
2506 of women and children have been exposed shampoos that cause
2507 extraordinary hair loss, lip balm that can cause blistering and
2508 rashes, and eye shimmer and makeup tainted by asbestos.

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2509 Unfortunately, FDA does not have the authority today to hold
2510 these manufacturers responsible and has very little ability to
2511 ensure that cosmetics are safe.

2512 This cannot continue and I hope that when we complete our
2513 work on this issue we can move forward to provide FDA with the
2514 tools and resources needed to oversee the rapidly growing and
2515 evolving cosmetic industry.

2516 We shouldn't stand idly by as American families and children
2517 are exposed to contaminated and tainted personal care products.

2518 But I support the underlying legislation, Mr. Chairman, and
2519 yield back.

2520 The Chairman. The gentleman yields back.

2521 Are there other members seeking recognition on this
2522 legislation?

2523 If not, then the question now --

2524 Mr. Pallone. I have an amendment.

2525 The Chairman. Oh, okay. The gentleman is recognized on
2526 -- for what purpose does the gentleman seek recognition?

2527 Mr. Pallone. I have an amendment at the desk, which I guess
2528 is amendment number one.

2529 The Chairman. The clerk will report the amendment.

2530 The Clerk. The amendment to H.R. 5333 offered by Mr.
2531 Pallone.

2532 The Chairman. Without further -- without objection,
2533 further reading of the amendment is dispensed with. The chair

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2534 recognizes the gentleman from New Jersey, Mr. Pallone, for five
2535 minutes to speak in support of his amendment.

2536 Mr. Pallone. Thank you, Mr. Chairman.

2537 This is an amendment on the exclusivity issue. As I've
2538 mentioned, I've been skeptical since industry first came to me
2539 with this proposal that exclusivity was truly needed or warranted
2540 to incentivize innovation in this market.

2541 It's especially true as the over-the-counter monograph
2542 reform legislation that we are considering today includes for
2543 the first time a pathway by which industry could initiate
2544 innovation for over-the-counter drugs.

2545 I've struggled to support exclusivity in this space, given
2546 the fact that industry has been very open about the fact that
2547 they are demanding exclusivity in exchange for paying user fees.

2548 Since the introduction of the discussion draft, industry
2549 has offered a number of different justifications for exclusivity
2550 such as negotiations with retailers may be lengthy, private label
2551 competition could begin right after an innovative product is
2552 launched, industry needs time to recoup their investment into
2553 innovation, or the most recent, industry needs time to build
2554 inventory.

2555 In no other user fee legislation was the user fee program
2556 created simultaneously with the award of exclusivity.

2557 In fact, exclusivity has only ever been contemplated when
2558 there has been evidence that the current marketplace was not

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2559 working as intended to incentivize the innovation.

2560 This was true when Congress extended six months of
2561 exclusivity to manufacturers that conduct pediatric studies and,
2562 more recently, when Congress extended six months of exclusivity
2563 to generic manufacturers that develop a competitor to current
2564 sole source drug products.

2565 But the current over-the-counter monograph reform
2566 legislation abandons this precedent and would award 18 months
2567 of exclusivity before even knowing if the industry-initiated
2568 innovation pathway works.

2569 And I am concerned about this precedent. I am concerned
2570 about awarding an arbitrary period of exclusivity for a category
2571 of products without a compelling justification.

2572 While I've supported incentives in the past to encourage
2573 certain development and innovation, it's been after a compelling
2574 case has been made that the current marketplace and regulatory
2575 pathways were not working.

2576 In considering such proposals, I've also always wanted to
2577 ensure that the incentives would not burden or impede access to
2578 the medications patients rely on and I do not believe that the
2579 proposal before us today meets this careful balance.

2580 I do, however, recognize that many members on both sides
2581 of the aisle feel that some exclusivity should be awarded to
2582 incentivize manufacturers to innovate and allow for the
2583 manufacture to recover the cost of development.

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2584 Therefore, I would urge my colleagues to support this
2585 amendment, which would offer over-the-counter drugs 12 months
2586 of exclusivity from the time the manufacturer begins commercially
2587 marketing the product.

2588 I believe this time period will give industry the head start
2589 they have asked for from private label competition and provide
2590 time for the manufacturer to begin to recoup the costs of their
2591 development.

2592 It also ensures that patient access to innovative
2593 over-the-counter drugs will not be unnecessarily delayed. So
2594 I would urge my colleagues to vote in support of the amendment
2595 and after further discussion would ask for a roll call on this,
2596 Mr. Chairman.

2597 The Chairman. Gentleman yield back?

2598 Mr. Pallone. Yes.

2599 The Chairman. Gentleman yields back the balance of his
2600 time.

2601 The chair recognizes the gentleman from Ohio, Mr. Latta,
2602 to speak on the amendment for five minutes.

2603 Mr. Latta. Well, thank you very much, Mr. Chairman.

2604 I move to speak in opposition to the amendment. It's always
2605 been pointed out by several members of the committee that there
2606 has been bipartisan work done on this legislation -- that we worked
2607 the compromise out to change that time frame from 24 to 18 months,
2608 I'd also like to point out that just this past April the Senate

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2609 Health Education Labor and Pensions Committee, by a vote of 22
2610 to 1, reported out the S. 2315 out of that committee that includes
2611 language for 24 months from the effective date.

2612 And I think it's important to point that out that, you know,
2613 we have been working in this committee in a bipartisan way and
2614 I believe that that 18 months is a good date.

2615 I think it's also important to point out that that proper
2616 incentive is important for innovation since most product launches
2617 fail and it takes a year or more to develop awareness and
2618 acceptance.

2619 That new launch needs that corner of the shelf to get started
2620 and I think, Mr. Chairman, it's very important that, as I said,
2621 with that agreement that we have had, moving from 24 to 18, and
2622 I again ask a defeat of that motion, and I yield back.

2623 Mr. Burgess. Will the gentleman yield?

2624 Mr. Latta. I yield to the chairman.

2625 Mr. Burgess. And I just wanted to add to what Chairman Latta
2626 just has pointed out. This, the bill that's before us today
2627 without the amendment, is the product of significant compromise,
2628 significant work on the part of the members and part of the staff.

2629 It is a good compromise. Reducing the period of exclusivity
2630 down to 12 months I think would jeopardize a good product. I
2631 see no need for the amendment and I would encourage a no vote.

2632 The Chairman. Gentleman yields back.

2633 Other members seeking recognition?

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2634 The chair recognizes the gentlelady from Illinois for five
2635 minutes to strike the last word on the amendment.

2636 Ms. Schakowsky. Thank you.

2637 I just want to go on record as opposing the 18-month
2638 exclusivity. In our subcommittee markup, I offered an amendment
2639 that would provide no exclusivity for over-the-counter drugs.

2640 In my view, all that exclusivity does is weaken completion
2641 and raise prices for consumers. Americans rely on affordable
2642 over-the-counter drugs. They account for 60 percent of our
2643 medicines on the market, and whether they are treatments for cold
2644 symptoms, headaches, stomach ailments, affordable and accessible
2645 over-the-counter drugs are essential for the health of Americans.

2646 The average U.S. consumer makes 26 trips per year to purchase
2647 over-the-counter drug products and they average household spends
2648 \$338 per year on these products.

2649 In the underlying bill a drug company could get 18 months
2650 of exclusivity for another over-the-counter drug that is no better
2651 than an older medicine, all by introducing a new delivery
2652 formulation.

2653 This could mean taking a tablet and making it into a gummy
2654 or a dissolvable strip and then shooting up the price. Drug
2655 companies could then stop selling their older over-the-counter
2656 version and only sell the higher price exclusive version.

2657 There would be no opportunity for a generic to enter the
2658 market for this new delivery formulation for 18 months.

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2659 Some claim that drug makers would only raise prices a few
2660 dollars for these new products. But, given exclusivity, there
2661 is no way to ensure that prices would be kept low.

2662 And even if that were true, it may not sound like a lot.

2663 But for the over 25 million American seniors who are economically
2664 insecure, a few dollars might mean the difference between getting
2665 the pain relief that works for them or going without.

2666 More and more, prescription drugs are switching over to --
2667 are switching to over-the-counter at the end of their prescription
2668 exclusivity. We can't let the over-the-counter process be
2669 another way for drug companies to game the system.

2670 This long 18-month exclusivity period is a handout to
2671 pharmaceutical companies. Extensive exclusivity periods have
2672 skyrocketed prescription drug prices and it is foolish to allow
2673 these monopolies to multiply in the over-the-counter market
2674 sector.

2675 If we truly want to help Americans with more access to
2676 medicines, we should focus on lowering prescription drug prices
2677 and consider my bill.

2678 I have legislation, Improving Access to Affordable
2679 Prescription Drug Act, that would allow Medicare to negotiate
2680 for lower drug prices in Part D, allow for importation of safe
2681 prescription drugs, and reduce monopolies for brand name drugs,
2682 and help generic competition come to marketplace.

2683 I yield back.

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2684 The Chairman. Time is expired.

2685 Any other member seeking recognition?

2686 If not, the vote now arises on the Pallone amendment.

2687 Those in favor, vote aye.

2688 Those no, and the clerk will call the roll.

2689 The Clerk. Mr. Barton.

2690 Mr. Barton. No.

2691 The Clerk. Mr. Barton votes no.

2692 Mr. Upton.

2693 Mr. Upton. No.

2694 The Clerk. Mr. Upton votes no.

2695 Mr. Shimkus.

2696 Mr. Shimkus. No.

2697 The Clerk. Mr. Shimkus votes no.

2698 Mr. Burgess.

2699 Mr. Burgess. No.

2700 The Clerk. Mr. Burgess votes no.

2701 Mrs. Blackburn.

2702 Mrs. Blackburn. No.

2703 The Clerk. Mrs. Blackburn votes no.

2704 Mr. Scalise.

2705 [No response.]

2706 Mr. Latta.

2707 Mr. Latta. No.

2708 The Clerk. Mr. Latta votes no.

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2709 Mrs. McMorris Rodgers.
2710 Mrs. McMorris Rodgers. No.
2711 The Clerk. Mrs. McMorris Rodgers votes no.
2712 Mr. Harper.
2713 Mr. Harper. No.
2714 The Clerk. Mr. Harper votes no.
2715 Mr. Lance.
2716 Mr. Lance. No.
2717 The Clerk. Mr. Lance votes no.
2718 Mr. Guthrie.
2719 Mr. Guthrie. No.
2720 The Clerk. Mr. Guthrie votes no.
2721 Mr. Olson.
2722 Mr. Olson. No.
2723 The Clerk. Mr. Olson votes no.
2724 Mr. McKinley.
2725 Mr. McKinley. No.
2726 The Clerk. Mr. McKinley votes no.
2727 Mr. Kinzinger.
2728 Mr. Kinzinger. No.
2729 The Clerk. Mr. Kinzinger votes no.
2730 Mr. Griffith.
2731 Mr. Griffith. No.
2732 The Clerk. Mr. Griffith votes no.
2733 Mr. Bilirakis.

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2734 Mr. Bilirakis. No.

2735 The Clerk. Mr. Bilirakis votes no.

2736 Mr. Johnson.

2737 Mr. Johnson. No.

2738 The Clerk. Mr. Johnson votes no.

2739 Mr. Long.

2740 Mr. Long. No.

2741 The Clerk. Mr. Long votes no.

2742 Mr. Bucshon.

2743 Mr. Bucshon. No.

2744 The Clerk. Mr. Bucshon votes no.

2745 Mr. Flores.

2746 Mr. Flores. No.

2747 The Clerk. Mr. Flores votes no.

2748 Mrs. Brooks.

2749 Mrs. Brooks. No.

2750 The Clerk. Mrs. Brooks votes no.

2751 Mr. Mullin.

2752 Mr. Mullin. No.

2753 The Clerk. Mr. Mullin votes no.

2754 Mr. Hudson.

2755 [No response.]

2756 Mr. Collins.

2757 Mr. Collins. No.

2758 The Clerk. Mr. Collins votes no.

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2759 Mr. Cramer.

2760 Mr. Cramer. No.

2761 The Clerk. Mr. Cramer votes no.

2762 Mr. Walberg.

2763 Mr. Walberg. No.

2764 The Clerk. Mr. Walberg votes no.

2765 Mrs. Walters.

2766 Mrs. Walters. No.

2767 The Clerk. Mrs. Walters votes no.

2768 Mr. Costello.

2769 Mr. Costello. No.

2770 The Clerk. Mr. Costello votes no.

2771 Mr. Carter.

2772 Mr. Carter. No.

2773 The Clerk. Mr. Carter votes no.

2774 Mr. Duncan.

2775 Mr. Duncan. No.

2776 The Clerk. Mr. Duncan votes no.

2777 Mr. Pallone.

2778 Mr. Pallone. Aye.

2779 The Clerk. Mr. Pallone votes aye.

2780 Mr. Rush.

2781 Mr. Rush. Aye.

2782 The Clerk. Mr. Rush votes aye.

2783 Ms. Eshoo.

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2784 Ms. Eshoo. Aye.
2785 The Clerk. Ms. Eshoo votes aye.
2786 Mr. Engel.
2787 Mr. Engel. Aye.
2788 The Clerk. Mr. Engel votes aye.
2789 Mr. Green.
2790 Mr. Green. Aye.
2791 The Clerk. Mr. Green votes aye.
2792 Ms. DeGette.
2793 Ms. DeGette. Aye.
2794 The Clerk. Ms. DeGette votes aye.
2795 Mr. Doyle.
2796 Mr. Doyle. Aye.
2797 The Clerk. Mr. Doyle votes aye.
2798 Ms. Schakowsky.
2799 Ms. Schakowsky. Aye.
2800 The Clerk. Ms. Schakowsky votes aye.
2801 Mr. Butterfield.
2802 Mr. Butterfield. Aye.
2803 The Clerk. Mr. Butterfield votes aye.
2804 Ms. Matsui.
2805 Ms. Matsui. Aye.
2806 The Clerk. Ms. Matsui votes aye.
2807 Ms. Castor.
2808 Ms. Castor. Aye.

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2809 The Clerk. Ms. Castor votes aye.
2810 Mr. Sarbanes.
2811 Mr. Sarbanes. Aye.
2812 The Clerk. Mr. Sarbanes votes aye.
2813 Mr. McNerney.
2814 Mr. McNerney. Aye.
2815 The Clerk. Mr. McNerney votes aye.
2816 Mr. Welch.
2817 Mr. Welch. Aye.
2818 The Clerk. Mr. Welch votes aye.
2819 Mr. Lujan.
2820 Mr. Lujan. Aye.
2821 The Clerk. Mr. Lujan votes aye.
2822 Mr. Tonko.
2823 Mr. Tonko. Aye.
2824 The Clerk. Mr. Tonko votes aye.
2825 Ms. Clarke.
2826 Ms. Clarke. Aye.
2827 The Clerk. Ms. Clarke votes aye.
2828 Mr. Loeb sack.
2829 Mr. Loeb sack. Aye.
2830 The Clerk. Mr. Loeb sack votes aye.
2831 Mr. Schrader.
2832 Mr. Schrader. Aye.
2833 The Clerk. Mr. Schrader votes aye.

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2834 Mr. Kennedy.

2835 Mr. Kennedy. Aye.

2836 The Clerk. Mr. Kennedy votes aye.

2837 Mr. Cardenas.

2838 Mr. Cardenas. Aye.

2839 The Clerk. Mr. Cardenas votes aye.

2840 Mr. Ruiz.

2841 Mr. Ruiz. Aye.

2842 The Clerk. Mr. Ruiz votes aye.

2843 Mr. Peters.

2844 [No response.]

2845 Mrs. Dingell.

2846 Mrs. Dingell. Aye.

2847 The Clerk. Mrs. Dingell votes aye.

2848 Mr. Hudson.

2849 Mr. Hudson. No.

2850 The Clerk. Mr. Hudson votes no.

2851 Mr. Peters.

2852 Mr. Peters. Aye.

2853 The Clerk. Mr. Peters votes aye.

2854 Chairman Walden.

2855 The Chairman. I'd like to vote no.

2856 The Clerk. Chairman Walden votes no.

2857 The Chairman. Thank you.

2858 Are there other members who have not been recorded?

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2859 Other members have not been recorded? Who's on your list
2860 there that hasn't been recorded?

2861 The Clerk. Mr. Scalise.

2862 The Chairman. Mr. Scalise is not here. Mr. -- anyone else?
2863 Mr. Peter is recorded? Yes. Okay.

2864 All right. The clerk the will report the result.

2865 The Clerk. Mr. Chairman, on that vote, there were 30 noes
2866 and 24 ayes.

2867 The Chairman. Thirty noes, 24 ayes. The amendment is not
2868 adopted. Are there any other amendments to this legislation?
2869 Are there any other members wishing to speak on this bipartisan
2870 legislation?

2871 If not, the question now occurs on favorably reporting H.R.
2872 5333 as amended, right, to the House.

2873 All those in favor shall signify by saying aye.

2874 Those opposed, nay.

2875 The ayes have it, and the bill is favorably reported.

2876 The chair calls up H.R. 5473. This is number 31 on the list
2877 and ask the clerk to report.

2878 The Clerk. H.R. 5473, to direct the secretary of Health
2879 and Human Services to update or issue one or more guidances
2880 addressing alternative methods for data collection on opioids
2881 barring an inclusion of such data in product labeling and for
2882 other purposes. [The Bill H.R. 5473 follows:]

2883

*****INSERT 28*****

2885 The Chairman. Without objection, the first reading of the
2886 bill is dispensed with. The bill will be open for amendment at
2887 any point.

2888 Are there any bipartisan amendments to this bill?

2889 Are there any amendments to this bill?

2890 Does anyone wish to strike the last word on this bill?

2891 Dr. Burgess, recognized for five minutes, to strike the last
2892 word.

2893 Mr. Burgess. Thank you, Mr. Chairman, and appreciate your
2894 recognition for striking the last word.

2895 I do want to speak in favor of this bill and I want to commend
2896 the authors, Representative Comstock and Representative Lujan,
2897 for their bipartisan work on this policy.

2898 This bill would take steps to facilitate the development
2899 of products that reduce, replace, or prevent the use of opioids.

2900 Specifically, this legislation will direct the Food and Drug
2901 Administration to hold a public meeting and update the agency's
2902 guidance on opioid-sparing data that can be used to support
2903 updated product labeling and claims.

2904 For many Americans dealing with chronic or acute pain, there
2905 are limited alternatives. But for some patients, there may be
2906 therapeutic alternatives which do not share the same risks
2907 inherent in the use of an opiate.

2908 This bill will facilitate the process of getting information
2909 to providers and patients at a critical juncture in their

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2910 treatment. By reducing the need to start an opiate we can stop
2911 addiction before it starts and save lives in the process.

2912 I, again, want to commend Representative Comstock and
2913 Representative Lujan for working on this and I urge members of
2914 the committee to vote in favor of this narrowly tailored common
2915 sense noncontroversial measure.

2916 I yield back.

2917 The Chairman. And the gentleman yields back.

2918 Any other members seeking recognition?

2919 The chair recognizes the gentleman from New Mexico, Mr.
2920 Lujan, for five minutes to strike the last word.

2921 I don't believe your microphone is on and we want to hear
2922 what you have to say.

2923 Mr. Lujan. There we go. Thank you, Mr. Chairman. I
2924 appreciate that.

2925 We must work with our FDA partners and with our
2926 pharmaceutical researchers and developers to make sure that
2927 patients across the country have nonaddictive pain management
2928 options.

2929 I come from a blue-collar district with iron workers and
2930 ranchers, and a whole lot of people where wear and tear on their
2931 bodies is inevitable.

2932 It's simply unrealistic to think that we won't have people
2933 who need access to pain management options. That's where
2934 nonaddictive therapies come in. This bill is another step

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2935 forward in making sure that everyone has more options to treat
2936 pain.

2937 While we are talking about nonaddictive pain medications
2938 and how important they are to break the cycle of addiction back
2939 home, I want to take a second to direct my comments towards all
2940 of the pharmaceutical manufacturers who are developing or
2941 planning to develop drugs in this space.

2942 This is important. We all need these innovative
2943 technologies and we all are grateful for your investment in these
2944 drugs.

2945 That being said, I am already starting to be concerned
2946 regarding the cost of these drugs. I am worried that families
2947 struggling to make ends meet will be left struggling with
2948 addiction to opioids.

2949 People that need these treatments should not be turned away.
2950 That's why all nonaddictive pain medications must be affordable,
2951 accessible, and high quality.

2952 I look forward to working with stakeholders on these issues
2953 and appreciate the committee for passing my bill, which will help
2954 get nonopioids to market sooner and with better data.

2955 And with that, Mr. Chairman, I yield back.

2956 The Chairman. Gentleman yields back.

2957 Other members seeking recognition on this legislation?

2958 Seeing none, the question now occurs on favorably reporting
2959 H.R. 5473 to the House.

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2960 All those in favor will signify saying aye.

2961 Those opposed, nay.

2962 The ayes have it and H.R. 5473 is favorably reported to the
2963 House.

2964 The chair now calls up H.R. 5554, so this would be number
2965 32 as forwarded by the Subcommittee on Health on April 25th, 2018.

2966 I ask the clerk to report.

2967 The Clerk. H.R. 5554, the amend the Federal Food, Drug,
2968 and Cosmetic Act to reauthorize user fee programs relating to
2969 new animal drugs and generic new animal drugs. [The Bill
2970 H.R. 5554 follows:]

2971

2972 *****INSERT 29*****

2973 The Chairman. Without objection, the first reading of this
2974 bill is dispensed with. The bill will be open for amendment at
2975 any point.

2976 Are there any bipartisan amendments to this bill?

2977 Mr. Hudson. Mr. Chairman.

2978 The Chairman. Mr. Hudson is recognized for what purpose?

2979 Mr. Hudson. Thank you, Mr. Chairman. I have an amendment.

2980 The Chairman. The clerk will report the amendment.

2981 The Clerk. Amendment to H.R. 5554, offered by Mr. Hudson.

2982 The Chairman. Without objection, further reading of the
2983 amendment is dispensed with. The chair recognizes the gentleman
2984 from North Carolina, Mr. Hudson, to speak on his amendment for
2985 five minutes.

2986 Mr. Hudson. Thank you, Mr. Chairman.

2987 First, I'd like to speak in favor of the underlying bill
2988 and thank you my colleagues, Representative Markwayne Mullin and
2989 Representative Kurt Schrader for their leadership on this bill.

2990 The reauthorization of these user fees is critical to the
2991 timely approval of animal drugs and I applaud their work to put
2992 together a great bill.

2993 Further, I'd like to offer a bipartisan amendment with
2994 Representative Schrader, Bucshon, Butterfield, Mullin, and
2995 Pallone to expand conditional approval to include major uses major
2996 species.

2997 Right now, there are numerous unmet medical needs in

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2998 veterinary medicine due to the complexity of providing clinical
2999 efficacy.

3000 We need to give drug developers the tools they need to deliver
3001 these drugs to pet owners, farmers, and veterinarians who need
3002 them to save their animals.

3003 I'd also like to yield -- actually, I'd like to ask Mr.
3004 Chairman if I could submit letters to the record that come from
3005 29 different organizations that support this expanded conditional
3006 approval.

3007 The Chairman. Without objection, so ordered.

3008 [The information follows:]

3009

3010 *****COMMITTEE INSERT 30*****

3011 Mr. Hudson. Thank you, Mr. Chairman. And with that, I'd
3012 like to yield the balance of my time to my good friend from North
3013 Carolina, Mr. Butterfield.

3014 The Chairman. Gentleman from North Carolina is recognized.
3015 I don't know -- is Mr. Butterfield here? Not at the moment,
3016 Mr. Hudson. So --

3017 Mr. Hudson. Well, if no one else -- one of the co-sponsors
3018 would like to speak, I would --

3019 Mr. Green. Would the gentleman yield?

3020 Mr. Hudson. Yes. I would be happy to yield.

3021 The Chairman. To Mr. Green?

3022 Mr. Hudson. Mr. Green. Yes, Mr. Chairman.

3023 Mr. Green. Thank you.

3024 I want to speak in support of both H.R. 5554 and this
3025 amendment -- the Animal Drug and Animal Generic Drug User Fee
3026 Amendments of 2018.

3027 I am proud to be a co-sponsor of this legislation that would
3028 reauthorize ADUFA and AGDUFA programs. This bill represents
3029 extensive negotiations between FDA and the animal health
3030 industry.

3031 It's necessary to reauthorize ADUFA and AGDUFA to ensure
3032 that there is no lapse in resources for the FDA to approve animal
3033 drugs in a timely manner.

3034 ADUFA and AGDUFA help FDA to streamline their approval
3035 process for animal drug applications in order for innovative and

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3036 lifesaving drugs to reach the market in a more predictable time
3037 line.

3038 We want our pets to have the best treatment options available
3039 and we want our food producing animals to be as healthy as
3040 possible.

3041 ADUFA and AGDUFA further both these goals. This legislation
3042 passed by the Health Subcommittee by voice vote two weeks ago
3043 with strong bipartisan support.

3044 I support the amendment expansion with conditional approval
3045 to medications for major species and major uses and I urge my
3046 colleagues to support this amendment and the bill.

3047 And I thank my colleague for yielding to me.

3048 Mr. Hudson. Reclaiming my time. If there are any other
3049 co-sponsors who would to speak in favor I'd be happy to yield.

3050

3051 The Chairman. Do you want your own time, Mr. Schrader?
3052 Okay.

3053 Mr. Butterfield is here. Mr. Butterfield, I think Mr.
3054 Hudson would like to yield the remainder of this time to you as
3055 a colleague from North Carolina as you get settled in there.

3056 Mr. Butterfield. Thank you, Mr. Chairman. I am here with
3057 my banana. I went back to the office to get it. Didn't realize
3058 this would go so quickly.

3059 But thank you, Mr. Chairman. Thank you for marking up this
3060 important Animal Drug User Fee Act and the Animal Generic Drug

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3061 User Fee Act legislation.

3062 These fee agreements are important to millions of North
3063 Carolinians living with companion animals. They are also
3064 important to the agricultural community.

3065 Some of you may not be aware that North Carolina is the second
3066 largest pork producer in the country, the second largest turkey
3067 producer, and the third largest poultry producer in the country.

3068 Our agricultural community and family farms are essential
3069 to feeding our nation. They depend on medicines to keep animals
3070 healthy.

3071 And so I rise in support of an amendment that I've worked
3072 with my friend, Mr. Hudson, to allow for expanded authority for
3073 conditional approval of medicines for animals.

3074 Under current law, the FDA already has some authority to
3075 allow some medicines for animals to receive conditional approval.

3076 This amendment reflects agreement between the FDA and industry
3077 on improving the pathway for animal medicine while still ensuring
3078 safety requirements.

3079 This amendment, Mr. Chairman, also includes protections to
3080 address concerns with antibiotics. And so I urge my colleagues
3081 to support and I thank you, Mr. Hudson, and I yield back.

3082 The Chairman. Gentleman yields back.

3083 Mr. Hudson.

3084 Mr. Hudson. Mr. Chairman, I yield back.

3085 The Chairman. The gentleman yields back.

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3086 Are there other members seeking recognition?

3087 The chair recognizes the gentleman from New Jersey, Mr.
3088 Pallone, for five minutes to strike the last word.

3089 Mr. Pallone. Thank you, Mr. Chairman, and I am speaking
3090 support of the amendment offered by Mr. Hudson and Mr. Butterfield
3091 and also thank them for incorporating my amendment as well.

3092 As I noted during the subcommittee markup two weeks ago,
3093 I have both procedural and policy concerns regarding expanding
3094 conditional approval for new animal drugs in certain cases for
3095 major uses in major species.

3096 However, at this time, many of those concerns have been
3097 addressed through the amendment we are considering.

3098 Currently, FDA has the authority to conditionally approve
3099 certain new animal drugs for minor uses or minor species for up
3100 to five years while manufacturers continue to demonstrate
3101 effectiveness.

3102 This amendment would expand this conditional approval
3103 pathway to major uses or for major species, given certain
3104 criteria.

3105 This represents a significant policy change in FDA's review
3106 and approval of new animal drugs, and I strongly believe that
3107 this policy must have guardrails in place to ensure FDA can
3108 effectively implement these changes while continuing to protect
3109 companion and food-producing animals.

3110 And for this reason, I am pleased that the amendment provides

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3111 specific dates by which FDA must issue guidance on the parameters
3112 for utilizing conditional approval for major uses and major
3113 species.

3114 Additionally, I remain very concerned about the threat of
3115 antibiotic resistance and the use of antibiotics in
3116 food-producing animals.

3117 Therefore, I am pleased that this amendment language
3118 excludes anti-microbials from the expanding conditional approval
3119 pathway. I share the view of my colleagues that our companion
3120 animals and food-producing animals are best served when they can
3121 access new and innovative treatments to protect their health and
3122 to protect human health as well.

3123 I appreciate that we have been able to reach consensus on
3124 a bipartisan basis to move forward with this amendment as well
3125 as my amendment concerning veterinary oversight for certain
3126 anti-microbials.

3127 The public health crisis resulting from anti-microbial
3128 resistance has received bipartisan concern and interest.
3129 According to the CDC, each year in the United States at least
3130 2 million people become infected with bacteria that are
3131 antibiotic-resistant and at least 23,000 people die each year
3132 as a result of these infections.

3133 Further, there is some evidence that some antibiotic
3134 resistance in bacteria is caused by antibiotic use in food animals
3135 raised for human consumption.

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3136 To that end, FDA has taken steps to increase oversight and
3137 transparency related to the use of anti-microbials in
3138 food-producing animals.

3139 FDA first published guidance in 2013 to bring the use of
3140 medically important anti-microbials in food-producing animals
3141 under veterinary oversight in order to limit or reverse resistance
3142 that has resulted from the overuse of antibiotics in animals.

3143 And since January of last year, all medically important
3144 anti-microbials used in feed or water for food animals are now
3145 under veterinary oversight.

3146 While anti-microbials administered in feed and water
3147 represent the majority of antibiotics sold and distributed for
3148 food animals, one gap in such oversight is medically important
3149 antibiotics administered in other dosage forms such as
3150 injectables or tablets.

3151 The amendment offered by Mr. Hudson and Mr. Butterfield
3152 incorporates language that is consistent with this recommendation
3153 by GAO and would require the FDA to submit a report to Congress
3154 by the end of fiscal year 2019 regarding how the agency intends
3155 to bring all medically important anti-microbial drugs intended
3156 for use in animals under veterinary oversight, including having
3157 them labeled to require that their use by -- under the professional
3158 supervision of licensed veterinarians, and this will build off
3159 of the work FDA has already done to encourage the judicious use
3160 of medically important anti-microbials and will ensure critical

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3161 oversight in their use in animals.

3162 So I look forward to moving the underlying legislation to
3163 the floor promptly and yield back, Mr. Chairman.

3164 The Chairman. Gentleman yields back.

3165 Other members seeking recognition on this legislation?

3166 The gentleman from Oregon, Mr. Schrader -- Dr. Schrader is
3167 recognized, my resident veterinarian.

3168 Mr. Schrader. Thank you, Mr. Chairman. Yes, I appreciate
3169 that. Appreciate that, particularly as a veterinarian, to see
3170 this bipartisan legislation come to the floor and particularly
3171 this amendment.

3172 I really commend Mr. Hudson working with his team and
3173 barnyard group and companion animal group veterinarians overtime
3174 to make sure we could get this to the floor in the best possible
3175 manner, and I think it's a good thing.

3176 It's a good thing. This will expand conditional approval
3177 for animal drugs for major uses in major species that holds the
3178 potential to expand a lot of opportunities for drugs to meet very
3179 specific requirements to fill unmet medical needs in the
3180 veterinary world.

3181 As a veterinarian, I am acutely aware of a lot of the great
3182 innovations that occur in the human pharmaceutical world that
3183 are unavailable for long periods of time to veterinarians and
3184 the animals.

3185 They just don't have the bandwidth to engage the

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3186 pharmaceutical industry to develop these drugs. So the
3187 conditional use process is critical to gain access to these things
3188 under very specific criteria to make sure our four-footed friends
3189 have some of the greatest and latest innovations that our human
3190 folks do.

3191 And I'd emphasize that under this conditional use process
3192 there has to be a reasonable expectation of effectiveness. The
3193 design has to be very difficult for a pharmaceutical firm to
3194 develop.

3195 It'd still have to have good studies, efficacy, and make
3196 sure that there is, you know, effectiveness over this five-year
3197 span and I'd emphasize there is a five-year span by which this
3198 drug has got to be made available through all the processes that
3199 FDA has or it goes away.

3200 So it's a very tight process. The goal here is just to make
3201 sure that folks have an opportunity in the veterinary world and
3202 the animal industry world to have access to some of these great
3203 drugs.

3204 Both ADUFA and AGDUFA build a unique and safe process for
3205 innovation, for new animal pharmaceuticals. This conditional
3206 use expands that in a very appropriate way, very careful way.

3207 I think all this is great for the -- for the veterinary
3208 community, the companion animal community, livestock owners and
3209 producers and, of course, animals themselves.

3210 Not sure I agree with our ranking member who I really

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3211 appreciate working with on this with regard to the anti-microbial
3212 concerns at least to the degree. But I think it's a very good
3213 idea to bring anti-microbial administration under veterinary
3214 supervision in one form or another. I do concur with that.

3215 So, again, I thank everybody for all their extremely hard
3216 work. I'd also urge support for the underlying bill, H.R. 5554,
3217 sponsored by myself and Representative Mullin.

3218 He brings a valuable livestock expertise to the legislation.
3219 I just wanted to emphasize that, based on our subcommittee
3220 hearings to make sure that was clarified.

3221 So I thank you and I yield back the balance of my time.

3222 The Chairman. The gentleman yields back the balance of his
3223 time and for those who want to see how AGDUFA -- what it means
3224 to animals, I would direct your attention to Ted Walks AGDUFA.

3225

3226 If you just Google that you'll find a little video our team
3227 put together with our new office dog and Ted walks us through
3228 how this -- he knows dog. He doesn't know English yet. So it's
3229 Ted Walks, not a Ted Talks.

3230 But anyway, you want to learn. You know, just trying to
3231 help communicate how a bill becomes law. Ted Walks AGDUFA. Ted
3232 Walks AGDUFA. Go there now. Be the first on your neighborhood.

3233 Are there other members seeking recognition? If -- oh, Mr.
3234 Mullin is recognized for five minutes to speak on legislation.

3235 Mr. Mullin. Thank you, Mr. Chairman, and I'd like to thank

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3236 our only veterinarian on the committee, Mr. Schrader, for his
3237 valuable into the bill and I do agree with his statement about
3238 the antibiotics.

3239 As a rancher, someone how has a lot of cattle at home, the
3240 difficulties that it causes but at the same time ADUFA is very
3241 important and it's wonderful to see us working in a bipartisan
3242 bill.

3243 I'd like to point out I've never seen a perfect bill come
3244 out of Congress, but it's part of negotiating, and when we can
3245 come together on a bipartisan approach, something that the
3246 industry has been doing for quite a while now, it is -- it shows
3247 that we can still work together.

3248 So thank you for everybody that's worked on this bill and
3249 thank you for my colleague from North Carolina, Mr. Hudson, for
3250 the amendment and making it stronger and being able to work with
3251 us.

3252 I do encourage everybody to support this amendment and the
3253 underlying bill. With that, Mr. Chairman, I yield back.

3254 The Chairman. Gentleman yields back.

3255 Are there other members seeking to speak on the amendment?

3256 If not, the question now arises on the Hudson amendment.

3257 Those in favor will say aye.

3258 Those opposed, no.

3259 The ayes appear to have it. The ayes have it. The amendment
3260 is adopted.

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3261 Are there any other amendments?

3262 Seeing none, no one else seeking -- oh, I am sorry. The
3263 gentlelady from Illinois, for what purpose do you seek
3264 recognition?

3265 Ms. Schakowsky. Thank you, Mr. Chairman.

3266 I offer this amendment with the intent to --

3267 The Chairman. Let's call it up.

3268 Ms. Schakowsky. Oh, I am sorry. I have an amendment at
3269 the desk.

3270 The Chairman. Thank you. The clerk will report the
3271 amendment.

3272 The Clerk. The amendment to H.R. 5554, offered by Ms.
3273 Schakowsky.

3274 Mr. Barton. Mr. Chairman?

3275 The Chairman. Yes.

3276 Mr. Barton. I'd like to reserve a point of order against
3277 this amendment.

3278 The Chairman. Mr. Barton reserves a point of order against
3279 the amendment.

3280 The gentlelady from Illinois is recognized for five minutes
3281 to speak on her amendment.

3282 Ms. Schakowsky. Thank you, Mr. Chairman.

3283 I offer this amendment with the intent to withdraw it. But
3284 it would direct the Food and Drug Administration to work with
3285 those making animal drugs and how we could implement duration

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3286 limits on the use of medically-important anti-microbial agents.

3287

3288 The development of anti-microbial agents is one of the most
3289 successful medical developments. Before them, a paper cut could
3290 kill.

3291 I do want to thank the bipartisan work of this committee
3292 and thank particularly Mr. Pallone, Mr. Schrader, Mr.
3293 Butterfield, Mr. Hudson, Mr. Mullin, and the majority who worked
3294 on a package exempting medically important anti-microbials for
3295 major food-producing animals from conditional approval.

3296 This is a great first step. But I think we need to do more
3297 to address anti-microbial resistance. As we have seen in
3298 increased use and misuse especially of antibiotics, the bacteria
3299 have evolved to be resistant.

3300 This means more and more bacteria cannot be killed with
3301 traditional antibiotics, making antibiotics less effective.

3302 I wanted to say this on behalf of my friend, the late --
3303 unfortunately, late Representative Louise Slaughter, who was a
3304 champion on this issue for many decades.

3305 And she stated, quote, "Antibiotic resistance threatens
3306 modern medicine. The scale and potential harm to public health
3307 from this crisis are almost unimaginable," unquote.

3308 More than 80 percent of the antibiotics used in this country
3309 are used on healthy farm animals. So what my legislation would
3310 do would help safeguard the anti-microbials that we have in over

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3311 -- and protect against its overuse in food production.

3312 So all this amendment does, as I said, which I withdraw,
3313 but would have a study -- have the FDA work with those that already
3314 make those animal drugs to see if we could implement duration
3315 limits saying how long you could use the particular drugs, which
3316 are -- which we know are medically important.

3317 So I will withdraw my amendment.

3318 The Chairman. The gentlelady withdraws her amendment. Are
3319 there other members seeking recognition on this legislation?

3320 If not, then the question arises to favorably report H.R.
3321 5554 as amended to the House.

3322 All those in favor will signify by saying aye.

3323 Those opposed, no.

3324 The ayes have it and the bill is favorably reported.

3325 The chair now calls up H.R. 5687. This would be 33 -- number
3326 33 on your list -- and ask the clerk to report.

3327 The Clerk. H.R. 5687, to amend the Federal Food, Drug, and
3328 Cosmetic Act to require improved packaging and disposal methods
3329 with respect to certain drugs and for other purposes. [The
3330 Bill H.R. 5687 follows:]

3331

3332 *****INSERT 31*****

3333 The Chairman. Without objection, the first reading of the
3334 bill is dispensed with. The bill will be open for amendment at
3335 any point.

3336 Are there any bipartisan amendments to this bill?

3337 Are there any amendments to this bill? Are there any members
3338 wishing to speak on this bill?

3339 Mr. Hudson. Mr. Chairman.

3340 The Chairman. The gentleman from North Carolina is
3341 recognized for five minutes to speak on the bill.

3342 Mr. Hudson. Thank you, Mr. Chairman.

3343 A city right in my back yard -- Fayetteville, North Carolina
3344 -- is one of the worst cities for abuse of opioids in the country.
3345 This issue has affected friends, family, neighbors, and entire
3346 communities.

3347 I applaud the committee for taking this initiative and I
3348 believe this bill that I've worked on with my good friend and
3349 colleague, Mr. Butterfield -- the SOUND Disposal and Packaging
3350 Act -- will help curb the excess opioids in our communities.

3351 I'd like to thank Mr. Butterfield for working with me on
3352 this important issue and, Mr. Chairman, without objection I'd
3353 like to submit a letter from Dispose RX, a company in my district
3354 that makes a product that helps us dispose of opioids safely.

3355 The Chairman. Without objection.

3356 [The information follows:]

3357

*****COMMITTEE INSERT 32*****

3359 Mr. Hudson. And with that, Mr. Chairman, I would just urge
3360 my colleagues to support this legislation and I yield back.

3361 The Chairman. The gentleman yields back.

3362 The chair recognizes the gentleman from New Jersey for five
3363 minutes to speak on the bill.

3364 Mr. Pallone. Mr. Chairman, I also want to speak in support
3365 of the bill. One of the overarching goals of this legislation
3366 is to leverage packaging and disposal technologies and controls
3367 to mitigate the risk of abuse and misuse by reducing the number
3368 of unused opioids that may be diverted with the idea that fewer
3369 individuals become addicted to these drugs to begin with.

3370 And this goal would be accomplished by providing FDA with
3371 the authority to require packaging and disposal technologies for
3372 Schedule II and III controlled substances that reflect the risk
3373 of these substances.

3374 FDA has been actively exploring the potential of these
3375 technologies and recently held a public workshop on the issue
3376 last winter where recently FDA directed manufacturers of
3377 loperamide to make changes to their packaging to allow for single
3378 dose limits that would help to reduce the number of doses that
3379 could be abused.

3380 Commissioner Gottlieb has noted that the use of technology
3381 such as packaging merits consideration through a careful
3382 science-based process and one that I hope will continue.

3383 The legislation builds on his work and allows FDA the

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flexibility to permit a range of options for packaging or disposal as long as such technologies demonstrate comparable effectiveness and this flexibility would be critical to reduce barriers to generic entry, one of the concerns I have had about this legislation, and to maintain appropriate patient access to these substances.

The bill also clarifies that labeling related to the inclusion of packaging or disposal cannot be used as a blocking strategy by brand manufacturers.

So I want to thank the FDA, Representatives Hudson and Butterfield, for addressing the concerns that have been raised related to generic entry.

The purpose of these changes has been to ensure that if there is a decision made by FDA to require the use of packaging that brand and generic manufacturers have to meet the same performance outcome but are also afforded enough flexibility to pursue the technology they believe are best suited for their products.

I still have some concerns that the costs of packaging or disposal could be passed down the supply chain to the patient.

But I am hopeful that the flexibility built into this bill will enable manufactures to pursue cost-effective solutions that meet the safety goals shared by FDA and the stakeholders.

So, again, thanks to Congressman Hudson and Butterfield and appreciate your consideration of my concerns and I support the bill.

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3409 I yield back, Mr. Chairman.

3410 The Chairman. I thank the gentleman and he yields back.

3411 Other members seeking recognition on this legislation?

3412 Seeing none, the question now arises on favorably reporting

3413 H.R. 5687 to the House.

3414 All those in favor shall signify by saying aye.

3415 Those opposed, no.

3416 The ayes have it. The bill is favorably reported.

3417 The chair calls up H.R. 4275 -- this would be number six

3418 -- number six on your list -- as forwarded by the Subcommittee

3419 on Health on April 25th, 2018 and ask the clerk to report.

3420 The Clerk. H.R. 4275, to provide for the development and

3421 dissemination of programs and materials for training pharmacists,

3422 health care providers, and patients on indicators that a

3423 prescription is fraudulent, forged, or otherwise indicative of

3424 abuse or diversion and for other purposes. [The Bill H.R.

3425 4275 follows:]

3426

3427 *****INSERT 33*****

3428 The Chairman. Without objection, the first reading of the
3429 bill is dispensed with. The bill will be open for amendment at
3430 any time.

3431 Are there any bipartisan amendments?

3432 Are there any amendments?

3433 Seeing none, does anyone want to strike the last word on
3434 this bill?

3435 Mr. Carter. Mr. Chairman.

3436 The Chairman. Mr. Carter.

3437 Mr. Carter. Move to strike the last word.

3438 The Chairman. You're recognized for five minutes.

3439 Mr. Carter. Thank you, Mr. Chairman.

3440 I urge swift passage of this legislation. The committee
3441 print before us today incorporates a simple amendment that --
3442 a simple amendment that was adopted by voice vote in subcommittee.

3443 This straightforward amendment changed the origination of
3444 the prescriber materials to the secretary of HHS in consultation
3445 with the administrator of the DEA.

3446 A previous version of this bill originated in materials
3447 through the administrator of DEA in consultation with the
3448 secretary of HHS.

3449 As a pharmacist and a member of the HELP Subcommittee, I
3450 believe that this is more appropriate, given that the secretary
3451 oversees the nation's health department.

3452 While law enforcement plays a key role in detecting and

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3453 stopping fraudulent prescriptions, the responsibility ultimately
3454 lies with pharmacists who are licensed health care professionals.

3455 As I previously said, this bill will complement the DEA's
3456 current efforts like the diversion control division's Pharmacy
3457 Diversion Awareness Conferences held throughout the country as
3458 well as their other meetings, presentations, and seminars.

3459 I encourage all members to favorably report this bill to
3460 the full House of Representatives for floor consideration and
3461 I yield back.

3462 The Chairman. Gentleman yields back the balance of his
3463 time.

3464 Other members seeking recognition?

3465 Seeing none, the question now occurs on favorably reporting
3466 H.R. 4275 as amended to the House.

3467 All those in favor shall signify by saying aye.

3468 Those opposed, nay.

3469 The ayes have it. The measure is favorably reported.

3470 The chair calls up H.R. 5041 -- this would be number seven
3471 -- as forwarded by the Subcommittee on Health on April 25th, 2018
3472 and ask the clerk to report.

3473 The Clerk. H.R. 5041, to amend the Controlled Substances
3474 Act to authorize the employees of a Hospice program to handle
3475 controlled substances in the residence of a deceased Hospice
3476 patient to assist in disposal. [The Bill H.R. 5041
3477 follows:]

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3478

3479

*****INSERT 34*****

3480 The Chairman. Without objection, the first reading of the
3481 bill is dispensed with. The bill will be open for amendment at
3482 any point. Are there any bipartisan amendments?

3483 For what purpose does the gentleman from Michigan seek
3484 recognition?

3485 Mr. Walberg. Mr. Chairman, I'd like to discuss the
3486 amendment.

3487 The Chairman. You have an amendment at the desk. The clerk
3488 will report the amendment.

3489 The Clerk. Amendment to H.R. 5041 offered by Mr. Walberg.

3490 The Chairman. Without objection, further reading of the
3491 amendment is dispensed with and the gentleman from Michigan is
3492 recognized for five minutes to speak on his amendment.

3493 Mr. Walberg. Thank you, Mr. Chairman.

3494 Before I discuss the amendment I would first like to speak
3495 generally on H.R. 5041, the Safe Disposal of Unused Medication
3496 Act, bipartisan legislation that I introduced with my good friend
3497 and colleague, Representative Debbie Dingell and Representative
3498 Richard Hudson.

3499 This is a common sense bill that will reduce the number of
3500 unused controlled substances at risk of misuse by simply allowing
3501 Hospice workers to safely dispose of medications in a patient's
3502 home after the patient has passed away.

3503 In my home state of Michigan we have seen real challenges
3504 with the diversion and misuse of leftover medications that have

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3505 contributed to the opioid crisis.

3506 During the committee's hearing, we heard from Dr. John Mulder
3507 with Trillium Institute in Grand Rapids, Michigan, testifying
3508 that because of current DEA regulations, Hospice workers across
3509 the country are potentially leaving huge quantities unused
3510 medication in a home after a patient's death.

3511 Hospices and Hospice personnel could play a key role in
3512 helping ensure these drugs are disposed in a responsible manner
3513 and to diverted for unintended purposes.

3514 H.R. 5041 simply allows the Hospice employees who have the
3515 appropriate licensing and training to responsibly dispose of
3516 unused medications after a patient has passed away.

3517 We know that tragically many people begin the cycle of
3518 addiction through the misuse of prescription medication. H.R.
3519 5041 is a common sense and simple step that can get many unused
3520 pills that are at risk of misuse and diversion off the streets.

3521 In regards to the amendment, I'd first like to thank Ranking
3522 Member Pallone for offering an amendment to this legislation
3523 during the Health Subcommittee markup.

3524 The amendment adopted by a voice vote in the subcommittee
3525 clarified that the training will be conducted by the Hospice
3526 program, not the federal government.

3527 It also added a record keeping standard for Hospice programs
3528 to maintain information with in patients' clinical charts of the
3529 controlled substance dosage, number of pills, and the way it's

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3530 disposed.

3531 The amendment before us today is a bipartisan amendment and
3532 incorporates technical comments from the DEA.

3533 I consider these to be technical in nature and urge the
3534 committee to adopt their recommendations. Of note, there is a
3535 change to the employee definition.

3536 Both the National Association for Home Care and Hospice as
3537 well as the National Hospice and Palliative Care Organization
3538 have reviewed and approved the DEA's recommendation.

3539 Again, this amendment is technical in nature and I urge
3540 support for both the amendment as well as the underlying bill,
3541 and Mr. Chairman, I yield back.

3542 The Chairman. The gentleman yields back.

3543 Other members seeking recognition on the Walberg amendment?

3544 The gentlelady from Michigan is recognized for five minutes
3545 to speak on the amendment.

3546 Mrs. Dingell. Thank you, Mr. Chairman. Move to strike the
3547 last word.

3548 The Chairman. Gentlelady is recognized.

3549 Mrs. Dingell. Thank you.

3550 I am just going to, first, tell you what an honor it's been
3551 to work with my colleague, Mr. Walberg, in addressing this issue,
3552 and this is just as he said.

3553 It's a simple fix. Hospice does really important work and
3554 I have to tell you, more and more when I am out there I am hearing

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3555 from people who are really scared that they are not going to have
3556 what they need as they are dying.

3557 We need to make sure they have the medicine but then we need
3558 to make sure that there is a responsible way to dispose of it.

3559 That's what this bill does. It's simple and it's commonplace.

3560 Mr. Walberg gave all the other reasons why we should be
3561 supporting it. So I urge my colleagues to support this as another
3562 step in public policy trying to get at this issue.

3563 And with that, I yield back the balance of my time.

3564 The Chairman. The gentlelady yields back.

3565 Other members seeking recognition on the Walberg amendment?

3566 Seeing none, the question now arises on passage of the Walberg
3567 amendment.

3568 All those in favor will say aye.

3569 Those opposed, nay.

3570 The ayes appear to have it. The ayes have it.

3571 The amendment is adopted.

3572 Are there other members seeking recognition on the bill?

3573 If not, then the question arises on proving the legislation
3574 as amendment and favorably reporting it to the House, H.R. 5041.

3575 All those in favor will signify by saying aye.

3576 Those opposed, nay.

3577 The ayes appear to have it. The ayes have it and the bill
3578 as amended is reported favorably to the House.

3579 The chair now calls up H.R. 5202 -- that would be number

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3580 eight on your list -- and ask the clerk to report.

3581 The Clerk. H.R. 5202, to amend the Controlled Substances
3582 Act to provide for the delivery of a controlled substance by a
3583 pharmacy to an administering practitioner. [The Bill H.R.
3584 5202 follows:]

3585

3586 *****INSERT 35*****

3587 The Chairman. Without objection, the first reading of the
3588 bill is dispensed with. The bill will be open for amendment at
3589 any point.

3590 Are there any bipartisan amendments?

3591 Are there any amendments?

3592 The chair recognizes the gentleman from Vermont for what
3593 purpose?

3594 Mr. Welch. I have an amendment at the desk.

3595 The Chairman. The clerk will report Mr. Welch's amendment.

3596 The Clerk. Amendment to H.R. 5202, offered by Mr. Welch.

3597 Mr. Barton. Mr. Chairman?

3598 The Chairman. For what purpose does the gentleman from
3599 Texas seek recognition?

3600 Mr. Barton. I reserve a point of order against the
3601 amendment.

3602 The Chairman. The gentleman reserves a point of order
3603 against the amendment.

3604 The chair now recognizes the gentleman from Vermont to speak
3605 on his amendment for five minutes.

3606 Mr. Welch. Thank you, Mr. Chairman.

3607 A little background -- one of the tools that the Drug
3608 Enforcement Administration has in order to try to keep illicit
3609 opioids off the market is a provision for an immediate suspension
3610 order.

3611 This committee took up legislation ensuring patient access

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3612 in effective Drug Enforcement Act and a provision that was
3613 included in that as it passed this committee was a standard that
3614 would say that in order for the DEA to act on that it would
3615 establish foreseeable risk.

3616 Prior to that, there really was no standard. It was creating
3617 confusion for legitimate activities of drug distributors like
3618 Burlington Drug, which is a family business in Vermont, and also
3619 creating legal uncertainty.

3620 This committee considered the bill that was offered by Mrs.
3621 Blackburn -- Congresswoman Blackburn -- in May. It passed it
3622 unanimously, where it then went to the Senate, and with Senator
3623 Hatch and members of the Senate and the DEA engagement, the
3624 standard was changed there to what was called substantial
3625 likelihood as the triggering event.

3626 The bill was passed unanimously with the input of the DEA,
3627 signed by President Obama. Subsequent to that, questions were
3628 raised as to whether -- whatever the intent was of Congress to
3629 provide clarification it was actually inhibiting the Drug
3630 Enforcement Administration from pursuing the immediate
3631 suspension order definition.

3632 After that, you may remember, Mr. Chairman, we had a hearing
3633 at which you invited the DEA and they testified, and we asked
3634 them very specifically what standard do you need that will help
3635 you be most effective in doing your work.

3636 And, Mr. Chairman, you sent a letter to the DEA asking them

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3637 for an answer to that question. That was on October 27, 2017,
3638 and on February 28th, 2018, the DEA responded by a letter to you,
3639 which I'd like to make part of the record.

3640 The Chairman. Absolutely, without objection.

3641 [The information follows:]

3642

3643 *****COMMITTEE INSERT 36*****

3644 Mr. Welch. And in that what the justice -- through the
3645 Justice Department they said that the substantial likelihood
3646 standard they recommended be amended to a probable cause standard.

3647 And just yesterday in the House Judiciary Committee, the
3648 acting administrator of the DEA was asked that question again,
3649 and I just, if I can, want to quote his response: "So foreseeable
3650 is certainly a lower standard than probable cause and, as I've
3651 discussed with you and others, I appreciate the ability to get
3652 that level as low as possible."

3653 But the reason why we have picked the DEA probable cause
3654 is it is well defined, essentially standard for our agency. As
3655 we looked at all of these issues, we found that we could meet
3656 probable cause every time.

3657 So I appreciate your effort to go to foreseeable. At the
3658 same time, I think that using probable cause strikes a balance
3659 between the industry and understanding where that is.

3660 My amendment would incorporate the recommendation of the
3661 DEA to amend the Ensuring Patient Access and Effective Drug
3662 Enforcement Act to the probable cause standard recommended by
3663 the DEA in its letter to you, Mr. Chairman, and through its
3664 testimony in the House Judiciary Committee yesterday.

3665 And I yield back.

3666 The Chairman. Gentleman yields back.

3667 The chair recognizes the gentleman from Texas.

3668 Mr. Barton. Mr. Chairman, I've listened closely to the

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3669 author's explanation of his amendment. I am not an attorney and
3670 I understand this is a complex issue.

3671 But under the rules of the House, it is not germane under
3672 Clause 7 of Rule 16. And so with reluctance, I would insist on
3673 that point of order.

3674 The Chairman. Would the gentleman yield to me?

3675 Mr. Barton. Always.

3676 The Chairman. I appreciate the gentleman and respecting
3677 the rules of the House. I also have been in conversation with
3678 Mr. Welch. We share a concern about this.

3679 I could go through a list of things, and I appreciate your
3680 hard work on this issue and look forward to working with you in
3681 the future and other members of this committee to address this
3682 issue.

3683 It did take, it seems to me, more than a year for the DEA
3684 to respond. They've been reluctant. It's been an issue.

3685 Our staffs are now in communication with the DEA. We still
3686 await the report through HHS on this whole matter and so despite
3687 the fact this is out of order today and not germane, we will
3688 continue to work to resolve this once and for all and get it right.

3689 Mr. Welch. May I enquire?

3690 The Chairman. Would you be willing to withdraw your
3691 amendment?

3692 Mr. Welch. Well, if there is a point of order I'd accept
3693 the ruling of the chair on the point of order.

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3694 The Chairman. Well, we haven't taken a vote on that. We
3695 can if you want. Or you can --

3696 Mr. Barton. It's your -- you get to make the decision.

3697 The Chairman. If you want to withdraw it, you can do that
3698 or we can proceed on the point of order on the germaneness issue.

3699 Mr. Welch. Mr. Chairman, I won't be calling for a vote on
3700 the point of order. If I can't -- I know we have a common desire
3701 here. But I think we really do want to get clarification and
3702 legal finality to what that standard is rather than have it be
3703 in limbo.

3704 So, Mr. Chairman, I don't know whether you could give us
3705 some assurances to when we might have a hearing, get the DEA back
3706 in here, and then get very concrete and specific about what the
3707 standard is.

3708 The Chairman. Yes. I can't give you a date specific,
3709 sitting here right now. But I do commit to working with you and
3710 others on the committee to resolve this once and for all in a
3711 way that works for the DEA and the safety of patients in our
3712 communities.

3713 It is Mr. Barton's time. Do you insist on a point of order?

3714 Mr. Barton. I do insist.

3715 The Chairman. The gentleman insists on the point of order
3716 and having reviewed the amendment and listened to the arguments,
3717 the chair finds the amendment does violate the subject matter
3718 provisions in respect to the underlying bill.

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3719 Therefore, the chair sustains the point of order.

3720 Is there further discussion on the bill?

3721 The chair --

3722 Mr. Costello. Just real quick. I do -- I want to --

3723 The Chairman. Further discussions on the bill. The chair
3724 recognizes the gentleman from Pennsylvania to strike the last
3725 word.

3726 Mr. Costello. -- further discussion on the amendment.

3727 The Chairman. The amendment is gone.

3728 Mr. Costello. She's gone. Okay.

3729 The Chairman. But you can -- you can --

3730 Mr. Costello. So I won't be applauding Mr. Welch for his
3731 amendment, even though I agree with it, although I do find Mr.
3732 Barton's point of order to be correct in the fact that it wasn't
3733 germane.

3734 We are going now -- are we going now to the amendment 5202?

3735 Excuse me --

3736 The Chairman. We are on the bill.

3737 Mr. Costello. H.R. 5202.

3738 The Chairman. Yes, if you want to speak on that, or I think
3739 Mr. Griffith is looking for time if you're planning to yield.

3740 Mr. Costello. So I'll speak on 5202.

3741 The Chairman. Yes, continue on. The time is yours.

3742 Mr. Costello. Thank you, Mr. Chairman.

3743 I appreciate the Health Subcommittee favorably reporting

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3744 this bill by voice vote, the intent of which is to update federal
3745 law to reflect technological advancements in medicine.

3746 At times, as we all know, innovation outpaces federal law.
3747 During the Health Subcommittee markup, Vice Chairman Guthrie
3748 made three points explaining the need for this legislation.

3749 First, the CSA does not account for the dispensing of
3750 injectable or intrathecal drugs. Second, under current law, a
3751 pharmacy cannot dispense a practitioner-administered version of
3752 buprenorphine, which is the case -- with new injectable forms
3753 of the treatment since the practitioner is not the end user.

3754 And third, what this bill clarifies is that pharmacies can
3755 dispense injectable and intrathecal controlled substances to a
3756 practitioner who will administer the drug to the patient in need.

3757 Following the Health Subcommittee markup, our staffs and
3758 industry stakeholders continued bipartisan discussions with CMS
3759 and DEA to confirm this language is airtight and it is my
3760 understanding that they have received confirmation that this bill
3761 is prepared for floor consideration from a technical perspective.

3762 I urge support for this legislation and look forward to House
3763 consideration of this proposal.

3764 The Chairman. Is the gentleman going to yield to the
3765 gentleman from Virginia maybe with the remainder of his time?

3766 Mr. Costello. That's what I was looking to do.

3767 The Chairman. Yes.

3768 Mr. Griffith. I thank the gentleman for yielding his time

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3769 and for him putting in this important legislation.

3770 In relationship to Mr. Welch's concern, I think we all share
3771 that. But I do have to take exception with the DEA looking at
3772 us.

3773 We passed legislation that they asked for, that they
3774 approved. Then they created a new standard that was the same
3775 standard as the reasonable doubt standard before they would issue
3776 immediate suspension orders and that's how we find ourself in
3777 this position.

3778 They took a position that I think is legally flawed based
3779 on language that they asked us for and then said it's our problem
3780 -- we needed to fix the language. They should have asked for
3781 the probable cause standard in the first place.

3782 I think we would have gladly given it to them. We have got
3783 to figure out how to fix it on an appropriate measure.

3784 That being said, I yield back to Mr. Costello of
3785 Pennsylvania.

3786 Mr. Costello. And I will yield back.

3787 The Chairman. The gentleman yields back the balance of his
3788 time. Other members seeking recognition on the underlying bill?

3789 Seeing none and no other amendments, the question now arises
3790 about final passage of H.R. 5202.

3791 Those in favor will say aye.

3792 Those opposed, nay.

3793 The ayes appear to have it. The ayes have it and the measure

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3794 is reported to the House favorably.

3795 The chair now calls up H.R. 5483 -- that would be number
3796 nine on your list -- as forwarded by the Subcommittee on Health
3797 on April 25th, 2018, and ask the clerk to report.

3798 The Clerk. H.R. 5483, to impose a deadline for the
3799 promulgation of interim final regulations in accordance with
3800 Section 311(h) of the Controlled Substances Act specifying the
3801 circumstances in which a special registration may be issued to
3802 a practitioner to engage in the practice of telemedicine and for
3803 other purposes. [The Bill H.R. 5483 follows:]

3804

3805 *****INSERT 37*****

3806 The Chairman. Mr. Costello, I think your microphone is
3807 still on.

3808 Without objection, the first reading of the bill is dispensed
3809 with. The bill will be open for amendment at any point.

3810 Are there any bipartisan amendments to this legislation?

3811 Are there any amendments to this legislation?

3812 Are there members seeking time?

3813 The gentleman from Georgia, Mr. Carter, is recognized for
3814 five minutes to speak on the legislation.

3815 Mr. Carter. Thank you, Mr. Chairman.

3816 Mr. Chairman, the committee printout under consideration
3817 today incorporates an amendment that was adopted by voice vote
3818 in subcommittee.

3819 I offered the amendment in response to a DEA request to
3820 lengthen the time in which they must publish rules for the
3821 establishment of the special waiver process.

3822 Under a previous version of this bill the DEA would have
3823 had up to 90 days to complete this task. At their request, this
3824 committee favorably reported an amendment extending this window
3825 to one year.

3826 Finalizing the rules for the special waiver process is on
3827 the unified agenda of the Justice Department and DEA, a signal
3828 that they understand the need to implement this provision of law.

3829 I urge member to support this practical legislation and I
3830 yield back.

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3831 The Chairman. The gentleman yields back the balance of his
3832 time.

3833 The chair recognizes the gentleman from New Jersey, Mr.
3834 Pallone, for five minutes to strike the last word.

3835 Mr. Pallone. Thank you, Mr. Chairman. I support this
3836 legislation. One critical component of any response to our
3837 opioid crisis must continue to be how we can work to provide those
3838 suffering from substance abuse and addiction with access to
3839 treatment.

3840 Telemedicine offers one opportunity to potentially reach
3841 more patients who could not otherwise access treatment, whether
3842 it's for geographic reasons, provider access issues, or financial
3843 concerns.

3844 While DEA has the authority to establish a special
3845 registration pathway for purposes of treating a patient via
3846 telemedicine, DEA has not initiated rulemaking to date to do so
3847 and the Special Registration for Telemedicine's Clarification
3848 Act authored by Representatives Bustos and Carter would direct
3849 the AG to issue regulations establishing a special registration
3850 process for engaging in the practice of telemedicine.

3851 This approach will enable telemedicine to finally be
3852 deployed in treating patients with addiction while still allowing
3853 DEA to ensure that there are appropriate safeguards in place to
3854 mitigate against the use of telemedicine in any manner that could
3855 further exacerbate the opioid crisis.

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3856 So I urge my colleagues to support this important bill.

3857 The Chairman. And the gentleman yields back the balance
3858 of his time.

3859 Any other members seeking recognition? If not, the question
3860 now occurs on favorably reporting H.R. 5483 as amended -- H.R.
3861 5483 to the House.

3862 All those in favor shall signify by saying aye.

3863 Those opposed, no.

3864 The ayes appear to have it. The ayes have it and the bill
3865 is reported.

3866 Now we will turn to our energy agenda and the chair call
3867 up H.R. 4606 -- this would be number one on the list -- and ask
3868 the clerk to report.

3869 The Clerk. H.R. 4606, to provide that applications under
3870 the Natural Gas Act for the importation or exportation of small
3871 volumes of natural gas shall be granted without modification or
3872 delay. [The Bill H.R. 4606 follows:]

3873

3874 *****INSERT 38*****

3875 The Chairman. Without objection, the first reading of the
3876 bill is dispensed with. The bill will be open for amendment at
3877 any point.

3878 Are there bipartisan amendments to the bill? The chair
3879 recognize the gentleman from Ohio for what purpose?

3880 Mr. Johnson. Mr. Chairman, I have a bipartisan amendment.

3881 The Chairman. Clerk will report the amendment.

3882 The Clerk. Amendment to H.R. 4606, offered by Mr. Johnson.

3883 The Chairman. Without objection, further reading of the
3884 amendment is dispensed with.

3885 The chair recognizes the gentleman from Ohio to speak on
3886 his amendment for the next five minutes.

3887 Mr. Johnson. Mr. Chairman, I am proud to offer this
3888 amendment along with my colleague, Representative Gene Green.

3889 While H.R. 4606 had always been bipartisan, this amendment
3890 is about furthering that support by ensuring environmental
3891 concerns that were raised during the subcommittee markup are
3892 addressed while maintaining the underlying purpose of the bill,
3893 and that is to help the U.S. realize its full economic potential
3894 regarding small-scale natural gas exports and associated
3895 technologies through greater regulatory certainty surrounding
3896 the export approval process.

3897 This amendment ensures that only application for small
3898 amounts of natural gas exports that also qualify for a categorical
3899 exclusion under DOE's NEPA regulations may qualify for expedited

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3900 treatment.

3901 It ensures that DOE must comply fully with NEPA regulations.

3902 H.R. 4606 will encourage the domestic industries involved in
3903 the emerging small-scale markets to take full advantage of the
3904 economic opportunities throughout our Western Hemisphere.

3905 It can help provide countries in the Caribbean and Central
3906 America with a stable source of energy, as many are relying on
3907 Venezuelan fuel oil that has been used to gain influence in the
3908 region.

3909 It's important to note the benefits of increased U.S. energy
3910 engagement within this region has long been recognized as the
3911 former administration created the Caribbean Energy Security
3912 Initiative while Secretary Perry is currently working through
3913 a proposed DOE rule to encourage small-scale exports.

3914 This bill helps further those bipartisan goals.
3915 Additionally, H.R. 4606 will help bring the Natural Gas Act into
3916 the 21st century to reflect this era of domestic energy abundance.

3917 I would like to thank Representative Green and his staff
3918 for working with me on this amendment and I am hopeful that more
3919 members across the aisle will recognize that hard work by
3920 supporting this bill.

3921 And before I yield the remainder of my time to
3922 Representative Green, I'd like to ask for unanimous consent to
3923 submit a letter of support for H.R. 4606 written by the Center
3924 for Liquefied Natural Gas.

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3925 The Chairman. Without objection, so ordered.

3926 [The information follows:]

3927

3928 *****COMMITTEE INSERT 39*****

3929 Mr. Johnson. And with that, Mr. Chairman, I yield to
3930 Representative Green.

3931 Mr. Green. Mr. Chairman, I want to thank my colleague for
3932 yielding but I think I'll just strike the last word so I can get
3933 five minutes, if that's okay.

3934 Mr. Johnson. That's fine, Mr. Chairman. I yield back.

3935 The Chairman. I could add five minutes and six seconds but
3936 not anymore.

3937 Mr. Johnson. I yield back.

3938 The Chairman. Gentleman yields back.

3939 The chair recognizes the gentleman from Texas.

3940 Mr. Green. Thank you, Mr. Chairman, and thank my good
3941 friend, Mr. Johnson, for yielding me four seconds.

3942 But this amendment is a good faith effort that we reached
3943 working across the aisle, as Congress should. I've always said
3944 that Congress should streamline the regulatory process where
3945 possible to encourage development that we don't have to sacrifice
3946 bedrock environmental protections to do so.

3947 This amendment could codify existing environmental
3948 protections under the National Environmental Policy Act and I
3949 encourage my colleagues to support it.

3950 These protections include both the potential direct and
3951 potential indirect environmental impacts of any decision that
3952 are considered -- currently considered at the DOE in consultation
3953 with other agencies.

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3954 There are strong interests in U.S. natural gas all throughout
3955 the Caribbean and Central America where stable sources of energy
3956 are hard to find.

3957 The U.S. gas will help reduce emissions throughout the region
3958 and spur development of the stable grids with varied fuel
3959 generation sources.

3960 This would include Puerto Rico and we know the problems
3961 Puerto Rico has had because of their -- and rebuilding their grid.
3962 Natural gas would be a good baseload for them.

3963 I'd like to thank Mr. Johnson and his staff for their
3964 willingness to address these environmental concerns with this
3965 amendment.

3966 I did not support the bill at the subcommittee level but
3967 I am happy to vote in favor of it now with these improvements.

3968
3969 This amendment represents a good faith effort to address
3970 the concerns that many of us had on this side of the aisle raised
3971 at the subcommittee level. It is another demonstration how a
3972 bill can be improved through regular order.

3973 I urge my colleagues to support the amendment and the bill
3974 itself and yield back the balance of my time.

3975 The Chairman. The gentleman yields back the balance of his
3976 time.

3977 The chair recognizes the gentleman from Michigan for five
3978 minutes to strike the last word.

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3979 Mr. Upton. Well, thank you, Mr. Chairman.

3980 I just want to tell my colleagues not on the Energy
3981 Subcommittee that we had a long discussion about this. I made
3982 the point that we wanted to make sure that NEPA was not violated,
3983 as the gentleman from Texas indicated in his statement.

3984 Also, nothing in this bill will have any effect on FERC's
3985 authority to any requirement to obtain a permit for an export
3986 facility either. So we are where we should be. I think we
3987 strengthen the bill with this amendment.

3988 Many of us -- a number of us went down to the Caribbean after
3989 the terrible hurricanes that struck the U.S. and Puerto Rico and
3990 American Virgin Islands.

3991 We know that there is a real need for alternative energy
3992 there that's not relying on the old naphtha fuel or archaic grids
3993 that they have to provide for the millions of folks that live
3994 there.

3995 This is a bill that could make the difference throughout
3996 the entire Caribbean region. So I'd like to think that we can
3997 pass this bill with a good bipartisan vote and this amendment
3998 strengthens that and makes that in fact we are not taking away
3999 from NEPA or FERC the normal authorities that they might have.

4000 And I yield back the balance of my time.

4001 The Chairman. Gentleman yields back the balance of time.

4002 The chair now recognizes the gentleman from New Jersey, Mr.
4003 Pallone, for five minutes to strike the last word.

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4004 Mr. Pallone. Thank you, Mr. Chairman.

4005 I just wanted to commend Mr. Green and Mr. Johnson for working
4006 together on this amendment to fix the NEPA earmark in the
4007 underlying bill and I believe this amendment improves the
4008 legislation and should be adopted.

4009 However, as I said in my opening statement, I can't support
4010 the underlying bill. I still don't understand why we should spend
4011 the committee's time on legislation that codifies a proposed rule
4012 that is in the process of being finalized.

4013 The Trump administration has taken every opportunity, using
4014 every relevant official, and at least one irrelevant one, to
4015 promote U.S. natural gas abroad.

4016 LNG exports are, clearly, a priority for this administration
4017 and I have seen no indication that DOE's small-scale LNG rule
4018 would be delayed or pushed aside.

4019 So why not wait for the final to be -- go into effect? There
4020 are drawbacks to codifying a proposed rule with such a
4021 prescriptive volume requirement, which is the reason to question
4022 the wisdom of this bill.

4023 For example, should the circumstance arise where exporting
4024 0.14 billion cubic feet per day of LNG is no longer in the public
4025 interest?

4026 Then Congress would have to enact a new law to make any
4027 necessary changes. Furthermore, DOE isn't even sure that the
4028 0.14 is the right volume limit for these projects.

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4029 The proposal asks for public input on the appropriate volume
4030 limit for a small-scale application so this number could change
4031 in DOE's final rule.

4032 So, again, we should wait for the final rule to go into
4033 effect. What's the rush? This is not to say that the DOE's
4034 small-scale LNG rule is without fault.

4035 I believe it's problematic. It's a carve-out for a subset
4036 of LNG applications. It declares that all small-scale exports
4037 are always in the public interest, removes long-standing consumer
4038 protections, prevents the public from having an opportunity to
4039 know about or provide input on export proposals, violates the
4040 public hearing requirement of the Natural Gas Act, and fails to
4041 justify any of these changes to the existing approval process.

4042 I understand my colleagues' interest in helping our friends
4043 and neighbors in the Caribbean, but nothing in this bill or the
4044 proposed rule requires small-scale shipments to go to these areas.

4045

4046 In fact, Puerto Rico is the largest importer of LNG in the
4047 region and the problems associated with getting them natural gas
4048 are due to Jones Act restrictions, not DOE approval of export
4049 applications.

4050 So the proposal also fails to prevent applicants from using
4051 this new process to evade the public interest determinations
4052 required for large-scale exports by segmenting a large volume
4053 gas export into a series of smaller proposals.

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4054 And finally, it's unclear the small-scale rule is even
4055 necessary. To date, DOE has received 13 applications to export
4056 small volumes of LNG to destinations in the Caribbean as well
4057 as Central and South America.

4058 All but two have been approved and one of those outstanding
4059 applications requires an environmental review under NEPA so it
4060 doesn't qualify for the rules' expedited procedures.

4061 So, again, I see no problem here. I certainly don't see
4062 a problem that requires action from Congress. I believe that
4063 an unrestricted LNG export policy could significantly impact
4064 domestic natural gas prices and adversely affect American
4065 consumers and manufacturers.

4066 Furthermore, unfettered exports could be even worse for
4067 climate change by incentivizing widespread fossil fuel extraction
4068 with virtually no environmental protections and adding more
4069 fossil fuels to the electricity mix.

4070 So in my opinion, H.R. 4606 does not represent sound or timely
4071 policy and I would -- I intend to oppose it.

4072 Thank you, Mr. Chairman. I yield back.

4073 The Chairman. Gentleman yields the balance of his time.

4074 The chair recognizes the gentleman from Texas for five
4075 minutes to speak on the amendment.

4076 Mr. Barton. I rise in support of the amendment.

4077 I think some of what the ranking member just said has merit.

4078 I think you can honestly debate whether the volume limitation

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4079 is the exact correct volume metric requirement.

4080 I will say this. The real effect of Mr. Johnson and Mr.
4081 Green's legislation, if it's enacted, passed, and becomes law
4082 that it will make it somewhat easier for Caribbean nations that
4083 have no existing free trade agreement with the United States to
4084 expedite the process of getting a small amount of LNG to their
4085 -- to their market.

4086 If you have an existing free trade agreement, under current
4087 law it is automatically deemed in the national interest to export
4088 LNG -- if you have an existing free trade agreement.

4089 Unfortunately, not every Caribbean nation has an existing
4090 free trade agreement. So the real effect of Mr. Johnson and Mr.
4091 Green's legislation is that those Caribbean nations that don't
4092 have existing free trade agreements can get these limited amounts
4093 of natural gas liquids into their market without going through
4094 a lengthy permitting process and I think that's commendable.

4095 So I am very happy and supportive of what they are trying
4096 to do and hope the committee would pass it.

4097 The Chairman. Thank the gentleman. Yields back the
4098 balance of time.

4099 Any other members seeking recognition? Seeing none, there
4100 -- the vote now occurs on the Johnson amendment.

4101 So all those in favor shall signify by saying aye.

4102 Those opposed, no.

4103 The ayes appear to have it. The ayes have it and the

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4104 amendment is agreed to.

4105 Are there any other amendments or any members seeking
4106 recognition on the underlying bill?

4107 If not, the question now occurs on favorably reporting H.R.
4108 4606 as amended to the floor.

4109 All those in favor shall signify by saying aye, those oppose,
4110 no, and the clerk will call the roll. This is a recorded vote,
4111 for those watching.

4112 The Clerk. Mr. Barton.

4113 Mr. Barton. Aye.

4114 The Clerk. Mr. Barton votes aye.

4115 Mr. Upton.

4116 Mr. Upton. Aye.

4117 The Clerk. Mr. Upton votes aye.

4118 Mr. Shimkus.

4119 Mr. Shimkus. Aye.

4120 The Clerk. Mr. Shimkus votes aye.

4121 Mr. Burgess.

4122 Mr. Burgess. Aye.

4123 The Clerk. Mr. Burgess votes aye.

4124 Mrs. Blackburn.

4125 [No response.]

4126 Mr. Scalise.

4127 [No response.]

4128 Mr. Latta.

4129 Mr. Latta. Aye.

4130 The Clerk. Mr. Latta votes aye.

4131 Mrs. McMorris Rodgers.

4132 Mrs. McMorris Rodgers. Aye.

4133 The Clerk. Mrs. McMorris Rodgers votes aye.

4134 Mr. Harper.

4135 Mr. Harper. Aye.

4136 The Clerk. Mr. Harper votes aye.

4137 Mr. Lance.

4138 Mr. Lance. Aye.

4139 The Clerk. Mr. Lance votes aye.

4140 Mr. Guthrie.

4141 Mr. Guthrie. Aye.

4142 The Clerk. Mr. Guthrie votes aye.

4143 Mr. Olson.

4144 Mr. Olson. Aye.

4145 The Clerk. Mr. Olson votes aye.

4146 Mr. McKinley.

4147 Mr. McKinley. Aye.

4148 The Clerk. Mr. McKinley votes aye.

4149 Mr. Kinzinger.

4150 Mr. Kinzinger. Aye.

4151 The Clerk. Mr. Kinzinger votes aye.

4152 Mr. Griffith.

4153 Mr. Griffith. Aye.

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4154 The Clerk. Mr. Griffith votes aye.
4155 Mr. Bilirakis.
4156 Mr. Bilirakis. Aye.
4157 The Clerk. Mr. Bilirakis votes aye.
4158 Mr. Johnson.
4159 Mr. Johnson. Aye.
4160 The Clerk. Mr. Johnson votes aye.
4161 Mr. Long.
4162 [No response.]
4163 Mr. Bucshon.
4164 Mr. Bucshon. Aye.
4165 The Clerk. Mr. Bucshon votes aye.
4166 Mr. Flores.
4167 Mr. Flores. Aye.
4168 The Clerk. Mr. Flores votes aye.
4169 Mrs. Brooks.
4170 Mrs. Brooks. Aye.
4171 The Clerk. Mrs. Brooks votes aye.
4172 Mr. Mullin.
4173 Mr. Mullin. Aye.
4174 The Clerk. Mr. Mullin votes aye.
4175 Mr. Hudson.
4176 Mr. Hudson. Aye.
4177 The Clerk. Mr. Hudson votes aye.
4178 Mr. Collins.

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4179 [No response.]

4180 Mr. Cramer.

4181 Mr. Cramer. Aye.

4182 The Clerk. Mr. Cramer votes aye.

4183 Mr. Walberg.

4184 Mr. Walberg. Aye.

4185 The Clerk. Mr. Walberg votes aye.

4186 Mrs. Walters.

4187 Mrs. Walters. Aye.

4188 The Clerk. Mrs. Walters votes aye.

4189 Mr. Costello.

4190 Mr. Costello. Aye.

4191 The Clerk. Mr. Costello votes aye.

4192 Mr. Carter.

4193 Mr. Carter. Aye.

4194 The Clerk. Mr. Carter votes aye.

4195 Mr. Duncan.

4196 Mr. Duncan. Aye.

4197 The Clerk. Mr. Duncan votes aye.

4198 Mr. Pallone.

4199 Mr. Pallone. No.

4200 The Clerk. Mr. Pallone votes no.

4201 Mr. Rush.

4202 [No response.]

4203 Ms. Eshoo.

4204 Ms. Eshoo. No.

4205 The Clerk. Ms. Eshoo votes no.

4206 Mr. Engel.

4207 [No response.]

4208 Mr. Green.

4209 Mr. Green. Yes.

4210 The Clerk. Mr. Green votes aye.

4211 Ms. DeGette.

4212 Ms. DeGette. No.

4213 The Clerk. Ms. DeGette votes no.

4214 Mr. Doyle.

4215 Mr. Doyle. Aye.

4216 The Clerk. Mr. Doyle votes aye.

4217 Ms. Schakowsky.

4218 [No response.]

4219 Mr. Butterfield.

4220 Mr. Butterfield. Aye.

4221 The Clerk. Mr. Butterfield votes aye.

4222 Ms. Matsui.

4223 Ms. Matsui. No.

4224 The Clerk. Ms. Matsui votes no.

4225 Ms. Castor.

4226 Ms. Castor. No.

4227 The Clerk. Ms. Castor votes no.

4228 Mr. Sarbanes.

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4229 Mr. Sarbanes. No.

4230 The Clerk. Mr. Sarbanes votes no.

4231 Mr. McNerney.

4232 Mr. McNerney. Aye.

4233 The Clerk. Mr. McNerney votes aye.

4234 Mr. Welch.

4235 Mr. Welch. No.

4236 The Clerk. Mr. Welch votes no.

4237 Mr. Lujan.

4238 Mr. Lujan. Aye.

4239 The Clerk. Mr. Lujan votes aye.

4240 Mr. Tonko.

4241 Mr. Tonko. No.

4242 The Clerk. Mr. Tonko votes no.

4243 Ms. Clarke.

4244 Ms. Clarke. No.

4245 The Clerk. Ms. Clarke votes no.

4246 Mr. Loeb sack.

4247 Mr. Loeb sack. No.

4248 The Clerk. Mr. Loeb sack votes no.

4249 Mr. Schrader.

4250 Mr. Schrader. Aye.

4251 The Clerk. Mr. Schrader votes aye.

4252 Mr. Kennedy.

4253 Mr. Kennedy. No.

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4254 The Clerk. Mr. Kennedy votes no.
4255 Mr. Cardenas.
4256 [No response.]
4257 Mr. Ruiz.
4258 Mr. Ruiz. No.
4259 The Clerk. Mr. Ruiz votes no.
4260 Mr. Peters.
4261 Mr. Peters. No.
4262 The Clerk. Mr. Peters votes no.
4263 Mrs. Dingell.
4264 Mrs. Dingell. No.
4265 The Clerk. Mrs. Dingell votes no.
4266 Chairman Walden.
4267 The Chairman. Aye.
4268 The Clerk. Chairman Walden votes aye.
4269 Mr. Long.
4270 Mr. Long. Aye.
4271 The Clerk. Mr. Long votes aye.
4272 The Chairman. Mr. Rush.
4273 Mr. Rush. No.
4274 The Clerk. Mr. Rush votes no.
4275 The Chairman. I believe Mr. Scalise is on his way.
4276 Mr. Hudson, you're not.
4277 Mr. Hudson. Aye.
4278 The Chairman. Oh, you are?

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4279 The Clerk. Mr. Hudson is recorded as aye.

4280 The Chairman. The whip of the House. Mr. Scalise,
4281 delighted to have you here. Would you like to be recorded on
4282 this bill as a yes?

4283 Mr. Scalise. Yes.

4284 The Chairman. That's a great vote.

4285 The Clerk. Mr. Scalise votes aye.

4286 The Chairman. Mr. Scalise votes aye. I think that -- any
4287 other members wishing to be recorded?

4288 If not, the clerk will report the tally.

4289 The Clerk. Mr. Chairman, on that vote there were 35 ayes
4290 and 15 nays.

4291 The Chairman. The ayes have it and the bill is favorably
4292 reported as amended to the House floor.

4293 And the chair now calls up H.R. 5174 -- this would be number
4294 two on your programs -- and ask the clerk to report.

4295 The Clerk. H.R. 5174, to amend the Department of Energy
4296 Organization Act with respect to functions assigned to assistant
4297 secretaries and for other purposes. [The Bill H.R. 5174
4298 follows:]

4299

4300 *****INSERT 40*****

4301 The Chairman. Without objection, the first reading of the
4302 bill is dispensed. The bill will be open for amendment at any
4303 point.

4304 Are there any bipartisan amendments to the bill?

4305 Are there any amendments to the bill?

4306 Does anyone wish to speak on the bill?

4307 If not, the question now occurs on favorably reporting H.R.
4308 5174 to the House.

4309 All those in favor will say aye.

4310 Those opposed, nay.

4311 The ayes appear to have it. The ayes have it and the bill
4312 is favorably reported.

4313 The chair now calls up H.R. 5175 -- this would be number
4314 three on your list -- as forwarded by the Subcommittee on Energy
4315 on April 18th, 2018, and ask the clerk to report.

4316 The Clerk. H.R. 5175, to require the secretary of energy
4317 to carry out a program relating to physical security and
4318 cybersecurity for pipelines and liquefied natural gas facilities.

4319 [The Bill H.R. 5175 follows:]

4320

4321 *****INSERT 41*****

4322 The Chairman. Without objection, the first reading of the
4323 bill is dispensed with. The bill will be open for amendment at
4324 any point.

4325 Are there any bipartisan amendments?

4326 The chair recognizes for what purpose the gentleman from
4327 Michigan?

4328 Mr. Upton. I have an amendment at the desk.

4329 The Chairman. Clerk will report the amendment.

4330 The Clerk. Amendment to H.R. 5175, offered by Mr. Upton.

4331 The Chairman. Without objection, the reading of the
4332 amendment is dispensed with. The gentleman is now recognized
4333 for five minutes to speak on his amendment.

4334 Mr. Upton. Thank you, Mr. Chairman.

4335 This amendment is pretty straightforward. It's an
4336 amendment that we worked out with the minority. It has the
4337 support of the pipeline owners and operators who understand the
4338 importance of strong physical and cybersecurity protections for
4339 our energy infrastructure.

4340 I would note that the American Gas Association, the
4341 Interstate Natural Gas Association of America, and the
4342 Association of Oil Pipelines have all submitted letters in support
4343 of this bill now.

4344 It's no small feat that all of these groups are in agreement.

4345 I would ask unanimous consent that the letters be included as
4346 part of the record.

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4347 The Chairman. Without objection.

4348 [The information follows:]

4349

4350 *****COMMITTEE INSERT 42*****

4351 Mr. Upton. I want to thank Mr. Loeb sack for working with
4352 me. This bill -- this amendment clarifies and enhances the
4353 authorities of the DOE. It is not intended to be a regulatory
4354 program. It, instead, is intended to strengthen DOE's role to
4355 be able to coordinate cyber response, collaborate, and build
4356 capacity within states in the energy sector.

4357 So as I said all along, this bill is about conducting
4358 research, communicating threats, and a coordinated incident
4359 response across the government.

4360 I would note that it passed by a voice vote in subcommittee.
4361 I would like to think we can do it the same in full committee.
4362 I appreciate the hard work of the staff as we reached out in
4363 a number of round tables over the last number of months to make
4364 sure that this bill moves forward in the proper direction.

4365 With that, I yield back my time.

4366 The Chairman. The gentleman yields back.

4367 Is there further discussion on the Upton amendment?

4368 Seeing no one seeking time, then the vote now arises on
4369 approving the Upton amendment.

4370 All those in favor shall signify by saying aye.

4371 Those opposed, no.

4372 The ayes have it and the amendment is agreed to.

4373 Are there any other amendments?

4374 Are there other members seeking recognition?

4375 If not, the question now occurs on favorably reporting H.R.

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4376 5175 as amended to the House.

4377 All those in favor shall signify by saying aye.

4378 Those opposed, no.

4379 The ayes have it and the bill is favorably reported as amended
4380 to the House.

4381 The chair now calls up H.R. 5239 -- this is number four on
4382 your agenda -- as forwarded by the Subcommittee on Energy on April
4383 18th, 2018 and ask the clerk to report.

4384 The Clerk. H.R. 5239, to require the secretary of energy
4385 to establish a voluntary CyberSense program to identify and
4386 promote cybersecure products intended for the use in the bulk
4387 power system and for other purposes. [The Bill H.R. 5239
4388 follows:]

4389

4390 *****INSERT 43*****

4391 The Chairman. Without objection, the first reading of the
4392 bill is dispensed with. The bill will be open for amendment at
4393 any point.

4394 Are there any bipartisan amendments?

4395 Are there any amendments?

4396 The chair recognizes the gentleman from Ohio, Mr. Latta,
4397 to strike the last word.

4398 Mr. Latta. Thank you, Mr. Chairman.

4399 I just want to thank all the members for working on this
4400 piece of legislation and on the amendment in the nature of the
4401 substitute that we did in the subcommittee. Again, with the
4402 CyberSense, we want to make sure that we had the hearings with
4403 the secretary of energy and with -- when FERC was here. That
4404 is very, very important to make sure that we have cybersecure
4405 for the bulk power system out there -- that people can be assured
4406 that the equipment is -- can meet the needs, especially in this
4407 time of cyberattacks.

4408 And so with that, Mr. Chairman, I urge passage of the bill.

4409 The Chairman. And yields back the balance of his time.

4410 Any other members seeking recognition?

4411 If not, the question now occurs on favorably reporting H.R.
4412 5239 as amended to the House.

4413 All those in favor shall signify by saying aye.

4414 Those opposed, no.

4415 The ayes appear to have it. The ayes have it and the bill

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4416 is favorably reported to the House.

4417 The chair now calls up H.R. 5240 -- this would be number
4418 five -- and ask the clerk to report.

4419 The Clerk. H.R. 5240, to provide for certain programs and
4420 developments in the Department of Energy concerning the
4421 cybersecurity and vulnerabilities of and physical threats to the
4422 electric grid and for other purposes. [The Bill H.R. 5240
4423 follows:]

4424

4425 *****INSERT 44*****

4426 The Chairman. And without objection, the first reading of
4427 the bill is dispensed with. The bill will be open for amendment
4428 at any point.

4429 The chair recognizes the gentleman from Ohio for what
4430 purpose?

4431 Mr. Latta. Mr. Chairman, I had an amendment at the desk.

4432 The Chairman. Clerk will report the amendment.

4433 The Clerk. Amendment to H.R. 5240 offered by Mr. Latta.

4434 The Chairman. Without objection, further reading of the
4435 amendment is dispensed with and the gentleman from Ohio is
4436 recognized for five minutes to speak on this amendment.

4437 Mr. Latta. Well, thank you very much, Mr. Chairman.

4438 And first, I would like to thank my friend and colleague,
4439 the gentleman from California, Mr. McNerney, for all of his hard
4440 work that we have done on the past bill and this bill.

4441 We want to make sure -- we wanted to make sure that we were
4442 enhancing grid security out there through this legislation.

4443 And this amendment to H.R. 5240, the Enhancing Grid Security
4444 Through Public-Private Partnerships Act, adds the term "electric
4445 reliability organization" to Section 2 of the bill.

4446 The electric reliability organization -- ERO -- is an
4447 organization certified by the Federal Energy Regulatory
4448 Commission and is responsible for establishing and enforcing
4449 reliability standards for the bulk power system.

4450 Currently, the North American Electric Reliability

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4451 Corporation serves as the ERO. This amendment directs the
4452 secretary of energy to consult with the electric reliability
4453 organization in addition to state regulatory authorities,
4454 industry stakeholders, and other relevant federal agencies in
4455 carrying out its program to promote and advance physical security
4456 and cybersecurity of electric utilities.

4457 The valuable expertise of the electric reliability
4458 organization has to offer will only improve the effectiveness
4459 of this DOE program and, Mr. Chairman, I would urge adoption of
4460 the amendment.

4461 The Chairman. And gentleman yields back.

4462 Are there any members seeking recognition on the Latta
4463 amendment?

4464 Gentleman from California is recognized for five minutes
4465 to strike the last word.

4466 Mr. McNerney. Strike the last word. Thank you, Mr.
4467 Chairman.

4468 I want to thank my friend, Mr. Latta, for working on this
4469 bill. I support the amendment and I support the underlying bill.

4470 Basically, everyone here knows that there is a potential
4471 threat to our grid from cyberattacks. The results could be
4472 catastrophic so we need to take steps to protect ourselves.

4473 This bill and the last one, 5239, do that. I urge all my
4474 colleagues to not only support this bill but to think about how
4475 we can support securing our grids from cyberattacks in the future.

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4476 I yield back.

4477 The Chairman. Here. Here.

4478 The gentleman yields back the balance of his time.

4479 Other members seeking recognition on the Latta amendment?

4480 Seeing none, and if there is no further discussion those

4481 in favor will say aye, those opposed, no.

4482 Those in favor say aye.

4483 Those opposed, no.

4484 The ayes appear to have it. The ayes have it.

4485 The amendment is agreed to.

4486 Are there any other amendments on this, our final piece of

4487 legislation today? Not that I need you all to get too creative

4488 as we wrap things up.

4489 Anyone else seeking recognition?

4490 Okay. Then I just want to thank the members -- we will vote

4491 on this -- but for your participation. We passed 31 bills today,

4492 30 of which went unanimously, I think, and the 31st was by an

4493 overwhelming majority.

4494 So thanks for your good work. We will have a markup next

4495 week. We know some of the more complicated issues will be taken

4496 up then.

4497 The question now occurs -- well, the question now occurs

4498 on favorable reporting H.R. 5240 as amended to the House.

4499 Those in favor shall signify by saying aye.

4500 Those opposed, no.

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4501 The ayes have it and the bill as amended is favorably reported
4502 to the House.

4503 For what purpose does the gentleman from New Jersey seek
4504 recognition?

4505 Mr. Pallone. Mr. Chairman, House Rule 11 Clause 2(1)
4506 accords the committee minority two additional calendar days to
4507 file a supplemental and dissenting views on legislation that is
4508 reported out and forwarded to the House.

4509 Pursuant to that rule and clause, I am giving notice of our
4510 intent to file such views, and again, thank you, Mr. Chairman.

4511 I yield back.

4512 The Chairman. You're more than welcome and I'd like to
4513 submit statements from the following for the record: the Advanced
4514 Medical Technology Association and the
4515 American Society of Addiction Medicine and statement from
4516 Congressman Burgess.

4517 [The information follows:]

4518 *****COMMITTEE INSERT 45*****

4519 The Chairman. Without objection, the Committee on Energy
4520 and -- whoops. Without objection, the staff is authorized to
4521 make technical and conforming changes to the legislation
4522 considered by the committee today. So ordered.

4523 Without objection, the committee stands adjourned. Good
4524 work, everyone.

4525 [Whereupon, at 12:34 p.m., the committee was adjourned.]