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1 {York Stenographic Services, Inc.}
2 RPTS MEYERS
3 HIF129.140

4 ``MARKUP ON H.R. _____, TO AMEND THE FEDERAL FOOD, DRUG, AND
5 COSMETIC ACT TO REVISE AND EXTEND THE USER FEE PROGRAMS FOR
6 PRESCRIPTION DRUGS AND FOR MEDICAL DEVICES, TO ESTABLISH USER
7 FEE PROGRAMS FOR GENERIC DRUGS AND BIOSIMILARS, AND FOR OTHER
8 PURPOSES''
9 TUESDAY, MAY 8, 2012
10 House of Representatives,
11 Subcommittee on Health
12 Committee on Energy and Commerce
13 Washington, D.C.

14 The Subcommittee met, pursuant to call, at 10:05 a.m.,
15 in Room 2123 of the Rayburn House Office Building, Hon. Joe
16 Pitts [Chairman of the Subcommittee] presiding.

17 Members present: Representatives Pitts, Burgess,
18 Myrick, Murphy, Blackburn, Gingrey, Latta, Lance, Cassidy,

19 Upton (ex officio), Pallone, Dingell, Towns, Capps, Ross and
20 Waxman (ex officio).

21 Staff present: Clay Alspach, Counsel, Health; Gary
22 Andres, Staff Director; Michael Beckerman, Deputy Staff
23 Director; Mike Bloomquist, General Counsel; Allison Busbee,
24 Legislative Clerk; Howard Cohen, Chief Health Counsel; Nancy
25 Dunlap, Health Fellow; Paul Edattel, Professional Staff
26 Member, Health; Julie Goon, Health Policy Advisor; Debbee
27 Keller, Press Secretary; Peter Kielty, Associate Counsel;
28 Ryan Long, Chief Counsel, Health; Alexa Marrero,
29 Communications Director; Carly McWilliams, Legislative Clerk;
30 Katie Novaria, Legislative Clerk; Charlotte Savercool,
31 Executive Assistant; Heidi Stirrup, Health Policy
32 Coordinator; Jen Berenholz, Chief Clerk; Alli Corr, Policy
33 Analyst; Eric Flamm, FDA Detailee; Elizabeth Letter,
34 Assistant Press Secretary; Karen Lightfoot, Communications
35 Director and Senior Policy Advisor; Karen Nelson, Deputy
36 Committee Staff Director for Health; Rachel Sher, Senior
37 Counsel; and Roger Sherman, Chief Counsel.

|
38 H.R. _____

39 Mr. {Pitts.} The subcommittee will come to order.

40 The Chair recognizes himself for an opening statement.

41 Today we will mark up the latest FDA user fee package
42 discussion draft. This draft is the product of over a year
43 of hard work by various parties. While the individual
44 industries--prescription drugs, medical devices, generic
45 drugs and biosimilars drugs--represented in this draft were
46 negotiating with FDA on their user fee agreements, this
47 subcommittee was holding at least ten hearings on subjects
48 related to the draft.

49 After intense negotiation between both sides of the
50 aisle, as late as this past weekend, we have arrived at a
51 discussion draft that I hope all members of the subcommittee
52 will be able to support. There are still some outstanding
53 issues that staff continues to work on, and I hope that they
54 can be resolved before Thursday's full committee markup.

55 This package is critical to patients. It will ensure
56 that FDA has the resources and reforms needed to speed new
57 drugs, devices and treatments to those who are ill. Good-
58 paying jobs in the drug and device industries, like those in
59 my home State of Pennsylvania, will be critical to our
60 economic recovery, and we can't afford to outsource them.

61 These user fee agreements will make the approval process
62 more transparent, more consistent and more predictable,
63 benefiting patients, but also keeping the United States the
64 preeminent leader in drug and device development and
65 manufacturing.

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

67 ***** COMMITTEE INSERT *****

|
68 Mr. {Pitts.} I now recognize my friend from New Jersey,
69 the ranking member, Mr. Pallone, for 3 minutes for his
70 opening statement.

71 Mr. {Pallone.} Thank you, Chairman Pitts, for holding
72 today's markup.

73 The bill before us reflects weeks of negotiations
74 between the staffs on both sides and represents strong
75 bipartisan collaboration and compromise. While it is not
76 entirely perfect, it is a consensus product that we should
77 all be proud of. We set out in this process with the
78 intention to work together, and we have done that
79 exceptionally well.

80 The user fees are an essential component of FDA's
81 funding and it is important to ensure that the American
82 people have access to safe and effective health care
83 products. This bill sets out to renew existing FDA programs
84 that charge user fees to review product approval applications
85 from pharmaceutical and medical device manufacturers. It
86 also establishes new user fee programs for generic drugs and
87 for lower-cost versions of biotech drugs.

88 In addition, the bill also reauthorizes the Best
89 Pharmaceuticals for Children Act and the Pediatric Research
90 Equity Act, which both help to foster the development and

91 safe use of prescription drugs for children.

92 A significant improvement was also made to FDA's ability
93 to police an ever-growing global drug supply chain. These
94 provisions are based on the ideas and proposals contained in
95 the Drug Safety Enforcement Act, which I introduced with Mr.
96 Dingell, Mr. Waxman and Ms. DeGette, and I want to thank Mr.
97 Dingell for his leadership and hard work in this area as well
98 as Chairmen Upton and Pitts for your willingness and
99 sincerity. Together we have given the FDA critical tools to
100 keep our medicines safer.

101 I would also like to thank Dr. Burgess, who worked with
102 me personally to address current conflict of interest
103 statutes that apply to the FDA. These have unfortunately
104 resulted in a system that was out of balance. Together we
105 have maintained critical public disclosure of potential
106 conflicts and strengthened current recruitment activities at
107 the FDA while avoiding unnecessary duplication of other
108 existing conflict of interest protections.

109 Our comprehensive agreement also includes provisions to
110 address the recent increase in drug shortages and other FDA
111 policy reforms. In addition, it includes a part of my bill,
112 the Generic Drug Application Fairness Act, which aims to
113 provide temporary relief from an unintended consequence of
114 current law.

115 Reauthorizing and revitalizing the FDA drug and device
116 user fee system is a top priority for members on both sides
117 of the aisle so I want to thank you again, Chairman Pitts and
118 Chairman Upton, and the staffs of both sides for the hard
119 work they put into today's bill. They have been working so
120 hard over the last I don't know how many months, 4, 6 months,
121 I have lost track, and I want to particularly mention Tiffany
122 Guarascio to my left, who is my staff person who has been
123 working long hours, but all of the staff have been, and we
124 are going to have to continue to do more as we move on to
125 full committee and then move this bill to the Floor and have
126 it eventually signed into law.

127 This is all pretty much on course in terms of the
128 timetable we set up, Mr. Chairman, and I think that is
129 particularly amazing in this climate that we are able to keep
130 to our timetable. Thank you.

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

132 ***** COMMITTEE INSERT *****

|
133 Mr. {Pitts.} The Chair thanks the gentleman and agrees
134 with your comment on the staff on my side, particularly Ryan
135 and Clay. Thank you to all the staff for all your good work.

136 I now recognize The Chairman of the full committee, Mr.
137 Upton, for 3 minutes for his opening statement.

138 The {Chairman.} Well, thank you, Chairman Pitts, and I
139 certainly want to start off by commending you for your
140 tremendous leadership on this issue.

141 At the beginning of this user fee process, I set three
142 basic goals. First, I expected the process to be bipartisan.
143 Second, I wanted the user fee bill enacted by the end of
144 June, next month. And third, I believed the user fee bill
145 needed to foster American innovation so that we could get new
146 treatments to American patients and create jobs here at home,
147 and I am proud to report that we are on track to accomplish
148 all three goals, three for three.

149 I want to thank particularly Mr. Waxman, Mr. Pallone,
150 Mr. Dingell and members on both sides of the committee for
151 their bipartisanship throughout the entire process. The bill
152 before us today is a reflection of their hard work and their
153 willingness to put partisanship aside to look at issues
154 together, and because of that hard work and dedication, the
155 bill is much improved, which will help American patients and

156 American innovators.

157 My second goal was to get this user fee bill enacted
158 into law by the end of June, and we are in fact on track to
159 accomplish that goal as well. The full committee will mark
160 up this bill later this week, and I expect the bill to be on
161 the Floor yet this month. That will give us time to work
162 with our good friends in the Senate to have this bill to the
163 President before the Fourth of July.

164 Finally, I want the bill to foster American innovation,
165 which is essential in getting new treatments to patients and
166 creating American jobs. Because of the hard work of the
167 committee members, I think we have done that. Let me
168 highlight some of these provisions.

169 The user fee titles of the bill contain important
170 metrics that will hold the FDA accountable for its
171 performance. Because of the efforts of Mr. Barton, we will
172 get the FDA data down to the review division level and have
173 the independent, third-party assessments of FDA's performance
174 for drug and devices written into the statute.

175 Due to the leadership of the good Mike Rogers, Ms. Eshoo
176 and Mr. Markey, Title V of the bill makes the Best
177 Pharmaceuticals for Children Act and Pediatric Research
178 Equity Act permanent. This well help in getting new
179 therapies to our Nation's children.

180 Through the efforts of Dr. Burgess and Mr. Guthrie,
181 Title VI contains provisions that will significantly improve
182 scientific exchange at FDA's advisory committees and ensure
183 transparency and public input in the development FDA's
184 guidance documents.

185 Title VII will significantly improve FDA's regulation of
186 medical devices, and because of the hard work of Mr. Shimkus,
187 we will fix the current problems with the investigational
188 device exemption and the device modifications guidance.
189 Fixing these problems will bring clinical trials back to the
190 United States and reduce regulatory uncertainty and delay
191 that is hurting American medical device innovators.

192 Title VIII will foster American innovation because of
193 Dr. Gingrey's GAIN Act, Mr. Stearns' and Mr. Towns' FAST Act,
194 and Mr. Lance's medical gas bill.

195 Finally, Title IX will help our Nation's patients,
196 doctors, hospitals and nurses as they deal with drug
197 shortages, so critical to deal with. Again, I want to thank
198 Ms. DeGette, Mr. Walden, Dr. Gingrey, Mr. Bass and Mr. Latta
199 for their leadership on this issue. I don't know that I have
200 missed anyone but I certainly have listed a good number of
201 Republicans and Democrats that work together. I want to
202 particularly thank Ryan and Clay. Clearly, they were the
203 glue on our side that indeed kept everything from falling

204 apart, and I yield back the balance of my time.

205 [The prepared statement of Mr. Upton follows:]

206 ***** COMMITTEE INSERT *****

|
207 Mr. {Pitts.} The Chair thanks the gentleman and now
208 recognizes the gentleman from California, the ranking member
209 of the full, Mr. Waxman, for 3 minutes for his opening
210 statement.

211 Mr. {Waxman.} Thank you very much, Mr. Chairman. I
212 want to start off by commending you for holding this markup
213 and for leading our subcommittee to a bipartisan achievement.
214 The consideration of this bill should be a model for
215 legislative action.

216 This landmark legislation touches on some of the most
217 essential areas at the FDA. With this bill, we will
218 reauthorize the drug and medical device user fee programs,
219 which will ensure that FDA has the resources necessary to
220 review applications and give patients access to therapies at
221 the earliest possible time. We will also reauthorize the
222 Best Pharmaceuticals for Children Act--the BPCA--and the
223 Pediatric Research Equity Act--the PREA--which give FDA the
224 authority to obtain information about the use of drugs in
225 children. And this year, for the first time, we will be
226 establishing two new programs to help speed FDA's review of
227 low-cost generics and biosimilars.

228 We will give FDA new tools to address the challenges
229 posed by our increasingly globalized drug supply chain. We

230 based these provisions on the Drug Safety Enhancement Act
231 introduced by Mr. Dingell, Mr. Pallone, Ms. DeGette, and
232 myself. We have worked hard to come to bipartisan agreement
233 in this area, and when these provisions are enacted,
234 Americans can take comfort in knowing that the drug supply
235 will be safer as a result.

236 When we started this process, we had disagreements, but
237 we resolved those disagreements. We also have included some
238 important provisions that will go a long way toward
239 addressing the problems associated with drug shortages, which
240 have unfortunately now become an all-too frequent occurrence.

241 Our bipartisan work has paid off, and I support this
242 bill, but it is no secret that I continue to have strong
243 concerns in the area of antibiotics. As I have mentioned at
244 previous hearings on this issue, I agree that we need to look
245 at ways to incentivize the development of new antibiotics,
246 given that our pipeline is running dangerously low. The GAIN
247 Act is a good first step at achieving this goal. However, I
248 regret that we failed to narrowly tailor the bill to target
249 only drugs that treat dangerous infections for which we don't
250 have adequate treatments. As the bill reads now, essentially
251 any antibiotic can qualify for the incentives included in the
252 bill. I hope we can continue to work on this issue.

253 I want to thank our colleagues on both sides of the

254 aisle, and I particularly want us to pay recognition to the
255 hard work that our staffs have done. On the Democratic side,
256 we have Rachel Sher, Eric Flamm, Arun Patel, and of course,
257 Karen Nelson, Tiffany Guarascio, and Mr. Dingell's staff, Kim
258 Trzeciak, on the Republican side, Ryan Long and Clay Alspach.
259 Congratulations to all the staffs. They worked very, very
260 hard and had to deal with a lot of complicated, difficult
261 issues, but they accomplished what all of us wanted, which is
262 a strong, bipartisan bill that we can move forward.

263 Thank you, Mr. Chairman. I yield back the balance of my
264 time.

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

266 ***** COMMITTEE INSERT *****

|
267 Mr. {Pitts.} The Chair thanks the gentleman and now
268 recognizes the vice chairman of the committee, Dr. Burgess,
269 for 1 minute for an opening statement.

270 Dr. {Burgess.} I thank The Chairman for the
271 recognition. I also want to thank The Chairmen and ranking
272 members of the subcommittee and full committee for moving
273 this reauthorization expeditiously and in a bipartisan
274 fashion.

275 The true impact of the medical device, pharmaceutical,
276 biologic and generic industries in the United States is that
277 they are partners in providing our physicians and other
278 providers with the tools they need to prevent and most
279 importantly, to alleviate human suffering. I also need to
280 thank my staff, Mr. Paluskiewicz, who really went above and
281 beyond in working several sections of this bill. I
282 appreciate the committee allowing me to be involved in the
283 crafting and the drafting of this bill.

284 I also want to thank Mr. Pallone for the new guidelines
285 of how the FDA approaches, thinks about and is allowed to
286 ensure that they have the most up-to-date and scientific
287 medical expertise needed to accomplish their critical mission
288 to ensure medical products are safe and effective and to be
289 the gateway to providing patients with better products in

290 their lives. This markup has been transparent and
291 respectful, and again, I thank The Chairmen and ranking
292 members of both the full subcommittee and the subcommittee.
293 The hearings that we have had have been insightful. I look
294 forward to expeditious passage of this bill. I yield back.

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

296 ***** COMMITTEE INSERT *****

|
297 Mr. {Pitts.} The Chair thanks the gentleman and now
298 recognizes the gentleman from Michigan, the ranking member
299 emeritus, Mr. Dingell, for 3 minutes for his opening
300 statement.

301 Mr. {Dingell.} Mr. Chairman, I thank you for your
302 courtesy. I commend you for your leadership, and I also
303 commend my dear friend, Chairman Upton, and Ranking Members
304 Pallone and Waxman and their staffs, in fact, the staffs of
305 all who were involved including my own for the superb work
306 done in presenting this proposal to the committee today. It
307 has the support of Food and Drug, it has the support of the
308 government, it has the support of the industry and it has the
309 bipartisan support of the members who have worked together on
310 this in a long and difficult way.

311 If you look around the room, you will see that the lack
312 of controversy here reflects the extraordinary work of the
313 committee, of the members and of the staff in achieving the
314 success that we are about to enjoy in moving forward a superb
315 piece of legislation.

316 Is it everything that we want? Not exactly. I don't
317 think anybody could ever agree on all of the things in the
318 bill. But it is, however, a significant and meaningful
319 advance in the law. In fact, it is probably the first real

320 change that we have seen since the early 1960s and so we
321 should feel very good.

322 I want to commend you for your leadership and also our
323 chairman, and specifically on the work that you and Mr.
324 Waxman and Mr. Pallone have done working with me on the drug
325 supply chain provisions included in the proposal before us.
326 The provisions will provide FDA with up-to-date information
327 on domestic and foreign drug manufacturers, allow FDA to
328 detain or destroy drugs that are found to be counterfeit or
329 adulterated, require importers to register with the FDA, and
330 to comply with good importer practices. We will also
331 encourage the prohibition of entry of imported drugs that
332 have delayed or denied inspection by FDA and encourage parity
333 in the inspections of domestic and foreign drug manufacturing
334 establishments. This has been a top priority of mine for a
335 long time, and I believe that we can be proud of all the
336 things in this bill including providing FDA with the
337 desperately needed tools and information to secure our supply
338 chain at a time when we import massive amounts of
339 pharmaceuticals from abroad and the building blocks that are
340 used in manufacturer pharmaceuticals here in this country.

341 Today's markup will advance user fee agreements
342 negotiated by the industry and FDA and build upon the work
343 already being done by FDA. Again, I commend you and Chairman

344 Upton, and I am particularly pleased that we are moving
345 forward with bipartisanship, cooperation and compromise as we
346 work toward final passage, and we are showing that this
347 committee can work as it has in the past by pulling together
348 and by following the regular order.

349 I commend you, Mr. Chairman, and my colleagues who have
350 worked on this. Thank you.

351 [The prepared statement of Mr. Dingell follows:]

352 ***** COMMITTEE INSERT *****

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353 Mr. {Pitts.} The Chair thanks the gentleman and now
354 recognizes the vice chairman of the full committee, the
355 gentlelady from North Carolina, Ms. Myrick, for 1 minute for
356 opening statement.

357 Mrs. {Myrick.} I will yield my time, Mr. Chairman.

358 [The prepared statement of Mrs. Myrick follows:]

359 ***** COMMITTEE INSERT *****

|
360 Mr. {Pitts.} The gentle lady yields to Ms. Blackburn
361 from Tennessee for 1 minute.

362 Mrs. {Blackburn.} Thank you, Mr. Chairman. I
363 appreciate this.

364 The work on the legislation that we have before us, for
365 us in Tennessee, this is a jobs issue, plain and simple. The
366 life sciences industry employs more than 25,000 people in our
367 State. Their average wage is \$69,000 per year. The medical
368 device industry in Tennessee ranks seventh in the country.
369 Memphis is the second largest center for orthopedic devices
370 in the United States, and these companies paid a total of
371 \$275 million in wages to Tennessee. So we look forward to
372 have some certainty out of the fad with this bill.

373 Clinical trials are also important to our State. Many
374 are conducted through St. Jude's and Vanderbilt and other
375 institutions. I also want to mention CPATH and the Critical
376 Path Initiative, and Mr. Engel and Congresswoman Giffords and
377 I worked on this 5 years ago putting it in place. It is an
378 important role in bridging the gap between scientific
379 research and product development, and I am looking forward to
380 having that continue.

381 This bill will get us on the right track. I look
382 forward to the discussion that ensures in passage, and yield

383 back.

384 [The prepared statement of Mrs. Blackburn follows:]

385 ***** COMMITTEE INSERT *****

|
386 Mr. {Pitts.} The Chair thanks the gentlelady and now
387 recognizes the gentlelady from California, Ms. Capps, for 1
388 minute for opening statement.

389 Mrs. {Capps.} Thank you, Mr. Chairman, and I thank you
390 and Ranking Member Pallone, Chairman Upton, Ranking Member
391 Waxman, Mr. Dingell, particularly, for your leadership on
392 this bill.

393 The bill before us certainly represents the spirit of
394 compromise, compromise across the aisle and between the many
395 stakeholders that work toward innovation to improve our
396 health.

397 I am especially pleased my bill to address postmarket
398 surveillance of medical devices and implementation of the
399 unique device identifier program, the Safe Devices Act, has
400 been incorporated into the base text. This is an important
401 provision to know our devices work and identify potential
402 problems early when they are easier and less costly to
403 address. And while I think there is more we could do to
404 address the root causes of advisory panel vacancies, ensure
405 devices work in diverse populations and also support
406 pediatric clinical trial networks for rare diseases like SMA,
407 spinal muscular atrophy, the bill before us is an important
408 step to ensure that our drug and device pipelines continue to

409 produce needed cures and treatments to keep us healthy.

410 So I look forward to supporting this bill and I yield
411 back.

412 [The prepared statement of Mrs. Capps follows:]

413 ***** COMMITTEE INSERT *****

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414 Mr. {Pitts.} The Chair thanks the gentlelady and now
415 recognizes the gentleman from Georgia, Dr. Gingrey, for 1
416 minute for an opening statement.

417 Dr. {Gingrey.} I yield, Mr. Chairman. I have no
418 opening statement. Thank you.

419 Mr. {Pitts.} Mr. Latta for 1 minute.

420 Mr. {Latta.} Thank you, Mr. Chairman, and thank you for
421 holding today's markup on this very important issue regarding
422 the legislation to reauthorize user fee programs for
423 prescription drugs and medical devices, establish user fee
424 programs for generic drugs and reforming FDA programs.

425 I want to thank you and committee staff for working with
426 me on an important issue to hospital systems in Ohio and
427 across the country regarding repackaging of drugs in a drug
428 shortage. Specifically, I worked on language in the bill
429 draft to assist hospital systems in coping with drug
430 shortages by allowing them to repackage those drugs into
431 smaller doses. Currently law does not allow for a hospital
432 to repackage a drug for use in another hospital within their
433 own system. I am very pleased that all parties worked
434 together in agreeing to the language that is include in the
435 bill draft that allows hospital systems to repackage and
436 transport the drug in a shortage to another hospital within

437 the same health system.

438 There are many important reforms contained in this
439 legislation, and I look forward to supporting the bill today.

440 Thank you, Mr. Chairman, and I yield back.

441 [The prepared statement of Mr. Latta follows:]

442 ***** COMMITTEE INSERT *****

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443 Mr. {Pitts.} The Chair thanks the gentleman and now
444 recognizes the gentleman from New Jersey, Mr. Lance, for 1
445 minute for an opening statement.

446 Mr. {Lance.} Thank you, Mr. Chairman.

447 This is my first term on this committee and
448 subcommittee, and from my observation, this is precisely the
449 way the Congress of the United States should work.

450 I am pleased to see that the committee has included the
451 Medical Gas Safety Act, a bill that I introduced to ensure
452 access to medical gases by addressing regulatory uncertainty.
453 The Medical Gas Safety Act is the product of compromise
454 between the FDA and the industry to provide regulatory
455 clarity that will ensure access to these lifesaving products
456 for patients while protecting jobs.

457 I thank you, Mr. Chairman. I thank the ranking member.
458 I thank your staffs for your support throughout the process.
459 I also thank Jeff Last of my staff on working on this
460 important issue.

461 Thank you, and I yield back the balance of my time.

462 [The prepared statement of Mr. Lance follows:]

463 ***** COMMITTEE INSERT *****

|
464 Mr. {Pitts.} The Chair thanks the gentleman and now
465 recognizes the gentleman from Louisiana, Dr. Cassidy, for 1
466 minute.

467 Dr. {Cassidy.} I yield back.

468 [The prepared statement of Dr. Cassidy follows:]

469 ***** COMMITTEE INSERT *****

|
470 Mr. {Pitts.} The gentleman yields back.

471 The Chair reminds members that pursuant to the committee
472 rules, all members' opening statements will be made part of
473 the record.

474 Are there any further opening statements?

475 Mr. {Pallone.} Mr. Chairman, I just wanted to ask for
476 unanimous consent to enter a support letter from the Pew
477 Foundation into the record, and I believe you have it.

478 Mr. {Pitts.} We have it. Without objection, so
479 ordered.

480 [The information follows:]

481 ***** COMMITTEE INSERT *****

|
482 Mr. {Pitts.} At this time The Chair calls up the
483 discussion draft and asks the clerk to report.

484 The {Clerk.} Committee print to amend the Federal Food,
485 Drug, and Cosmetic Act to revise and extend the user fee
486 programs for prescription drugs--

487 [H.R. ____ follows:]

488 ***** INSERT 1 *****

|
489 Mr. {Pitts.} Without objection, the first reading of
490 the discussion draft is dispensed with and the discussion
491 draft will be open for amendment at any point. So ordered.

492 The Chair recognizes himself to offer an amendment, and
493 the clerk will report the amendment.

494 The {Clerk.} Amendment to committee print offered by
495 Mr. Pitts of Pennsylvania.

496 [The amendment follows:]

497 ***** INSERT 2 *****

|
498 Mr. {Pitts.} Without objection, the reading of the
499 amendment is dispensed with, and I would like to recognize
500 myself to speak on the amendment.

501 My amendment does not represent any substantive changes
502 to policy but rather contains technical changes to the
503 discussion draft circulated on Friday. These changes were
504 recommended by the Food and Drug Administration and
505 stakeholders. I ask the subcommittee to approve these
506 changes to the discussion draft.

507 Is there further discussion on the amendment?

508 Mr. {Pallone.} Mr. Chairman.

509 Mr. {Pitts.} The Chair recognizes Mr. Pallone.

510 Mr. {Pallone.} Mr. Chairman, I support this amendment,
511 which would make technical changes to the committee print
512 released on Friday. There are no substantive policy changes
513 but still there are significant improvements to the
514 underlying bill.

515 I do know there are still some small outstanding issues
516 that need to be worked out before full committee, and I stand
517 ready to work through those issues with you expeditiously.

518 Thank you, and I yield back.

519 Mr. {Pitts.} The Chair thanks the gentleman.

520 Anyone else wishing to speak on the amendment? If there

521 is no further discussion, the vote occurs on the amendment.

522 All those in favor shall signify by saying aye.

523 All those opposed, no.

524 The ayes have it and the amendment is agreed to.

525 Mr. {Pallone.} Mr. Chairman.

526 Mr. {Pitts.} The Chair recognizes Mr. Pallone for
527 colloquy.

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

529 I am pleased that we have been able to work in a
530 bipartisan fashion to put together a strong user fee bill.
531 It has been a culmination of many months, and I am proud of
532 what this committee was able to accomplish.

533 However, one area that we did not include in today's
534 bill was reform of FDA's cosmetic laws. Cosmetics and
535 personal care products are used by Americans each and every
536 day, and yet the regulation of this billion-dollar industry
537 has gone largely unchanged since the 1930s.

538 I along with my colleague, Mr. Dingell, have introduced
539 legislation that would strengthen FDA's role in regulating
540 cosmetics in the United States, but unfortunately, through no
541 fault of anyone, we were not able to fully develop this
542 legislation in time for its inclusion, Mr. Chairman.

543 Mr. {Pitts.} Thank you, Mr. Chairman. I agree with my
544 colleague. I am also interested in addressing the reform of

545 FDA's cosmetic law, and I want to note the important impact
546 that this cosmetic reform legislation would have on
547 harmonizing regulations nationwide, encouraging innovation
548 and promoting the U.S. cosmetic industry, which employs 8.2
549 million Americans and generates a \$5 billion annual trade
550 surplus.

551 Further, I know that Mr. Lance also has legislation to
552 modernize the cosmetic laws.

553 Mr. {Pallone.} Mr. Chairman, I appreciate the interest
554 in these issues from my Republican colleagues on the
555 committee. While we couldn't come to a bipartisan agreement
556 before the deadline of getting user fee legislation
557 completed, I am hopeful that we can enact bipartisan cosmetic
558 reforms this Congress, which would modernize the law,
559 strengthen consumer protections and streamline out-of-date
560 regulations.

561 Following the subcommittee's work on user fee
562 legislation, I intend to work hard to secure an agreement
563 that can be broadly supported by regulated industry, consumer
564 advocates and the FDA alike.

565 Mr. {Pitts.} I believe that this legislation is
566 important for this subcommittee and Congress to act on this
567 year, and I look forward to working with my colleagues to
568 complete this important work as standalone legislation.

569 The Chair thanks the gentleman and now recognizes the
570 gentleman from Louisiana for a colloquy.

571 Dr. {Cassidy.} Mr. Chairman, the committee mark
572 includes a bill that I introduced related to valid
573 prescriptions. While federal law clearly defines a valid
574 prescription for the purposes of obtaining a controlled
575 substance, no such definition exists for a non-controlled
576 substance.

577 The language included in the mark is included to close a
578 statutory loophole that has been exploited by unscrupulous
579 and dangerous online drug sites. However, we discovered that
580 the bill as currently drafted may adversely impact legitimate
581 telehealth services. We must ensure that this legislation
582 restricts illegal online prescriptions, not undermine access
583 to legitimate telehealth services. As we look to cut health
584 care costs, we must not inadvertently constrict medical
585 innovation.

586 I have and continue to work with members on both sides
587 of the aisle to address this issue so that we reach a
588 resolution before the full committee considers the user fee
589 package.

590 Mr. {Pitts.} I thank the gentleman from Louisiana and
591 appreciate his work to address the issue of online pharmacies
592 and ensuring the safety of prescription drugs purchased

593 online. I believe we can collectively reach a resolution
594 without adversely impacting innovation in the telehealth
595 space before our full committee markup. The Chair thanks the
596 gentleman.

597 The gentleman, Mr. Towns, is recognized.

598 Mr. {Towns.} Mr. Chairman, I have a copy of a press
599 release in support of the FAST Act and a letter from BIO and
600 of course the Ever Life Foundation and 50 other patient
601 groups, and I would like to submit this for the record.

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

603 [The information follows:]

604 ***** COMMITTEE INSERT *****

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605 Mr. {Pitts.} The Chair thanks the gentleman.

606 The question now occurs on favorably reporting the
607 discussion draft as amended to the full committee.

608 All those in favor, say aye.

609 Those opposed, no.

610 The ayes appear to have it. The ayes have it, and the
611 discussion draft is favorably reported.

612 Without objection, staff is authorized to make technical
613 and conforming changes to the discussion approved by the
614 subcommittee today. So ordered.

615 Without objection, the subcommittee stands adjourned.

616 [Whereupon, at 10:34 a.m., the subcommittee was
617 adjourned.]