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3 HEARING ON EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC

4 DRUG COMPETITION

5 THURSDAY, JUNE 11, 2009

6 House of Representatives,

7 Subcommittee on Health

8 Committee on Energy and Commerce

9 Washington, D.C.

10 The Subcommittee met, pursuant to call, at 10:08 a.m.,
11 in Room 2123 of the Rayburn House Office Building, Hon. Frank
12 Pallone, Jr. (chairman of the subcommittee) presiding.

13 Present: Representatives Pallone, Dingell, Gordon,
14 Eshoo, Green, DeGette, Capps, Schakowsky, Baldwin, Matheson,
15 Harman, Barrow, Christensen, Castor, Sarbanes, Murphy of
16 Connecticut, Space, Sutton, Braley, Waxman (ex officio),
17 Deal, Whitfield, Shimkus, Buyer, Pitts, Myrick, Murphy of
18 Pennsylvania, Burgess, Blackburn, and Gingrey.

19

Also present: Representative Inslee.

|

20 Mr. {Pallone.} The meeting of the subcommittee is
21 called to order, and I will recognize myself initially.
22 Today, the subcommittee is meeting to discuss the Federal
23 Trade Commission report entitled Emerging Health Care Issues:
24 Follow-on Biologic Drug Competition. This is an extremely
25 timely report and goes to the very heart of our President and
26 this Congress' commitment to ensuring affordable and quality
27 health care for every American. Creating a statutory pathway
28 for the approval of follow-on biologics presents us with an
29 opportunity to improve millions of lives at a more affordable
30 cost. Currently, brand biologics account for approximately
31 15 percent of total U.S. prescription drug sales, and the
32 industry is growing at a rate of around 20 percent annually.
33 In a couple years, we could be spending over \$100 billion
34 just on biologic drugs.

35 According to data from the Centers for Medicare and
36 Medicaid Services, CMS, just 4 biologics account for 30
37 percent of all Medicare Part B spending. Obviously, these
38 drugs are costing the health care system a lot of money, and
39 it is not just the health system that is being burdened by
40 these high costs. For American families biologics can cost
41 in the tens of thousands of dollars for the most popular
42 drugs. In some cases the life-saving biologic can cost a

43 patient over \$300,000 a year. There is no doubt that these
44 innovative drugs provide Americans access to ground breaking
45 treatments for devastating illnesses, including cancer,
46 arthritis, and multiple sclerosis.

47 But I have heard too many stories from my home district
48 in New Jersey and from all around the country of hard-working
49 people who just can't afford the tremendous cost of these
50 life-saving and life-improving drugs. In a country of the
51 best and the brightest, which we are, I have to believe that
52 we can do better. We must continue to innovate and push the
53 envelope to discover more effective treatments and cures for
54 the scourges of our time. In the same vein, we must also
55 ensure that these innovative products are available to
56 patients at an affordable price. We are faced with a
57 delicate balance moving forward between ensuring reasonable
58 drug prices and expenditures, increasing access for more
59 Americans, and supporting innovation. And I know that we
60 have different bills on this subject and we have significant
61 disagreements, but I also think that we all believe that we
62 need to move forward with a pathway for these follow-on
63 biologics, and this hearing today is the beginning of that
64 process.

65 There are some principles, the same principles that
66 essentially guided us with chemical substances I think can

67 guide us in the creation of legislation today. We all know
68 about the Hatch-Waxman Act. Mr. Waxman isn't here, but I am
69 sure he will be.

70 The {Chairman.} I am.

71 Mr. {Pallone.} Oh, you are. I am sorry.

72 Mr. {Chairman.} It is Waxman-Hatch.

73 Mr. {Pallone.} Yes, I know. I was going to say that.
74 I see in the document it says Hatch-Waxman. I said it is
75 Waxman-Hatch, not Hatch-Waxman. But we know that Waxman-
76 Hatch has been a great success since its passage or since it
77 went into effect in 1984. And since its passage more generic
78 drug manufacturers have entered the market driving down costs
79 to the consumer. Also, pioneer drug companies have given
80 protections that have spurred innovation leading to
81 advancements that are helping us to live longer and healthier
82 lives. In addition to driving innovation, Waxman-Hatch was
83 also able to effectively and without any market interference
84 drive down the cost of drugs. In fact, the U.S. health care
85 system has saved over \$700 billion in the past 10 years
86 through the use of generic pharmaceuticals. In a time when
87 we are facing an economic crisis partly brought on by
88 skyrocketing health care costs, this is a staggering figure.

89 If biologics are the future, then we should do
90 everything we can now to control costs while aiding

91 innovation just like Waxman-Hatch did. So today we are
92 hearing testimony on the newly-released Federal Trade
93 Commission report looking specifically at the issues of
94 innovation, cost, and competition. The FTC has decades of
95 expertise in this area and I value their objective and
96 comprehensive analysis. I am anxious to hear from the FTC
97 about what factors we must consider when moving forward with
98 legislation and how follow-on biologics are likely to behave
99 in the market setting as compared to generics. I am
100 especially curious to hear about what incentives and
101 protections will be necessary in a biologic and follow-on
102 biologic world that are similar or different than the current
103 brand and generic arena.

104 And I want to welcome FTC Commissioner Harbour to the
105 committee today. She comes from the State of New Jersey.
106 Thank you for coming to testify before us. I would also like
107 to welcome the author of the FTC report, Michael Wroblewski,
108 who has been invited along with the Commission to answer more
109 technical questions about the report. So thank you both for
110 being here. I now recognize Mr. Deal for 5 minutes.

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

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113 Mr. {Deal.} Thank you, Chairman Pallone, for holding
114 this hearing today on the issue of surrounding the
115 establishment of an approval pathway and of patent protection
116 concerns on follow-on biologics at the Food and Drug
117 Administration and the resulting impact that this may have on
118 competition and innovation in the biologic drug marketplace.
119 I also want to thank Commissioner Harbour for joining us
120 today to discuss the results of the Commission's very
121 recently completed report. I look forward to that testimony
122 and to the questions and answers that will follow regarding
123 that report, and we hope she will be able to provide us some
124 definition to the debate that currently surrounds this issue.
125 As this subcommittee prepares to consider fundamental health
126 reform this summer, I believe a critical component of such
127 reform must include the establishment of appropriately
128 abbreviated approval processes for follow-on biologic drugs,
129 a priority upon which innovators engineers, and manufacturers
130 both agree.

131 In 2007, global sales of biologic drugs reached \$75
132 billion, and current estimates suggest that over half of all
133 drugs, both chemical and biologic in nature, will be bio-
134 pharmaceutical products next year. Biologic drugs have
135 provided some of the most promising benefits for a wide range

136 of diseases, including anemia, hemophilia, cancer, diabetes,
137 HIV, rheumatoid arthritis, and other debilitating medical
138 conditions that affect millions of Americans every day.
139 Access to lower cost biologics represents a critical step
140 forward in reducing the overall high cost of health care and
141 will provide greater access to patients in need of these
142 critical life-saving therapies. In doing so, Congress must
143 be certain a balanced approach is established, which
144 encourages new innovation in new bio-pharmaceuticals while
145 providing more affordable options for the American people.

146 At the center of this issue, the period of marked
147 exclusivity given to innovator products, as well as patent
148 dispute resolution procedures, and the flexibility which
149 Congress will give to FDA to approve bio-similars will direct
150 our nation's ability to expound upon the advancements in the
151 biologic arena and to serve a growing number of patients in
152 dire need of these drugs. In the report under consideration
153 today produced by the Federal Trade Commission, a number of
154 arguments are made which support the robustness of our
155 current patent system as it applies to biologics and
156 highlights the question how long of a period of market
157 exclusivity must an innovator of biologic products be
158 afforded in order to yield net profit results, notably with
159 respect to the significant outlays expended in bringing the

160 product to market and how the current intellectual property
161 rights translate into the field of bio-pharmaceuticals.

162 I recognize the critical need for innovators to earn a
163 profit on innovative and cutting edge therapies, but also
164 recognize the importance of ensuring access to the American
165 people who simply cannot gain access to these critical
166 therapies solely based upon their significant cost.
167 Therefore, a delicate balancing act must be played as we
168 pursue congressional establishment of an appropriate approval
169 pathway and patent resolution processes under FDA for these
170 unique drugs. Among the report's findings, I am particularly
171 interested in the stated dynamic of competition which follow-
172 ons are likely to face upon an appropriate approval mechanism
173 once it is in place. According to the report, pioneer
174 manufacturers, potential follow-on biologic manufacturers,
175 and payors were virtually unanimous in their predictions that
176 competition from follow-on biologic drug entry is likely to
177 resemble brand to brand competition rather than brand to
178 generic drug competition.

179 And unlike chemical generic drug entry, follow-on
180 biologic entry would not result in steep price discounting or
181 rapid acquisition of market share by follow-on biologic
182 manufacturers. Therefore, although the introduction of a
183 bio-similar may result in a 10 to 30 percent reduction in

184 innovator price and an introduction of a competing product
185 into the marketplace innovator companies are still capable of
186 securing adequate positive returns on investment for years to
187 come and maintain significant market share. And it is
188 important to note the exorbitant cost of many of these
189 therapies which thousands of Americans across the country are
190 forced to accept. For example, taking a conservative 15
191 percent reduction in cost of a hypothetical follow-on bio-
192 pharmaceutical which would cost \$40,000 per year. Allowing
193 bio-similars into the marketplace could potentially save this
194 individual \$6,000 per year, which is a dramatic step toward
195 reigning in the cost of these drugs while encouraging
196 innovation.

197 There are a lot of questions which remain. I remain
198 committed to working on this issue, an issue which I do
199 believe cannot wait any longer to be addressed. I appreciate
200 the cooperation of my colleagues on this committee. I look
201 forward to the testimony. I look forward to working together
202 cooperatively as we move this issue forward. Thank you, Mr.
203 Chairman.

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

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

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206 Mr. {Pallone.} Thank you, Mr. Deal, and thank you for
207 prioritizing this issue. And now the chairman, Mr. Waxman.

208 The {Chairman.} Thank you very much, Mr. Chairman.
209 Today, we are going to hear from the Federal Trade Commission
210 on an issue of paramount importance to the debate on a
211 pathway for approval of follow-on biologics, how long a
212 period of exclusive marketing must we give to biotech drugs
213 to sustain innovation. As was true when Congress passed the
214 Hatch-Waxman Act 25 years ago, an effective follow-on
215 biologics bill must maintain a balance between increasing
216 consumer access to affordable medicines on the one hand and
217 providing adequate incentives for innovation on the other.
218 Life-saving drugs are useless if no one can afford them, yet
219 making today's drugs affordable does us little good if we cut
220 off the supply of future breakthroughs. We have made great
221 progress in the last 3 years toward a consensus on how to
222 ensure that follow-on biologics are safe and effective. Just
223 2 years ago the drug industry argued that it was impossible
224 to make follow-on biologics. Now there is agreement that it
225 can be done.

226 But we remain divided on what incentives are needed for
227 innovation. It is no longer a matter of whether patients
228 will get generic versions of these life-saving medicines but

229 when. In assessing how much exclusive marketing is needed to
230 sustain innovation, I began with a basic premise. The
231 balance we struck in the Hatch-Waxman Act has worked well for
232 25 years. It has given us access to affordable drugs and it
233 has not damaged innovation. Pharmaceutical R&D expenditures
234 have not just been maintained, but have steadily risen
235 throughout these 25 years. Under Waxman-Hatch innovative
236 drugs get 5 years of exclusivity. The drug industry has been
237 engaged in a massive and expensive lobbying campaign to
238 convince the members of this committee that the supply of
239 life-saving drugs will dry up if they don't get triple the
240 monopoly protection available to all other drugs. The drug
241 industry is demanding 12 or even 14 years of exclusivity for
242 biotech drugs.

243 To support this extraordinary request, the industry
244 makes 2 main arguments. First, that their patents are much
245 weaker than drug patents and won't block competition from
246 follow-ons. Second, that it takes 12 to 16 years for biotech
247 drugs to break even so that is the period of exclusivity they
248 need. Though I have seen little or no persuasive evidence to
249 support these arguments, the industry has blanketed Capitol
250 Hill with them. The outcome of this debate is too important
251 for our nation's health to let lobbying cloud decided. The
252 cost of reaching the wrong decision is simply too high.

253 Instead, the appropriate length of exclusivity must be
254 decided on the basis of evidence and analysis by objective
255 experts, experts who are not being paid by one side or the
256 other. That is why I am so pleased that the Federal Trade
257 Commission has undertaken an in-depth review of all the
258 evidence and arguments on both sides of this debate. The FTC
259 employs economists, patent lawyers, and experts in the
260 pharmaceutical marketplace. Their job is to assess the
261 impact of laws, regulations, and marketing practices on both
262 competition and innovation in the prescription drug
263 marketplace.

264 The FTC has overseen this marketplace for decades and
265 has produced highly respected reports on generic drug
266 competition and anti-competitive practices in the drug
267 marketplace. For example, in 2002 the FTC produced a report
268 on abuses of Hatch-Waxman that inappropriately delayed
269 consumer access to generic drugs. The report resulted in
270 important amendments to our law enacted the following year.
271 Today, the FTC will tell us whether the methods we have used
272 to sustain innovation in the drug industry, patents, and the
273 market-based pricing with perhaps a short period of
274 exclusivity are adequate to sustain innovation for biotech
275 drugs, and they will tell us whether the argument is in favor
276 of 12 to 14 years of exclusive marketing hold up to scrutiny.

277 Objective evidence-based answers to these questions from the
278 expert agency charged with overseeing competition and
279 innovation of the drug marketplace will provide critical
280 information to the committee as we move forward. I look
281 forward to exploring the FDC's analysis and conclusions on
282 these questions. Thank you very much, Mr. Chairman.

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

284 ***** COMMITTEE INSERT *****

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285 Mr. {Pallone.} Thank you, Chairman Waxman. Next is the
286 gentleman from Kentucky, Mr. Whitfield.

287 Mr. {Whitfield.} Mr. Chairman, thank you very much for
288 this important hearing today on an important subject matter.
289 All of us are in total agreement that some type of generic
290 pathway for biological drugs must be created. I think it
291 demonstrates by the different bills that we have that there
292 are some significant differences in how we create that
293 pathway. We all understand yesterday that the Federal Trade
294 Commission's report was submitted and it leaves many of us
295 with some serious concerns with their findings, specifically
296 the claim that data exclusivity is essentially unnecessary in
297 a generic pathway. The scenario outlined by the FTC would, I
298 believe, unfairly tilt competition in favor of bio-similars
299 by allowing them to capitalize on innovators substantial
300 research and development efforts at any time. This would
301 create even more uncertainty, I believe, for innovators when
302 they make their R&D decisions.

303 I might also say that Professor Dr. Henry Grabowski at
304 Duke University, and you all can correct me if I am wrong on
305 this, but I believe he has the only peer-reviewed document on
306 this, and he summarized the findings of his study that
307 concludes that without a data exclusivity period of between

308 13 and 16 years the future introduction of important new
309 medicines could be delayed significantly or deterred
310 altogether and that a strong innovative industry is necessary
311 for an industry to thrive over the long term. So we find
312 ourselves today trying to balance the need for new drugs
313 providing low cost medicines for our senior citizens, and so
314 this hearing is vitally important, and I certainly look
315 forward to hearing from the Federal Trade Commission today
316 and learning more about their report and how it compares with
317 Dr. Grabowski's report. And thank you very much.

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

319 ***** COMMITTEE INSERT *****

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320 Mr. {Pallone.} Thank you. Next is the gentlewoman from
321 California, Ms. Eshoo, and I want to thank her also for all
322 her work on this issue.

323 Ms. {Eshoo.} Thank you, Mr. Chairman, and good morning
324 to everyone that is here. I am pleased to be here to discuss
325 competition in the biotechnology industry, but I have to say
326 that I am puzzled and somewhat disappointed by the
327 subcommittee's approach to this critical issue. Everyone
328 understands that this is not only critical, it is extremely
329 complex. In May of 2007, over 2 years ago, the Health
330 Subcommittee had a hearing on bio-similars. In October of
331 2007 subcommittee members met to discuss bio-similar, and the
332 result of that meeting, as members might recall, was a series
333 of questions that the members provided to stakeholders and
334 the FDA several months later in April of 2008. We received
335 thoughtful, thorough responses from a large number of
336 interested organizations and experts.

337 Now today this is the first committee action on bio-
338 similars in more than 2 years and a hearing on an FTC report
339 we received less than 24 hours ago. When we were informed
340 that there was going to be this hearing, we immediately
341 called the FTC to ask for a copy of the report. They said
342 that we could not have it, that it would be available the

343 morning of the hearing. I then, Mr. Chairman, approached you
344 and asked if members could at least see this the day before.
345 Why have a hearing if you can't read the report that you are
346 having the hearing on? So we did receive it. I don't know
347 how many members have read this report, and I don't think
348 that this process really reflects well on I think the most
349 distinguished full committee and subcommittee in the House.

350 Now I assume that the FTC has devoted significant
351 efforts and resources in putting this report together, but I
352 am not convinced that the FTC Commission is--and what they
353 have in this report are exactly what we have been waiting for
354 2 years to hear about. I have met with many scientists,
355 doctors, patients, who have much to contribute to the
356 subcommittee's deliberations, but we only have the FTC here
357 today, and I guess it was the decision of the chairman not to
358 have anyone else. This is a report that has not even had
359 been subjected to the scrutiny of the public. I think that
360 we can do better than that. Now what does the FTC report, as
361 I read it as quickly as I could, what does it conclude? It
362 says that increased competition in the biotechnology industry
363 would result in lower prices for biologics. It is exactly
364 why I introduced along with Mr. Inslee, Mr. Barton, the
365 Pathway for Bio-Similars Act.

366 This is the Kennedy legislation in the House. Now

367 competition is always healthy. Anyone that has known me over
368 the 16-1/2 years I have been in the Congress knows that I
369 believe that it benefits consumers whether it is in
370 biotechnology, whether it is in telecommunications, whether
371 it is in energy, whether it is health care, or whether it is
372 baseball. I am a staunch advocate of fair competition and
373 open markets, and I believe that my legislation will provide
374 new competition while promoting sound science, and above all
375 else protect patients. Any new pathway for bio-similars must
376 provide effective safeguards for patients and sufficient
377 incentives for the development of new treatments for the most
378 deadly diseases that affect humankind today.

379 I am pleased that my bill enjoys the support of just shy
380 of 100 members, bipartisan members, of the House, and it has
381 received the endorsements of over 70 patient, physician,
382 industry, and academic groups, as well as governors of 4
383 states. So I think that we need to be respectful of both
384 efforts. And I am very proud of this because this is a
385 complicated issue, and the amount of time spent with members,
386 as well as members of the public and others, has been
387 considerable. The establishment of a new regulatory pathway
388 for approval of bio-similars is a critical matter for this
389 subcommittee and the Congress to consider. I am eager to get
390 to work on this, and I encourage you, Mr. Chairman, to hold

391 more thorough and more inclusive hearings in the near future.
392 I am glad that the FTC is here today. My understanding of
393 the FTC is that most of its work deals with anti-trust. In
394 my questions, I would like to know where the scientific data
395 and the basis for the report has come from, but I nonetheless
396 welcome the FTC here. You are an important agency. And I
397 thank you, Mr. Chairman, and I hope that when I ask you why
398 we were doing it this way, your response was it is the only
399 time we have before the August recess.

400 I think it could have been broader. I think the
401 subcommittee deserves that. I think the full committee
402 deserves that. I think the House of Representatives deserves
403 that on this issue which is so critical, so critical, to the
404 well-being of patients and a process by which we can reduce
405 the cost of biologics for people in our country. So, thank
406 you, and I yield back.

407 [The prepared statement of Ms. Eshoo follows:]

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409 Mr. {Pallone.} Thank you. And let me assure the
410 gentlewoman, as I said, that we will have additional hearings
411 on this very important issue.

412 Ms. {Eshoo.} When do you plan to do that?

413 Mr. {Pallone.} Well, as I mentioned, we are going into
414 the health care debate, so I can't say when, but I promise
415 you we will because this is a very important issue for the
416 members. Let me turn to the gentleman from Texas, Mr.
417 Burgess.

418 Mr. {Burgess.} Thank you, Mr. Chairman. Mark me down
419 as leaning ambivalent on this issue. Now just like everyone
420 who sits on this committee, I know we have all spent months
421 looking at the legislative proposals dealing with follow-on
422 biologics. I know I personally have been in meeting after
423 meeting with interested parties, and I have become convinced
424 that this committee needs to hold more hearings. We lack
425 sufficient information, primarily safety information, to
426 render an informed opinion. We do have 2 bills championed by
427 leaders on this committee, and we obviously need to explore
428 those divergent points of view involved. Certainly, like
429 Congresswoman Eshoo, I welcome Commissioner Harbour here.
430 There are lots of things that I would like to discuss with
431 the Federal Trade Commission. I am terribly interested in

432 the lack of the ability of our physician community to be able
433 to negotiate with our insurance community, but we don't get
434 to do that today.

435 So my excitement with this hearing was tempered when I
436 realized we really only going to be focusing on a very narrow
437 aspect of the bio-similars discussion, and that very narrow
438 aspect will not include patient safety. Market exclusivity
439 and patent integrity are important elements of any
440 legislation authorizing a pathway for follow-on biologics. I
441 was unaware that this committee had already achieved
442 consensus on issues of safety, science, and the Food and Drug
443 Administration. Assuming this committee has not reached such
444 a consensus, then it is just downright frustrating that the
445 Food and Drug Administration is not here in this room at this
446 hearing. Now assuming that we didn't want to hold a series
447 of hearings on points of disagreement and wanted our first
448 focus to be on market forces, as we will today, then a second
449 panel representing concurring or dissenting opinions from
450 industry would be appropriate in my opinion.

451 And then maybe we could even hear from the scientists
452 and the doctors. Mr. Chairman, I referenced last week I took
453 a field trip out to the Food and Drug Administration last
454 week. I had some wonderful interactions with some of the
455 scientists who are working on some of these very issues, the

456 issues of bio-similars as they relate to monoclonal
457 antibodies. This is the type of research that may unlock a
458 lot of secrets that have been kept from our physician
459 community for years, and it is just such terribly important
460 information that I cannot believe we are going to be asked to
461 make a decision without access to that information. I will
462 be interested to what extent the Commissioner will be able to
463 testify on the issue of interchangeability.

464 Interchangeability is one of the foremost at issue of
465 science, but it is importantly one of patient safety and that
466 should have a physician and patient at the heart of the
467 discussion.

468 I would not typically associate the Federal Trade
469 Commission with such discussion. Mr. Chairman, I am
470 fascinated by the prospect of a reliable, bio-similar
471 pathway. Texas is becoming a focal point for bio-technology
472 development. Not only does this mean new therapies for
473 previously untreatable diseases with just the chance of
474 projection that 50 percent of the drugs by 2020 will be
475 biologics so this is a huge economic issue for Texas as well.
476 Just as scientists and doctors have just scratched the
477 surface of potential biologics for the next generation of
478 cures and treatments, this committee has plenty of work to do
479 to find a compromise bill that solidifies our ambitions and

480 meets or exceeds our expectations. No artificial deadline,
481 and this goes to the health reform debate as well, no
482 artificial deadline should compel us to ride rough shod over
483 the deliberative nature of this body in regular order. To do
484 so not only tarnishes this great committee but could
485 literally mean life or death for our constituents. Thank
486 you, Mr. Chairman. I will yield back the balance of my time.

487 [The prepared statement of Mr. Burgess follows:]

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489 Mr. {Pallone.} Thank you. The chairman emeritus, Mr.
490 Dingell.

491 Mr. {Dingell.} Mr. Chairman, thank you, and I commend
492 you for holding this hearing, which is very important. We
493 are here to discuss the findings of the Federal Trade
494 Commission with respect to its study on how competition
495 between pioneer biologics and follow-on biologics is likely
496 to develop. This is a series of hearings, which I hope will
497 take place, which is wrought with many, many questions of
498 great importance and many fewer answers of any relevance or
499 importance. We have a tremendous opportunity here to develop
500 a follow-on biologics policy that will bring the competition
501 needed to provide greater access on life-saving biological
502 drugs. However, we also have a responsibility to ensure that
503 the innovation that develops the current biologic products
504 continues in a way that will breed new effective therapies or
505 a new group of conditions.

506 One thing the FTC report makes abundantly clear is that
507 biologic products are different from small molecule chemical
508 drugs. They are enormously complex, much longer, and they
509 are also either products of or sometimes living organisms.
510 The science is clearly different. The safety considerations
511 between the 2 categories of drugs are different. And as the

512 FTC report concludes, the competition between pioneer
513 products and generic competitors is different. It must be
514 noted that we will find that the traditional questions that
515 FDA has had to address will be somewhat different either in
516 form or in total. And the question of whether it is safe,
517 biologically equivalent, what are the side effects,
518 contraindications, and whether it is effective are going to
519 be interesting and different questions that have to be
520 addressed.

521 It also is going to be a major question before us as to
522 how we address the question of biological equivalency and
523 whether or not one drug is an honest, safe substitute for
524 another which could properly be prescribed with expectation
525 of helping rather than hurting the patient. In 1984,
526 Congress granted the FDA authority to approve generic drugs,
527 and we all commend Chairman Waxman for his leadership in that
528 effort. We did not foresee the need for similar pathway for
529 generic biologics. The science has exploded under our feet
530 since then and in certain instances biotechnology provides
531 clear technical advantages over other traditional therapies.
532 We also need to examine if exclusivity limitations that we
533 create is reflective of true costs in time and resources.

534 We also need to know how this is going to affect the
535 cost of medicine and how it is going to impact on our efforts

536 to reduce the tremendous skyrocketing now going on in health
537 care costs. We also want consumers to make sure that there
538 is affordable access to these life enhancing and sustaining
539 therapies. What is the path forward on exclusivity? Is it 5
540 years, 12 years or 14 years, more or less? Eleven years the
541 European has set forth. We need to create a framework that
542 balances good science and the public health. We can also
543 focus on patient safety and at the same time ensure that
544 incentives remain for private innovation.

545 The FTC report does a good job of laying out the
546 economic and competitive effects of a follow-on biologics
547 policy. However, we should be reminded that safety should be
548 our number 1 priority, and protection of the American
549 consuming public should be of the highest priority. Policies
550 that protects the safety of the patient is paramount as we
551 forge ahead in the new area of follow-on biologics. We
552 should be thoughtful as we move forward but not allow fear to
553 restrict us, but above all else we have got to move forward
554 to get the answers to the question. Here are a few questions
555 that I find troublesome. What standards will ensure that
556 follow-on biologics are as safe as the original products, and
557 that we provide the necessary knowledge to medical
558 practitioners in the use of these products.

559 As we study potential competition models, should we be

560 guided by a one size fits all approach or should we allow
561 different approaches, and, if so, when, how, and what
562 discretion should we give FDA to use those, or should there
563 be a variation from one product to another? What study
564 should support follow-on biological applications? Can a
565 generic biologic product be created that is genuinely or
566 sufficiently interchangeable? People tell us yes, people
567 tell us no. But in this area of enormous complexity, I am
568 not convinced that we can give a decent answer to that
569 question. I am convinced that all these questions could be
570 answered and that there is a way forward in developing sound
571 follow-on biologic policy that provides greater access to
572 current products and supports innovation in developing new
573 ones.

574 I look forward to contributing to that discussion, and I
575 know that this committee is fully up to the task for which we
576 were created, and that is dealing with questions of this
577 kind. I am pleased this hearing is being held. I look
578 forward to the testimony, and I anticipate much needed
579 feedback from our members. And I thank you, Mr. Chairman.

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

581 ***** COMMITTEE INSERT *****

|
582 Mr. {Pallone.} Thank you, Chairman Dingell. The
583 gentlewoman from Tennessee, Ms. Blackburn.

584 Ms. {Blackburn.} Thank you, Mr. Chairman, and I want to
585 say welcome to our witnesses today. Members on this
586 committee have heard me talk a little bit about serving in
587 the State Senate in Tennessee, and one of the things that I
588 worked very diligently on while I was there was starting our
589 Tennessee Biotech Association. And now that has 130 members
590 across our state, and they really have become the recognized
591 authority on biotech research in our state. Right now we
592 have got about 300 companies that are life science companies
593 that are working in Tennessee that are innovating every day,
594 and they are working with pharmaceutical companies and bio-
595 science companies large and small to create new products and
596 therapies and protocols. And we are very pleased with the
597 work that they are doing.

598 We are also pleased with the work that is being done by
599 many of our universities in Tennessee, which have taken a
600 lead in this. And they received \$580 million in external
601 funding for biotech related research in our universities in
602 the past year, and the University of Tennessee Health Science
603 Center has Memphis Bioworks. We have complimentary work that
604 is being done at St. Jude's. We have the life sciences

605 center where Vanderbilt has a partnership and that is in the
606 mid state area East Tennessee State University of Tennessee
607 and Oak Ridge over on the east side of our state, and in the
608 past 6 years along with the funding that has gone to the
609 universities you have seen just under \$1 billion in venture
610 capital go into innovations.

611 So I am pleased to be able to praise that innovative
612 industry in our state but I will tell you I am very concerned
613 about protecting the intellectual property of the industry in
614 that state, and, quite honestly, as I read through your
615 report, it was something that was of concern to me. And I am
616 going to have some questions for you today as we move forward
617 with this hearing. One of the things that I felt as I read
618 your report, if you followed the scenario, the patient
619 scenario that you lay forth, then it appears that bio-
620 similars could be brought to market while they are still
621 infringing on valid patents. And as my colleagues know, last
622 week when we debated the energy bill, I sought to bring
623 intellectual property protection for those innovators that
624 are working in the energy sector. Yesterday on the Floor,
625 Congressman Larson, Congressman Kirk and I had an amendment
626 that went in to provide protection for this innovation.

627 So this raises some red flags with me of how
628 infringement could be allowed and product brought to market.

629 It raises red flags to me that it is uncertainty that would
630 be placed on our innovators. And I see that as a hamper to
631 R&D which we badly need. I know I am over my time, and we
632 are going to have votes. I will yield back, and I do look
633 forward to the questions. Thank you, Mr. Chairman.

634 [The prepared statement of Ms. Blackburn follows:]

635 ***** COMMITTEE INSERT *****

|
636 Mr. {Pallone.} Thank you. The gentleman from Utah, Mr.
637 Matheson.

638 Mr. {Matheson.} Thank you, Mr. Chairman. I think we
639 all know as we go into the 21st century and we look at the
640 U.S. economy innovation is such a key factor in how our
641 economy is going to succeed. I think it is very important to
642 remember that in the context of today's hearing because
643 within the innovation economy few industries have more
644 promise and more uncertainty and risk than the biotechnology
645 industry. The biotech industry supports more than 3.2
646 million jobs in the United States, and we all know many of
647 these are high wage jobs, but we should also acknowledge that
648 this is an industry where the U.S. is still the leader in the
649 world. This is one of those centers of excellence that is in
650 the United States when you look at the global economy.

651 Yet with all that good news more than 80 percent of the
652 biotech companies in our country remain unprofitable, and a
653 third of the companies had less than 6 months cash on hand.
654 And this is with no competition from follow-on products. The
655 companies that make up the majority of this industry are
656 small. They have no source of revenue and they are operating
657 solely on the hope that they will achieve a major
658 breakthrough in medicine. So one of the main issues up for

659 discussion today is the issue of date of exclusivity, how
660 much time should an innovative biotechnology product have on
661 the market to try to recoup investment in research and
662 development before a follow-on biologic is approved. The
663 average cost of developing a biologic is about \$1.2 billion.

664 Clearly, that is an expensive investment, particularly
665 when you have no revenues coming in the door. I think we all
666 can agree that competition in the market for medicines is a
667 good thing. It brings down costs for individuals and for the
668 health care system as a whole, and I fully support
669 establishing a pathway for approval of follow-on biologics.
670 However, I believe we need to be sure we are creating
671 appropriate incentives for biotechnology companies to take
672 the risks involved in bringing these medicines to patients.
673 Now I understand that the FTC believes that 5 years is a
674 sufficient period for data exclusivity for innovative
675 biotechnology products. I disagree.

676 As I said earlier, this is one of America's strengths,
677 but we got to look at the context of global competition. The
678 exclusivity period in Europe is longer than 5 years. This is
679 an industry that can move offshore in a moment, and as
680 members of Congress, we need to take that in consideration
681 when we set this type of policy. A recent report from Duke
682 University shows that the break even point for most biologics

683 is somewhere between 12 and 16 years. With an appropriate
684 incentive, the researchers at Duke believe a few companies or
685 venture capitalists will invest the necessary capital to
686 research and develop a biotech product.

687 These products are going to be developed in this
688 country, not necessarily with taxpayer dollars. That last
689 statement I just made about this is an industry that is
690 financed through venture capital and other private capital
691 markets, and the public policy platform we wet will establish
692 proper incentives, I hope, to allow that private investment
693 to happen. These are the issues we ought to be talking about
694 today. It is our job to take these steps to make sure this
695 innovation agenda has an opportunity to succeed in this
696 country. And I would hope, Mr. Chairman, as others have
697 voiced that this subcommittee can bring in other witnesses
698 besides just the one panel today to bring in other points of
699 view as we examine this very important issue. I look forward
700 to working with the committee on that, and I will yield back
701 the balance of my time.

702 [The prepared statement of Mr. Matheson follows:]

703 ***** COMMITTEE INSERT *****

|
704 Mr. {Pallone.} Thank you. The gentleman from Georgia,
705 Mr. Gingrey.

706 Mr. {Gingrey.} Mr. Chairman, thank you very much. I
707 would tend to agree with Ms. Eshoo that getting the report
708 from the FTC at 2:00 yesterday afternoon really allows very
709 little time to go through the 120 pages. I have to admit
710 that I haven't had an opportunity to go through any of it, so
711 I certainly do look forward to the witness that we are going
712 to hear from shortly. This is a hugely important issue, this
713 issue of follow-on biologics, and as we all know there are 2
714 bills introduced on the one hand by leadership on the
715 majority side combined with some leadership from the minority
716 side, and also a bill on the minority side co-authored by
717 Ranking Member Barton. I looked at these bills. I have
718 studied them. I have tried to understand on the one hand 16
719 years, I guess, of exclusivity and on the other hand 8 years.
720 The issue of interchangeability, once these generic
721 biologics, follow-on biologics, are actually approved by the
722 FDA, I think is a very important issue.

723 And it is tough. It is a tough thing to decide on, and
724 we just need, as my colleagues have said, as much information
725 as we can possibly get, particularly in regard to patient
726 safety because as the chairman emeritus said these are not

727 single molecules or small molecules as we dealt with back in
728 1984 under Hatch-Waxman. These are different. These are
729 living cells, and every manufacturing process for these drugs
730 are different, and there is no way to make them completely
731 the same, so it is going to be a tough thing. I would hope
732 that maybe there is room for compromise, quite honestly. As
733 we listen to the debate and study further the 2 particular
734 bills because there are great members that are trying to do
735 the right thing and trying to make sure that we get cost
736 effective, I don't want to say cheap, but cost effective,
737 the very expensive medications to the public as soon as
738 possible, but also that we have to always keep in mind
739 safety. So I look forward, Mr. Chairman, to the hearing and
740 getting more information on this hugely important issue. And
741 yield back.

742 [The prepared statement of Mr. Gingrey follows:]

743 ***** COMMITTEE INSERT *****

|
744 Mr. {Pallone.} Thank you. The gentlewoman from
745 California, Ms. Harman.

746 Ms. {Harman.} Thank you, Mr. Chairman. I am a new
747 member to this subcommittee, and I surely agree with Ms.
748 Eshoo that this subject is complex, and I am persuaded that I
749 don't know enough about it to have a final opinion. That is
750 why I am happy we are having this hearing, and that we will
751 have a series of hearings in the fall. I have not co-
752 sponsored either of the pending bills because I feel I need
753 to learn more. But surely I know enough to believe that we
754 should be getting reports more than 18 hours in advance of
755 hearings, and I hope that in the future that will happen so
756 that all of us can be as knowledgeable as possible. I just
757 want to say a couple things about the general subject.

758 First of all, although new to the committee, I am not
759 new to this earth and I am not new to Congress, and I
760 remember 1984 when Henry Waxman did something very
761 impressive, and that was to strike an agreement with his
762 political opposite Orin Hatch on a bill that the drug
763 industry strongly opposed and that has led to considerable
764 progress, so I really think these things can happen and be
765 done right, and that is a history in our committee, and
766 hopefully we will follow it again. But this time, I think

767 this subject is more complicated and I think the
768 implications, as Mr. Matheson said, for the future of the
769 U.S. industry are grave. I don't know much about this
770 subject, but I do know what we did to the U.S. commercial
771 satellite industry when in my opinion we got it wrong in the
772 late 1990's, and we basically took away the market edge for
773 our U.S. satellite makers.

774 Now we are trying to get it back. Hopefully we will,
775 but we lost 10 years, and so I just want to make sure we get
776 this right, and I want to be sure that I make the best
777 contribution I can as a hopefully thoughtful member of this
778 committee. So I thank you for holding this hearing, and I
779 look forward to learning a lot more about this subject. I
780 yield back.

781 [The prepared statement of Ms. Harman follows:]

782 ***** COMMITTEE INSERT *****

|
783 Mr. {Pallone.} Thank you. The gentleman from
784 Pennsylvania, Mr. Pitts.

785 Mr. {Pitts.} Thank you, Mr. Chairman. I would like to
786 thank you for convening this hearing on the Federal Trade
787 Commission's report, Emerging Health Care Issues: Follow-on
788 Biologic Drug Competition. I think all of us realize the
789 potential of follow-on biologics, and I believe we all agree
790 on the need to set up a pathway sooner rather than later. I
791 must say also that it would have been more helpful to give
792 the members a little more time until we had a time to read
793 and analyze this 120-page report, which was released just
794 yesterday before having the hearing. I am quite concerned by
795 the report's assertion that no period of data exclusivity is
796 necessary for pioneer or brand biologics because patents and
797 market pricing should provide sufficient protection and
798 incentive. This logic has worked well for small molecule
799 drugs governed by Hatch-Waxman but as this report points out
800 multiple times there are significant differences between
801 small molecule drugs and biologics.

802 As the report acknowledges, a generic small molecule
803 drug is identical to its brand counterpart. A follow-on can
804 only be similar to the brand biologic. It is this space
805 between identical and similar that opens the door for a

806 follow-on to circumvent or skirt one or more of the brand
807 biologic's patents. With this uncertainty over whether a
808 patent will actually protect the brand biologics investment
809 biotech companies and the venture capitalists that fund them
810 may reassess the cost and risk involved in the development of
811 new biologics and opt not to go forward with new drug
812 development. Stifling innovation and potentially impeding
813 patients' access to the most promising, cutting edge
814 biologics is surely not the goal of anyone on this
815 subcommittee.

816 Data exclusivity provides the certainty brand biologics
817 need to spend hundreds of millions of dollars and years
818 investing in the research, development, and approval of new
819 drugs, and the assurance that this investment can be
820 recouped. I would ask our witnesses to carefully explain why
821 they believe that patent circumvention by bio-similar
822 companies is not a valid scenario. Thank you, and I yield
823 back the balance of my time.

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

825 ***** COMMITTEE INSERT *****

|
826 Mr. {Pallone.} Thank you, Mr. Pitts. The gentlewoman
827 from the Virgin Islands, Ms. Christensen.

828 Ms. {Christensen.} Thank you, Mr. Chairman, and thank
829 you for beginning this discussion on this very important and
830 complex issue at this hearing. As I understand it, the
831 report was requested basically to determine if follow-on
832 biologics would result in reductions in cost of these complex
833 but very important therapeutic drugs, and anyone who knows me
834 would know that one of my concerns is that life improving or
835 saving medication be accessible to everyone, and, yes, cost
836 is an important barrier to that. But as a physician, safety
837 trumps everything. I have seen substandard meds marketed in
838 the Caribbean, and in small molecular drugs that may not be a
839 dangerous difference. The situation with bio-similars or
840 follow-up biologics is totally different. I only had a
841 chance to read the executive summary and some of the first
842 pages of the report, but what I have taken away so far is a
843 clear understanding that biologics are very complex, large
844 molecules produced under very sensitive conditions that are
845 not easy to reproduce exactly, that significant investment is
846 made in their production and that if reduction of cost is
847 what has generated the request for this report FOBs are not
848 likely to result in much of a price decrease.

849 If the latter is true then why sacrifice safety? And
850 some questions remain unanswered. Why accept a similar
851 rather than the same in the case of such a complex medication
852 when a tiny difference could make a difference in its action
853 and its immunogenicity. I am puzzled by the assertion also
854 that a shortened patent life will not stifle innovation. If
855 it takes 12 to 14 years to recoup investment as demonstrated
856 by a peer review article by Duke Professor Grabowski, and
857 that is likely after many trials have failed at that company
858 and they have experienced financial losses, why should these
859 complex molecules not have a longer time? Very importantly,
860 the report states that technology is not yet, and I am
861 quoting here, ``technology is not yet robust enough to
862 determine whether an FOP product is interchangeable with the
863 pioneer product.''

864 That statement, plus the fact that not a single country
865 in the EU has authorized interchangeability, and several have
866 outlawed it, should slow down any rush to allow products that
867 are only similar to the pioneer, and to require more of any
868 follow-on manufacturer to prove safety. It seems to me that
869 sufficient uncertainty exists so that the FTC didn't even
870 make a specific recommendation for a period of exclusivity.
871 I would like to see these important drugs reach everyone, and
872 that means exploring ways to ensure that that happens,

873 including having the pharmaceuticals look after a period of
874 time perhaps reducing the costs, but I am convinced that
875 shortening the time of patent and data exclusivity would
876 adversely impact needed innovation, and it seems to me that
877 based on the complexity of the large molecules and the lack
878 of information on several factors, we should err on the side
879 of safety and make sure that we do no harm. So I welcome
880 Commissioner Harbour and look forward to your testimony.
881 Thank you, Mr. Chairman.

882 [The prepared statement of Ms. Christensen follows:]

883 ***** COMMITTEE INSERT *****

|
884 Mr. {Pallone.} Thank you. The gentleman from Indiana,
885 Mr. Buyer.

886 Mr. {Buyer.} I have come here today, I also like my
887 colleague, Jane Harman, I have not co-sponsored either of
888 these 2 bills yet, and I find myself in a curious position
889 why we are even seeking the counsel of the Federal Trade
890 Commission on an issue whereby we are most concerned with
891 regard to the drug safety and efficacy. When I look at the
892 commissioners from the Federal Trade Commission, none of them
893 have any experience in public health whatsoever. We got
894 lawyers. Well, I am a lawyer too, so what I need is not the
895 advice or counsel of another lawyer. I need advice and
896 counsel from public health, from scientists. So we have a
897 conversation today lawyer to lawyer. You can give me your
898 opinion on what you think the marketplace is and what it is
899 like, and I guess if you are going to tell me about trying to
900 promote competition in the drug industry, big versus small,
901 and how we protect innovation as part of your core mission of
902 the FTC, I guess we may as well ask you to report on NASA.

903 Gee, let us talk about what big company it out there and
904 how we can promote innovation to do exploration in space.
905 Hey, the last frontier isn't even space, it is marine. So
906 maybe we should ask for a report from the FTC about the

907 exploration on the ocean floor. You can give me an opinion
908 on that. Maybe I should ask for--I will just make it up. So
909 I am sitting here today as a curious member of Congress that
910 I have come here to listen to lawyers tell us what they think
911 about drug efficacy and safety. Now I haven't had a chance
912 to read this. I am more than anxious to look at it. I am
913 also curious as to who initiated this. Did anyone from
914 Congress ask you to do this? I don't know. So I am
915 interested for you to let us know why you initiated this, why
916 this group of lawyers think that your opinion is so important
917 with regard to efficacy and the safety of drugs.

918 Now what bothers me the most is that what I have learned
919 over the years in dealing with the drug industry and
920 biologics is that we do everything we can to promote this
921 innovation, yet we try to find science in narrow populations,
922 and it is very challenging because when you go into the
923 marketplace, how do you raise that at risk capital, and if we
924 don't give these companies an opportunity to recoup their
925 cost and make a profit, they won't go into narrow spectrums,
926 and if they won't go into narrow spectrums then people then
927 turn to government and say that government, you have to do
928 it. And if it is all about innovation, safety, and efficacy,
929 I want to hear from the experts, Mr. Chairman. So what I am
930 hopeful is that if you are going to do this today, please

931 bring us a panel of experts, the FDA, bring in the scientists
932 so that we can have equal quality here with regard to
933 substantive testimony. That is what I am looking for. That
934 would be my request of you, Mr. Chairman. I yield back.

935 [The prepared statement of Mr. Buyer follows:]

936 ***** COMMITTEE INSERT *****

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937 Mr. {Pallone.} The gentleman from Texas, Mr. Green.

938 Mr. {Green.} Thank you, Mr. Chairman, and like my
939 colleagues, I have concerns about this hearing on the FTC's
940 report that we received yesterday on follow-on biologics
941 competition. We have heard this will be the only hearing on
942 the issue of follow-on biologics because the schedule will
943 not accommodate additional hearings on the topic. If we are
944 going to have a fair debate on follow-on biologics and the
945 issues surrounding H.R. 1548, the Eshoo-Barton-Inslee Pathway
946 to Bio-Similars Act, which I am a co-sponsor, and H.R. 1427,
947 the Waxman-Pallone-Deal Promoting Innovation and Access to
948 Life-Saving Medicine Act, the arena for those should not be
949 centered around a hearing with one witness from the FTC.

950 Follow-on biologics are extremely complex issues and
951 members of this committee are divided between the 2 bills
952 pending before us. One hearing with one witness who isn't
953 from the FDA, an innovator company, a generic drug company,
954 or even a patient who has used biologics is not a true
955 hearing on the difficult issues surrounding follow-on
956 biologics. We believe we need to have a hearing with at
957 least the FDA before this committee moves forward with any
958 legislation on follow-on biologics. I think we can all agree
959 that there needs to be a regulatory path in this country to

960 follow-on biologics, and however we resolve the differences
961 between the 2 bills, we need to consider the implications for
962 employers, innovators, the generic industry, and, most
963 importantly, the patients who depend on these life improving
964 and life-saving therapies.

965 Biologics offer tremendous promise in the treatment of
966 disease but there is no question we have to get it right.
967 The undeniable fact is biologics are different from the small
968 molecule drugs and present unique concerns about their safety
969 and effectiveness. Holding one hearing that doesn't allow us
970 to explore the questions such as what effect does a small
971 change in immunoacid sequence produce, is that effect large
972 enough and concerning enough to warrant additional clinical
973 trials before the follow-on biologics is available to the
974 public, can we in good conscience consider the follow-on
975 product safe if they are never even tested on the human
976 population?

977 I share the goal of lowering patients' costs to follow-
978 on pathway but not at the expense of the same patients'
979 safety. Any action by the committee must balance the desire
980 for the lower cost of biologics with the need to preserve the
981 incentives for innovation and patient safety so that more
982 Americans can benefit from the therapeutic promise of
983 biologics. And again I thank you and yield back my time.

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

985 ***** COMMITTEE INSERT *****

|
986 Mr. {Pallone.} Thank you. The gentleman from Illinois,
987 Mr. Shimkus.

988 Mr. {Shimkus.} I knew I could be here when the gavel
989 dropped and go to the next meeting and still make it, so I
990 apologize to the Commissioner. I would just read from the
991 report here on the executive summary. Current technology
992 does not yet allow the creation of an exact replica of a
993 pioneer biological drug product according to the FDA. In
994 addition, technology is not yet robust enough to determine
995 whether the follow-on biologic product is interchangeable
996 with the pioneer products such that a patient would be able
997 to switch between the 2 products without risk of an adverse
998 effect. Follow-on biologics are not chemical compounds. We
999 need more hearings on this, Mr. Chairman, and we need to have
1000 science brought in. And with all respect to the FTC, they
1001 are not the ones. They are not the ones to give us the
1002 direction on the safety and efficacy on follow-on biologics,
1003 so I look forward to that, and I hope we can follow up with
1004 more hearings. I yield back.

1005 [The prepared statement of Mr. Shimkus follows:]

1006 ***** COMMITTEE INSERT *****

|
1007 Mr. {Pallone.} Thank you. The gentlewoman from
1008 Wisconsin, Ms. Baldwin.

1009 Ms. {Baldwin.} Thank you, Mr. Chairman. And thank you,
1010 Commissioner Harbour, for joining us today. I have really
1011 been interested in the issue of follow-on biologics for a
1012 number of years. I happen to represent a district that is
1013 rich in intellectual capital in this area. The University of
1014 Wisconsin-Madison has produced some of the world's leading
1015 research in biologic drugs. We also have a unique entity in
1016 my district called the Wisconsin Alumni Research Foundation.
1017 We call it WARF. And what they do is they work with business
1018 and industry to transform university research into real
1019 products benefitting society at large. It was founded in
1020 1925 to manage the University of Wisconsin-Madison discovery
1021 that eventually eliminated the childhood disease rickets, and
1022 today WARF holds nearly 100 patents related specifically to
1023 biologics.

1024 I am certainly supportive of the creation of a pathway
1025 for the approval of bio-similars, and we will hear from the
1026 FTC this morning that when we do create this pathway current
1027 patent protections coupled with market-based pricing are
1028 sufficient to continue to spur innovation in the biologic
1029 drug market. And yet on the ground I hear often times the

1030 opposite is true. Even if with current patent protections
1031 and without a pathway for bio-similars, WARF is having
1032 trouble finding companies to buy and license those 100 plus
1033 biologic patents that I referred to and that they currently
1034 hold. Developing biologic drugs is a billion dollar
1035 enterprise with an extraordinarily high failure rate. To
1036 take that on knowing that another company could invest a
1037 fraction of that amount and take even a small portion of your
1038 market share may be enough to rethink the enterprise
1039 altogether.

1040 I am extraordinarily proud of the companies in my
1041 district who have taken on this risk in hopes of saving lives
1042 and improving health. Just one example is the example of
1043 Flugen located in Madison. They are working on developing
1044 influenza vaccines, and we know that this is a timely and
1045 critically important enterprise. Flugen, like the vast
1046 majority of biotech industry colleagues, is a very small
1047 company. It does not have the profit margins of 50 and 60
1048 percent, yet these are the profit margins that are used to
1049 conduct these economic analyses that conclude that only
1050 minimal data exclusivity is necessary. Without sufficient
1051 data exclusivity protection Flugen faces the risk that a
1052 company will really come in and take a free ride off of their
1053 clinical data and design around their patent forcing them out

1054 of the market entirely.

1055 One final point, Mr. Chairman. The FTC report seems to
1056 conclude that a long period of data exclusivity would hamper
1057 innovation. Currently, with no pathway biologics enjoy
1058 infinite data exclusivity and yet we have had an astounding
1059 innovation in this arena. So you really only need to look to
1060 the second congressional district in Wisconsin to see the
1061 best proof of that. Thank you, Mr. Chairman, and I yield
1062 back my balance of time.

1063 [The prepared statement of Ms. Baldwin follows:]

1064 ***** COMMITTEE INSERT *****

|
1065 Mr. {Pallone.} Thank you. The gentlewoman from North
1066 Carolina, Ms. Myrick.

1067 Ms. {Myrick.} Thank you, Mr. Chairman, but I will
1068 waive.

1069 [The prepared statement of Ms. Myrick follows:]

1070 ***** COMMITTEE INSERT *****

|
1071 Mr. {Pallone.} The gentleman from Pennsylvania, Mr.
1072 Murphy.

1073 Mr. {Murphy of Pennsylvania.} Thank you, Mr. Chairman.
1074 Part of what we have to do here with Solomon's sword is to
1075 understand that drugs that are not affordable offer little
1076 consolation, and a drug that is not invented offers little
1077 cure. A couple years ago when we had a hearing on this issue
1078 of follow-on biologics, I talked about a constituent of mine
1079 who had pancreatic cancer, and he at that time was taking
1080 experimental biologic drug which actually shrank his tumors
1081 down considerably, but unfortunately ended up with some
1082 kidney failure and he died in the process. It was exciting
1083 to watch how his cancer was going away and otherwise would be
1084 a lethal problem for him. It was troubling to see how he had
1085 to jump through a lot of hoops to get the treatments.

1086 But, moreover, I want to make sure that we are
1087 continuing to do everything we can to encourage companies to
1088 make the investments to come up with these cures. I know
1089 that part of what we are facing here is a way that once we
1090 come up with these cures, how do we make sure that people can
1091 afford these drugs, and that is what I hope we have a lot of
1092 discussions on, a lot of hearings to really work out some
1093 mechanism whereby these become affordable. But again I say

1094 that if the drug is not invented, there is no cure, and,
1095 therefore, no hope. And I hope that as we proceed with this,
1096 we will both hear from witnesses with some ideas along these
1097 lines, but also continue to deliberate among ourselves in
1098 using all that is possible to make sure that we do not stop
1099 either end of this. And with that, I yield back.

1100 [The prepared statement of Mr. Murphy of Pennsylvania
1101 follows:]

1102 ***** COMMITTEE INSERT *****

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1103 Mr. {Pallone.} Thank you. The gentleman from Ohio, Mr.
1104 Space.

1105 Mr. {Space.} Thank you, Mr. Chairman, for the
1106 opportunity to provide my perspective on what is clearly a
1107 very difficult and somewhat controversial issue. In
1108 listening to the opening statements of my colleagues on both
1109 sides of the aisle, it is clear that we are arriving at a
1110 consensus, and as very eloquently stated by Mr. Murphy from
1111 Pennsylvania, the need to innovate is directly conflicting
1112 right now with the need to provide affordable biologic
1113 medication. We have seen a tremendous boom in the
1114 manufacture of biotechnology and industry. Generally, the
1115 United States has been a leader, and it is something that we
1116 can be very proud of. I am sincerely torn right now on this
1117 issue because I have a child who suffers from a disease who
1118 is alive today because of biologics, and I understand the
1119 need to foster innovation to create an environment in which
1120 those biotech companies that are flourishing in this country
1121 right now are able to take the risks necessary to innovate
1122 and create new treatments and cures.

1123 At the same time, I come from a district where many
1124 people don't have quality health care. Many people do not
1125 have the ability to pay considerable sums for these

1126 sophisticated medicines. And I do take hope in listening to
1127 the opening statements of my colleagues on both sides of the
1128 aisle that this committee will face this challenge in a way
1129 that it should with a sincere and passionate desire to do the
1130 right thing. I look forward to working with you, Mr.
1131 Chairman. I appreciate the hard work that you have devoted
1132 to this issue. And I do look forward to hearing the
1133 testimony today, and I yield back. Thank you.

1134 [The prepared statement of Mr. Space follows:]

1135 ***** COMMITTEE INSERT *****

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1136 Mr. {Pallone.} Thank you. The gentleman from Georgia,
1137 Mr. Barrow.

1138 Mr. {Barrow.} I waive.

1139 [The prepared statement of Mr. Barrow follows:]

1140 ***** COMMITTEE INSERT *****

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1141 Mr. {Pallone.} The gentlewoman from Ohio, Ms. Sutton.
1142 Ms. {Sutton.} Thank you, Mr. Chairman for holding this
1143 extremely important hearing, and I look forward to hearing
1144 what the panelists have to say. In the United States,
1145 competition has always been an engine for innovation, and
1146 that has been true in the health care and the industry that
1147 supports it. And while national unemployment numbers
1148 continue to be a source of concern the Bureau of Labor
1149 Statistics reported that in May of this year health care
1150 employment increased by 24,000. This increase is in line
1151 with the average monthly job growth so far in 2009. Clearly,
1152 when it comes to the need for health care, demand far
1153 outweighs supply and it is important to nurture the
1154 technology and advancement that leads to medical
1155 breakthroughs. However, in doing so, we must also consider
1156 that those who use our health care system, we have to be
1157 accountable to them as well.

1158 Patient access to life-saving technology and drugs is
1159 critically important with the cost of health care bankrupting
1160 American families. We must consider how we can make things
1161 work for our citizens. It is important that we have a
1162 pathway for options such as biologics, but it is equally
1163 important that this pathway be safe. Our experience in the

1164 field of generics has taught us that multiple entrants into a
1165 pharmaceutical field or category can drastically drive down
1166 price and increase accessibility of drugs for patients.

1167 And I am eager to hear from our panelists about how the
1168 FTC envisions the market for follow-on biologics that will
1169 allow innovation to flourish, and also serve to better our
1170 health care system and protect the health and the wallet of
1171 Americans. I yield back.

1172 [The prepared statement of Ms. Sutton follows:]

1173 ***** COMMITTEE INSERT *****

|
1174 Mr. {Pallone.} Thank you. The gentleman from Iowa, Mr.
1175 Braley.

1176 Mr. {Braley.} Thank you, Mr. Chairman. If you have
1177 been paying attention to what my colleagues have been saying
1178 this morning, you will appreciate this is a tough job. This
1179 is a tough job that we have. I have friends on both sides of
1180 this issue. You hear great arguments on the strengths and
1181 weaknesses of these various proposals, and I think the thing
1182 that unites us all is a strong desire to make something
1183 happen that is going to benefit the people who are going to
1184 realize whatever potential medical gains there are to be
1185 realized from the research and development of biologics, and
1186 that is what brings us here and motivates us. I want to
1187 thank the chairman for holding this important hearing. And
1188 we all know that establishing a fair pathway for follow-on
1189 biologics is extremely important, and we stand to see
1190 tremendous health care improvements as biologics continue to
1191 come to the market.

1192 And when you look at the challenges we are facing with
1193 the broader health care reform debate these are questions
1194 that have enormous implications going forward, and that is
1195 why we are all so focused on this issue. We know that
1196 biologics have improved the treatment of many Americans and

1197 save countless lives, and these innovations will only see
1198 more and more use in coming years. The proteins that form
1199 the bases of biologics are extremely complex, and I must say
1200 the policy questions surrounding the creation of a pathway to
1201 the market are almost just as complex. Any pathway for
1202 follow-on biologics must ensure fair competition without
1203 discouraging innovation in the industry.

1204 We owe many of our biggest medical achievements to those
1205 who have spent significant time and resources researching and
1206 experimenting with drugs, and biologics is no different. We
1207 need to continue innovating and we must make sure that every
1208 American who needs them can access life-saving drugs and
1209 biologics that are a result of that innovation. I have been
1210 studying this issue closely since joining this committee and
1211 hearing from parties on all sides of the issue. I am glad to
1212 see that we are gearing up to address the issue today, and I
1213 am confident at the end of the day we will have a proposal
1214 that both encourages innovation and ensures affordable access
1215 to those life-saving biologics.

1216 I look forward to continuing in these negotiations to
1217 make sure that Iowans that I represent continue to benefit
1218 from innovative, affordable medications. The FTC has a great
1219 deal of expertise and a long record of ensuring fair
1220 competition in the marketplace, but that record is sometimes

1221 not always perfect. They have thoroughly examined Waxman-
1222 Hatch in the past, and I always take their findings very
1223 seriously. That is why I look forward to today's testimony,
1224 to the follow-up hearings we are going to have, and I want to
1225 thank the chairman for convening the hearing.

1226 [The prepared statement of Mr. Braley follows:]

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

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1228 Mr. {Pallone.} Thank you, Mr. Braley. The gentleman
1229 from Maryland, Mr. Sarbanes.

1230 Mr. {Sarbanes.} Thank you, Mr. Chairman. I don't have
1231 much to add to what has been said. Obviously, we have on one
1232 end of the equation the need for research and development to
1233 proceed in a way that is meaningful and leads us to new
1234 discoveries that can benefit consumers. On the other hand of
1235 the equation, we have got the interest of affordability and
1236 access for the consumer. And we are struggling, or we are
1237 not struggling yet, we are working hard to figure out where
1238 the right balance is going to be. The testimony today is
1239 obviously going to be helpful in that process. I just hope
1240 that when we reach the balance, we come to it principally
1241 through the perspective of what makes sense for the consumer.
1242 And so I look forward to the testimony, and I yield back my
1243 time.

1244 [The prepared statement of Mr. Sarbanes follows:]

1245 ***** COMMITTEE INSERT *****

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1246 Mr. {Pallone.} Thank you. The gentlewoman from
1247 Illinois, Ms. Schakowsky.

1248 Ms. {Schakowsky.} Thank you, Mr. Chairman. As we
1249 continue moving forward on health reform legislation, it is
1250 important that we take a long, hard look at prescription
1251 drugs and how we can work together to reduce drug prices and
1252 increase patient access to life-saving drug therapies. I am
1253 a co-sponsor of H.R. 1427, and I thank Chairman Waxman and
1254 Chairman Pallone for sponsoring this legislation because I
1255 believe this bill effectively safeguards against unsafe drugs
1256 entering the market while allowing patients to access lower
1257 cost generic drugs. I recognize the importance of
1258 encouraging innovation in the pharmaceutical industry. As
1259 the report authored by the FTC shows, innovation will not be
1260 hampered by allowing biologic generics into the market.

1261 First, the research shows that it will most likely take
1262 8 to 10 years to develop the manufacturing capacity to make a
1263 similar and interchangeable generic for a brand name
1264 biologic. More importantly, the amount of money required to
1265 produce the generic between \$100 million and \$200 million
1266 will limit the number of generic manufacturers. In other
1267 words, assuring that generic manufacturers can enter the
1268 market after a 5-year exclusivity period will pose little

1269 threat to the brand name industry but it would have enormous
1270 pay backs for consumers. I strongly believe that encouraging
1271 competition particularly in the health care industry not only
1272 promotes creativity and energizes researchers to discover
1273 better and more effective products but it reduces costs.

1274 I think it is important that we give this complex issue
1275 some context. Like many of the states represented on this
1276 committee, Illinois is facing a budget crisis, a deficit that
1277 is approaching \$11 billion. As a result, many of the
1278 programs currently in place to help our citizens are facing
1279 drastic cuts. Among those programs headed for a cut includes
1280 the Illinois Cares RX program, a program that provides
1281 prescription drug assistance to 172,000 seniors with high
1282 drug costs. Many of these drugs cost patients tens of
1283 thousands of dollars each year. Some can be over \$100,000,
1284 and out-of-pocket co-payments could run \$10,000 to \$20,000 a
1285 year. We obviously have to do all we can to bring down drug
1286 costs for patients.

1287 I believe that H.R. 1427 will help us do that. Mr.
1288 Chairman, I look forward to working with you and further the
1289 health and well-being of our constituents and bring drugs to
1290 the market in a safe and timely and affordable way. I yield
1291 back.

1292 [The prepared statement of Ms. Schakowsky follows:]

1293 ***** COMMITTEE INSERT *****

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1294 Mr. {Pallone.} Thank you. The gentlewoman from
1295 Colorado, Ms. DeGette.

1296 Ms. {DeGette.} Mr. Chairman, I will submit my statement
1297 for the record. Let me just say an issue that none of us
1298 knew one thing about, we now are quite conversant, and I
1299 think we need to move forward and talk about how we are going
1300 to resolve it. I am very much eager to hear the testimony of
1301 Commissioner Harbour today. I think that will lend some
1302 light onto this very tough decision we have to make. And
1303 with that, I will yield back.

1304 [The prepared statement of Ms. DeGette follows:]

1305 ***** COMMITTEE INSERT *****

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1306 Mr. {Pallone.} Thank you. I think we have heard all
1307 the opening statements. I just want to make sure that is
1308 true. Yeah. Okay. We will now turn to our witness, and
1309 thank you for being here. First, let me say our witness,
1310 actually we only have one witness, is the Honorable Pamela
1311 Jones Harbour, who is the commissioner from the Federal Trade
1312 Commissioner. However, my understanding is she has been
1313 joined by Mr. Wroblewski, who is the prime author of the
1314 report. And he is not going to testify, but will be
1315 available for questions is the way I understand it. And we
1316 know we have 5-minute opening statements, and then we may get
1317 back to you later with additional written questions as well,
1318 but we will have questions from all the panelists, from all
1319 the members of the subcommittee today. So if you would
1320 begin, thank you.

|
1321 ^STATEMENT OF PAMELA JONES HARBOUR, COMMISSIONER, FEDERAL
1322 TRADE COMMISSION

1323 } Ms. {Harbour.} Thank you, Chairman Pallone, Ranking
1324 Member Deal, and members of the subcommittee. I am Pamela
1325 Jones Harbour, a Commissioner of the Federal Trade
1326 Commission. I am joined by Michael Wroblewski, Deputy
1327 Director of the FTC's Office of Policy Planning. Thank you
1328 for inviting us to testify here today. I appreciate this
1329 opportunity to provide an overview of the Commission's
1330 recently released report called Emerging Health Care Issues:
1331 Follow-On Biologic Drug Competition. A primary goal of our
1332 report is to examine how competition is likely to evolve in
1333 biologics market in particular between pioneer biologics and
1334 follow-on biologics or FOBs. The report sets forth our
1335 findings regarding the competitive dynamics of FOBs, and we
1336 hope that our recommendations will inform the legislative
1337 debate.

1338 I note that the report does not address any specific
1339 bills. The Commission recognizes that legislators are
1340 balancing many different objectives, as they seek to craft a
1341 solution that best protects the public interest. The
1342 Commission has limited its recommendations to competition

1343 issues, which are our core area of expertise. We believe, of
1344 course, that this competition perspective is of critical
1345 importance in the FOB debate, which is why we are grateful to
1346 have been given, literally, a seat at the table today.

1347 If Congress can create a balanced pathway for FOBs, and
1348 also pass legislation to eliminate pay-for-delay patent
1349 settlements between branded and generic companies in small
1350 molecule markets, then Congress will have taken substantial
1351 steps to ensure that all Americans have access to affordable
1352 life-saving medicines. On behalf of Chairman Leibowitz, I
1353 commend the Commerce Committee for moving legislation to ban
1354 these patent settlements through the Consumer Protection
1355 Subcommittee last week. The report's basic premise is that
1356 competition between pioneer biologics and FOBs is likely to
1357 look much more like current competition between 2 or more
1358 branded drugs that treat the same medical condition, for
1359 example, Enbrel and Remicade, which both treat rheumatoid
1360 arthritis. It will look less like current competition
1361 between branded and generic versions of a drug and I will
1362 explain why the Commission reached this conclusion, and I
1363 will also identify some implications for legislation seeking
1364 to create an abbreviated regulatory approval pathway for
1365 FOBs.

1366 But first, I will begin by highlighting some important

1367 characteristics of the biologics marketplace. As you know,
1368 the emergence of biologic drugs has dramatically improved the
1369 lives of thousands of Americans over the past few decades.
1370 For example, the biologic Herceptin is used to treat breast
1371 cancer, and an annual course of treatment costs about \$48,000
1372 a year. One way to reduce the costs of biologics would be to
1373 authorize the Food and Drug Administration to permit follow-
1374 on biologics to enter the market once a biologic drug's
1375 patents expire. However, there is no statutory or regulatory
1376 pathway to allow abbreviated FOB entry without the FOB
1377 applicant having to duplicate existing knowledge about safety
1378 and efficacy. This duplication represents an inefficient use
1379 of limited R&D resources. Also, as the FDA has explained,
1380 repeating all of the clinical trials raises ethical concerns
1381 associated with unnecessary human testing.

1382 Elements of the Hatch-Waxman Act provide a model for
1383 reducing FOB entry costs and addressing ethical concerns.
1384 Hatch-Waxman does not require generic applicants to duplicate
1385 the clinical testing of branded drugs that have already been
1386 proven safe and effective. Hatch-Waxman has successfully
1387 reduced drug prices, has broadened access, and has hastened
1388 the pace of innovation. And if pay-for-delay settlements are
1389 prohibited, these benefits of Hatch-Waxman will be preserved.
1390 But as the report describes, according to the FDA, there are

1391 key scientific differences between biologic and small
1392 molecule drug products. Most notably, under Hatch-Waxman,
1393 the generic applicant must show that the product is bio
1394 equivalent to the branded drug product. This is important
1395 because it means that the product is identical.

1396 In stark contrast, according to the FDA, biologic
1397 products cannot be perfectly duplicated, at least not based
1398 on current science. Technology is not yet robust enough to
1399 determine whether an FOB product is interchangeable with the
1400 pioneer product. Current FOB legislative proposals reflects
1401 the complexities of biologics. They would permit FDA
1402 approval of an FOB drug that is similar to, but not an exact
1403 replica of the pioneer biologic product. Under these
1404 proposals, the FDA could rely on its previous findings
1405 regarding the pioneer biologic drug's safety and efficacy to
1406 the extent those findings would also be relevant to the FOB.
1407 An FOB manufacturer likely would save on some clinical
1408 testing expenses, which would reduce entry costs.

1409 So with that background in mind, let me turn to the
1410 Commission's report. The purpose of our study was to
1411 evaluate how FOB competition is likely to develop and evolve,
1412 paying particularly close attention to the differences
1413 between small molecule and biologic drugs. The study was
1414 coordinated by an interdisciplinary FTC team, headed by Mr.

1415 Wroblewski, that included not only pharmaceutical industry
1416 experts, but also patent lawyers and economists. As part of
1417 its inquiry, the Commission solicited 2 rounds of public
1418 comments which attracted submissions from approximately 30
1419 industry participants and other stakeholders.

1420 In November 2008, the Commission conducted a public
1421 roundtable discussion that included over 30 panelists. The
1422 Commission also has examined European markets where FOB entry
1423 has occurred. In the interest of time, let me briefly
1424 summarize the 4 major reasons why FOB competition is not
1425 likely to be like generic brand competition. First, it is
1426 the extraordinary cost and time necessary to develop an FOB,
1427 which will sharply limit the number of competitors who can
1428 afford to enter, and also will limit the discounts the FOB
1429 can offer in relation to the pioneer price. Second, follow-
1430 on entry will not radically erode the pioneer's market share.
1431 Third, the specialty pharmaceutical characteristics of FOBs
1432 are likely to further constrain the FOB entrant's ability to
1433 gain market share. And the fourth reason is because
1434 biologics are provided in clinic-type settings as part of
1435 medical treatments. They are not purchased and reimbursed in
1436 the same manner as small molecule drugs.

1437 As a result of all of these factors, the Commission's
1438 report predicts that FOB markets are likely to develop with

1439 the following characteristics. First, that FOB entry is
1440 likely to occur in biologic drug markets with more than \$250
1441 million in annual sales. Only 2 or 3 FOB manufacturers are
1442 likely to attempt entry in competition with a particular
1443 pioneer drug product. These FOB entrants likely will not
1444 offer price discounts larger than 10 percent to 30 percent of
1445 the pioneer product's price. Although this discount is not
1446 as steep as with small molecule generic drugs, it does
1447 represent millions of dollars in consumer savings for these
1448 very expensive products.

1449 Pioneer manufacturers are expected to respond by
1450 offering competitive discounts to maintain their market
1451 share. This price competition likely will increase consumer
1452 access and further expand the market. Without automatic
1453 substitution, FOB market share acquisition will be slowed.
1454 Pioneer manufacturers likely will retain 70 percent to 90
1455 percent of their market share. This means that a pioneer
1456 firm will continue to reap substantial profits for years,
1457 even after entry by an FOP. FOB market dynamics will
1458 contrast sharply with the market dynamics of generic drug
1459 competition, where lower-cost generic entry plus automatic
1460 substitution lead to rapid erosion of the branded drug's
1461 market share. When the first generic drug enters the market,
1462 it generally offers a 25 percent discount off the branded

1463 drug's price. As additional generic firms enter, and often
1464 there are 8 or more of them, the price discounts reach as
1465 high as 80 percent.

1466 Given these likely dynamics of FOB markets, the
1467 Commission next asked whether any additional--

1468 Mr. {Pallone.} Commissioner, I am sorry, but you are
1469 like twice the time so far so--

1470 Ms. {Harbour.} Okay. Then I will stop.

1471 Mr. {Pallone.} No, no. Just wrap up. I don't want to
1472 stop you completely. Just try to summarize the rest, if you
1473 could.

1474 Ms. {Harbour.} I would say that the findings have
1475 several implications for the design of an abbreviated
1476 approval system. I think first pioneer manufacturers are
1477 unlikely to need additional incentives to continue to
1478 innovate in the face of FOB entry beyond the existing patent
1479 protection and market-based pricing. I would be ready to
1480 answer questions now. We can engage in a Q and A, and I know
1481 that the committee is very interested to hear what we have to
1482 say, so thank you.

1483 [The prepared statement of Ms. Harbour follows:]

1484 ***** INSERT 1 *****

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1485 Mr. {Pallone.} Thank you very much. I always hate to
1486 stop anyone but we have time constraints. We are going to
1487 have a series of questions. I am going to start, and then we
1488 will go back and forth between Democrats and Republicans, as
1489 you know. First of all, I want to thank you for the report.
1490 As the expert agency charged with overseeing competition, as
1491 you mentioned, in the drug marketplace, the FTC's conclusions
1492 on how much exclusivity is needed to sustain innovation, I
1493 think is crucial to any resolution of many of the questions
1494 that have been raised on this issue. And I have to be honest
1495 to say that I, of course, hear mostly from people who have a
1496 financial stake in this, and I think it is essential that we
1497 have an objective assessment with regard to exclusivity, and
1498 that is one of the reasons why I think it is really crucial
1499 that you are here today and that this report came out.

1500 Now members of the biotech industry argue that their
1501 patents are not as strong as those on traditional drugs, and
1502 are not strong enough to protect them from competition from
1503 follow-on biologics. If I understand you correctly, the FTC
1504 has reviewed all the evidence provided by the industry, as
1505 well as relevant patent law, and has concluded that the
1506 industry's claim is unsupported by the evidence. And this is
1507 an extremely important point because members of the biotech

1508 industry have premised their argument for a 12 to 14-year
1509 exclusivity period on the claim that their patents cannot
1510 fulfill the role they are supposed to. And it is important,
1511 I mean this is important enough that I want to be sure I
1512 understand your conclusions, and that there is no doubt about
1513 it.

1514 So let me ask 3 questions. First, are patients on
1515 biotech drugs too narrow or too weak to protect them from
1516 competition from follow-on biologics? And, Mr. Wroblewski,
1517 obviously can answer as well.

1518 Ms. {Harbour.} Yes. Mr. Wroblewski is the expert here,
1519 but I would say that our research has shown that the patents
1520 are strong in this area. In fact, as we look at the sector,
1521 the biotech sector, they have been very strong. The stocks
1522 in that area actually has been very strong and the general
1523 sector stock prices have gone down 30 percent, but in the
1524 biotech sector they have only gone down 15 percent. So we
1525 have not seen as much erosion in that area, and I do believe
1526 that the patents are strong in that area.

1527 Mr. {Pallone.} Maybe I will just go to the second
1528 question. The second question is will biotech patents
1529 provide less protection from follow-on biologics than the
1530 protection against generic competition offered by patents on
1531 traditional drugs?

1532 Mr. {Wroblewski.} The patent questions are really
1533 central to this entire debate. What we did was we examined--
1534 currently there is branded competition between competitors,
1535 and so what we did is we looked to see--we looked at all of
1536 those cases, which the industry gave us, and the ones that we
1537 found--all the cases that are out there doing our own
1538 research, and we broke them into 2 groups. The first group
1539 was the patents have been very strong. Both the drug
1540 molecule patents and the process patents have been very
1541 strong to keep other branded competitors off the market.
1542 When we looked at those cases in which the branded competitor
1543 or the pioneer had lost, the cases really turned on a factual
1544 determination that was central to that patent or how those
1545 claims were drafted. It wasn't because the law prohibited
1546 them to draft their claims in a broader way.

1547 And there are PTOs written, description guidelines, that
1548 say this is how you can--the legal requirements to get a
1549 broad patent to protect against those types of claims that
1550 FOBs are likely to make. The written guidelines allow the
1551 claims to be drafted broadly enough to protect against those
1552 types of patents. The one last thing we did is there was a
1553 great study that came out about a year ago that surveyed all
1554 of the patent cases in terms of has the law changed so that
1555 it is very difficult to get a broad scope on your patent to

1556 kind of guard against the potential threat of an FOB, and it
1557 found that the law had not changed and that the patent
1558 holders have the ability to draft their claims, to draft
1559 their patents to provide a potent shield against FOB
1560 competitors.

1561 Mr. {Pallone.} All right. Let me just ask my third
1562 question quickly. Is there any defect in the protection
1563 offered by biotech drug patents that justifies a longer
1564 exclusivity period than the period available to traditional
1565 drugs?

1566 Mr. {Wroblewski.} We found that there are no defects.
1567 There is an argument that there may be drugs that have been
1568 discovered but somehow are unpatentable because they are not
1569 novel any longer, and the requirement to get a patent is that
1570 a drug has to be novel. If that is the case, and we haven't
1571 seen any evidence that that is the case, then an exclusivity
1572 period similar to the way Hatch-Waxman had a 5-year
1573 exclusivity period for a new chemical entity that didn't
1574 have patent protection. Hatch-Waxman also gives 3 years for
1575 a new indication because that indication couldn't get patent.
1576 If there is something new that is being delivered that the
1577 patents won't incentivize, then it may be very appropriate to
1578 have an exclusivity period to encourage the companies to
1579 engage in the expensive R&D to test those drugs.

1580 Ms. {Harbour.} Such as in the drugs for children
1581 population and the diseases that affect very small
1582 populations. That would be an example where one would offer
1583 an exclusivity period.

1584 Mr. {Pallone.} And not otherwise? But not otherwise?

1585 Ms. {Harbour.} Unless there was an unpatentable drug as
1586 Mr. Wroblewski indicated.

1587 Mr. {Pallone.} Okay. Thank you very much. Mr. Deal.

1588 Mr. {Deal.} First of all, let me make sure that I
1589 understand since there has been criticism about the scope of
1590 this hearing today, what I understand you to say is that your
1591 study and your testimony today is to deal with this question
1592 of competition and how it will evolve in a follow-on biologic
1593 marketplace, and questions like safety, interchangeability,
1594 those are issues that best address themselves to the Food and
1595 Drug Administration and not to you, am I correct?

1596 Ms. {Harbour.} That is precisely correct.

1597 Mr. {Deal.} I didn't want you to be criticized for
1598 something you were not undertaking to do here today, and I
1599 think that is important because we all are concerned about
1600 safety. We are all concerned about the things that are
1601 within the province of the FDA. Let me focus in on what you
1602 have testified to, and what your report identifies. Most of
1603 us have heard from the lobbying community about how long

1604 should the period of exclusivity be. Now what I hear and
1605 what I see at least in the summary that I have read of your
1606 report is that you don't even feel that there is even a need
1607 for any exclusivity period, and specifically I think your
1608 statement says the drug had already been incentivized through
1609 patent protections and market-based pricing, so you are
1610 saying that there are 2 protections that the pioneer drugs
1611 enjoy that is somewhat different from the chemical-based
1612 arena in these areas, one being that patents are strong
1613 enough.

1614 And let me ask you specifically about that. As I
1615 understand you to say, the reason you think patents are
1616 stronger than we might be led to believe is that in this
1617 arena there are more and varied patents in the follow-on
1618 biologic arena than in the chemical arena, specifically
1619 including patents on manufacturing and the technology
1620 platforms on which they are based, is that correct?

1621 Ms. {Harbour.} That is correct, and there is another
1622 component too that competition resembles brand to brand
1623 competition and in brand to brand competition the patents
1624 protect the innovation. In the follow-on context, you have
1625 the method of treatment patents. You have the product by
1626 process patents, the manufacturing process including the cell
1627 lines, so, yes, the report concludes that patents have been

1628 shown to be strong in this area.

1629 Mr. {Deal.} And the second component that gives
1630 protection that is more unique to this follow-on arena than
1631 chemicals is what you refer to as market-based pricing, and I
1632 think you have already told us that you do not expect the
1633 drastic reduction in pricing to occur on the pioneer product
1634 just because a follow-on comes on to the market.

1635 Ms. {Harbour.} That is right.

1636 Mr. {Deal.} And that is an additional protection that
1637 the pioneer enjoys in this arena that they do not necessarily
1638 enjoy in the chemical arena?

1639 Ms. {Harbour.} And the characteristics of this market
1640 is a follow-on, there would only be 2 to 3 follow-ons that
1641 would enter the market, and those follow-ons would only take
1642 10 percent to 30 percent of the market share away, so the
1643 branded pioneer manufacturer would still enjoy 70 percent of
1644 its market share, and so there would be enough incentive and
1645 competition and pricing to satisfy the entrants contrasted
1646 with the generic market where after the first generic comes
1647 in taking 25 percent of the branded firm, then you would have
1648 8 to 10 generics come in and then they would all cannibalize
1649 that 80 percent. So it is a very different competitive
1650 situation with the follow-on.

1651 Mr. {Deal.} Plus, also am I correct that the follow-on

1652 biologic will take a longer period of time for approval even
1653 with the exclusivity period even non-existent, it would still
1654 take longer to get a follow-on on the market than a
1655 traditional chemical-based generic would take?

1656 Ms. {Harbour.} I am not sure about that. I am going to
1657 turn to Mr. Wroblewski. I think not, but I will let Mr.
1658 Wroblewski answer that.

1659 Mr. {Wroblewski.} The time to bring a follow-on to the
1660 market, the evidence shows would be about 8 to 10 years. The
1661 time it takes to bring a generic drug to the market is 3 to 5
1662 years. The one thing about market-based pricing, the point
1663 that we were--to compliment what Commissioner Harbour just
1664 talked about was that when you have a patent that allows you
1665 to charge, and you are the only one on the market and you
1666 have developed innovation, that allows you to charge a price,
1667 any price, a monopoly price, so if the period of time in
1668 which you enjoyed that monopoly is shortened the ability to
1669 raise the price, that is what market-based pricing is all
1670 about to make up for that.

1671 Ms. {Harbour.} Mr. Deal, I misunderstood what you had
1672 said. I thought you meant FDA approval, whether that would
1673 take longer, and my answer was, no, it would not. But, as
1674 Mr. Wroblewski said, yes, FOB drugs would take about 8 to 10
1675 years to develop, and they would likely cost between \$100

1676 million to \$250 million as compared to small molecule generic
1677 drugs, which would take 3 to 5 years to develop, and would
1678 cost roughly between \$1 million to \$5 million.

1679 Mr. {Deal.} Thank you.

1680 Mr. {Pallone.} Thank you, Mr. Deal. Chairman Waxman.

1681 The {Chairman.} Thank you very much, Mr. Chairman.

1682 Could you just repeat that last point? For biologic drugs it
1683 takes 8 to 10 years?

1684 Ms. {Harbour.} Yes. Biologic drugs would take 8 to 10
1685 years. Follow-on biologic drugs would take 8 to 10 years to
1686 develop, and it would likely cost between \$100 million to
1687 4250 million, contrasted with the small molecule generic
1688 drugs where product development would take approximately 3 to
1689 5 years to develop and would cost between \$1 million and \$5
1690 million.

1691 The {Chairman.} So it costs more money.

1692 Ms. {Harbour.} Yes.

1693 The {Chairman.} And it takes more time to develop these
1694 biologic drugs.

1695 Ms. {Harbour.} Yes.

1696 The {Chairman.} And, therefore, they want to know they
1697 are going to have their full protection. Mr. Wroblewski.

1698 Mr. {Wroblewski.} I just want to make sure that we are
1699 talking about the follow-on and not the pioneer.

1700 The {Chairman.} Oh, I see. You are talking about the
1701 follow-on.

1702 Mr. {Wroblewski.} I just want to make sure.

1703 The {Chairman.} So if you got a new biologic drug, you
1704 got a patent and you think the patents are good, that is
1705 enough protection, we could give an exclusivity for that
1706 period of time. Patents, by the way, are for 20 years, isn't
1707 that right?

1708 Mr. {Wroblewski.} Correct.

1709 The {Chairman.} When we did the Hatch-Waxman Act, the
1710 patents were 17 years. We moved the patent period all the
1711 way to 20 now. And the Hatch-Waxman Act was a trade off. We
1712 said that we would allow generics to be approved through an
1713 abbreviated process in exchange for giving the brand name
1714 company additional time lost at FDA for the approval time.
1715 And that is called the patent term restoration. Well, we
1716 didn't know about biologic drugs in the mid-1980s, but these
1717 drugs get that patent term restoration, don't they?

1718 Mr. {Wroblewski.} Yes, they do.

1719 The {Chairman.} So they now have a longer patent time
1720 and they get the restoration period for the time spent at
1721 FDA. Your conclusion is pretty surprising because what you
1722 are saying is that if somebody says they need 12 to 14 years
1723 of exclusivity, you don't think they need it because patents,

1724 and they have market-based pricing available under the
1725 current law, which you believe provides sufficient incentives
1726 for innovation.

1727 Mr. {Wroblewski.} It is not only that we believe it, it
1728 is what the industry has said for years that patents have
1729 been so essential to their development.

1730 The {Chairman.} Now you also concluded, and Mr. Deal
1731 pointed to this, so let us say we say at some period of time
1732 there is going to be an approval process for a generic
1733 follow-on, and that may take 8 to 10 years, so that is a long
1734 period of time once they even start to get the generic
1735 follow-on to come into competition. But once it is approved,
1736 it is not the same as a small molecule drug where people know
1737 it is the exact same drug and it could be substituted. A
1738 generic follow-on drug, which is going to take longer to get
1739 on the market, and they can't even be considered until the
1740 patent period is up or the exclusivity period is up, won't be
1741 substitutable. It is going to be like another brand name
1742 drug competing with a different brand name drug. What will
1743 that mean in terms of the loss of market to the generic
1744 competitor?

1745 Mr. {Wroblewski.} One of the aspects of branded drug
1746 competition is the substantial first mover advantage that the
1747 pioneer has, and so what is going to have to happen is when

1748 that follow-on comes on it is going to have to develop its
1749 own marketing and sales force to show that its product is
1750 actually more safe or more effective or somehow improves
1751 safety, convenience, efficacy for treatment of that drug to
1752 gain any market share. And that is actually a huge benefit
1753 for competition. Competition brings not only price
1754 competition, but it also brings improvements to the products
1755 which are very, very important, so you have to look at both
1756 of them.

1757 The {Chairman.} But the competition doesn't start
1758 immediately to drop that price because they have to convince
1759 the doctors and others that this is a follow-on that can
1760 serve the same purposes of the original drug.

1761 Mr. {Wroblewski.} That is correct, and when we have
1762 looked at market experience in Europe in which they have a
1763 bio-similar pathway in the 2 markets that we have looked at
1764 there are 2 drug markets. Both of them, after 3 to 4 years
1765 where the bio-similars have already been on the market only
1766 had about a 15 percent combined market total, so that means
1767 the pioneers still retain 85 percent of the market share
1768 which is totally different from the generic drug model.

1769 The {Chairman.} Will follow-ons provide--going to make
1770 high price biotech drugs more affordable and will these
1771 follow-ons provide other benefits to consumers?

1772 Mr. {Wroblewski.} I think the evidence that we have
1773 seen shows that they will come in at a 10 to 30 percent
1774 discount and a 10 to 30 percent discount on a drug that for a
1775 course of treatment annual is \$50,000 is a substantial
1776 savings, and it will then prompt the pioneer to then move
1777 forward to further refine and develop and improve its drugs
1778 which benefit consumers.

1779 The {Chairman.} So having an end point and then having
1780 competition even if it is not as strong as generics are for
1781 small molecule drugs does spur innovation?

1782 Mr. {Wroblewski.} Of course it does. Of course it
1783 does.

1784 The {Chairman.} Thank you. Thank you, Mr. Chairman.

1785 Mr. {Pallone.} Thank you, Mr. Chairman. Next, we have
1786 the gentlewoman from North Carolina, Ms. Myrick.

1787 Ms. {Myrick.} Thank you, Mr. Chairman. A couple of
1788 questions. This is just kind of a regional question relative
1789 to North Carolina. The biotech sector you know is very
1790 important in North Carolina and in how it plays into our
1791 economy. We see a total employment impact of over 200,000
1792 jobs because of our rich biotech sector. No doubt a well-
1793 designed FOBs pathway could also generate additional economic
1794 growth. If the pathway were designed as the FTC describes,
1795 do you foresee any negative economic impact when it comes to

1796 profitability of innovative biotech companies?

1797 Ms. {Harbour.} I don't believe that the report
1798 identifies any, and as I had said earlier the biotech sector
1799 is doing better than a lot of other sectors in today's
1800 economy looking at our stock industry.

1801 Ms. {Myrick.} Right. I heard you say that, so you just
1802 don't think that there is any--the other thing I wanted to
1803 ask was about the European Union. You know their system is
1804 different than ours is, and when you look at the policies
1805 that we have and they have, do you think that their policies
1806 generally translate to the United States because we have such
1807 a glut of biotech companies here and our existing patent
1808 system the way it is set up?

1809 Mr. {Wroblewski.} The 2 things that we look at in terms
1810 of the European market, they do things a little bit
1811 differently in terms of their patent coverage, and they do
1812 things differently in determining at the European level, they
1813 decide what is safe and effective for a bio-similar and they
1814 are leaving to the states, the members states and the
1815 countries, to decide what would be interchangeable. That is
1816 a slightly different structure than we have here in the
1817 United States. But the commercial aspects in terms of what
1818 these large multi-national companies are doing can provide
1819 some insight--in Europe can provide some insights into what

1820 they are likely to do here in the U.S.

1821 Ms. {Myrick.} One more question. When you talk about
1822 the delay in the time it takes for the price differential
1823 between the FOBs and the innovative biologics, it becomes
1824 significant because the point of entry for these products is
1825 different than traditional generic drugs. The study says
1826 that the price differential would be 10 to 30 percent of the
1827 original therapy's price. Do you think that that would put
1828 pressure on the insurers in large companies, pressure on
1829 providers to make the time period shorter?

1830 Mr. {Wroblewski.} To make the time period shorter?

1831 Ms. {Myrick.} Yeah, of bringing them to market. You
1832 don't think there is a possibility that can even happen from
1833 what you said basically?

1834 Mr. {Wroblewski.} Right.

1835 Ms. {Myrick.} I think that is all at this point, Mr.
1836 Chairman. Thank you.

1837 Mr. {Pallone.} Thank you. Let me mention to everyone
1838 that we will have 2 votes. One has already been called, but
1839 I would like to get at least 2 more of our members to ask
1840 questions before we go. So next is the gentlewoman from
1841 Wisconsin, Ms. Baldwin.

1842 Ms. {Baldwin.} Thank you. Commissioner, the FTC report
1843 claims that the development time for small molecule and

1844 biological drugs are roughly equivalent, and I would like to
1845 highlight the example of Flugen, which is a company that I
1846 talked about during my opening remarks. They are currently
1847 working on an adjuvant to the standard flu vaccine which
1848 would allow 10 times as many doses from the same stock of
1849 vaccine, so basically allows what would be usually 1 does to
1850 be used for more vaccines. This adjuvant was patented from
1851 the University of Wisconsin-Madison research lab in the year
1852 2001, but will likely not make it to clinical trials until
1853 the year 2011, and then it is predicted to be another 7 years
1854 to get to market, which leaves only 3 years of patent
1855 protection. And so I am wondering how do companies like this
1856 factor into your analysis? Do you think the patent
1857 protections are sufficient in an instance like this?

1858 Ms. {Harbour.} Could I just clarify the first part of
1859 your question? I believe you said something was equivalent.
1860 Would you just go back to that, please?

1861 Ms. {Baldwin.} Absolutely. My understanding is that
1862 the FTC report claims that the development time for small
1863 molecule and biologic drugs are roughly equivalent.

1864 Ms. {Harbour.} They are not.

1865 Ms. {Baldwin.} Okay. Maybe you could shine some light
1866 on--

1867 Mr. {Wroblewski.} There are 2 things that we are

1868 talking about. One is if you are looking at a pioneer drug,
1869 the first in class, the innovator, if you look at a biologic
1870 drug or a chemical drug, they roughly cost the same amount to
1871 develop and it takes the same amount of time. If you then
1872 look at the follow-ons or the generics, the generic is much
1873 quicker to come to the market than a follow-on. Does that
1874 make sense? So the pioneers are equivalent. The second in
1875 the class, so to speak, take a little bit longer for follow-
1876 ons.

1877 Your question is whether the patent restoration that--
1878 the example that you gave is basically they are only going to
1879 have 3 years left or 4 years left on their patent. They get
1880 patent restoration now so they would be able to add back that
1881 time that was lost in FDA approval. That applies to them
1882 now. And if that isn't sufficient because of the long period
1883 of--the longer period, so to speak, of testing for FDA
1884 approval then the fix would be to fix the restoration of the
1885 patent, not to then add an additional layer somewhere else,
1886 but to fix the underlying problem, which is what the patent
1887 isn't providing the length of time that was caught up in the
1888 FDA approval process.

1889 Ms. {Baldwin.} Let me also ask you a little bit about
1890 changes in technology that take place over these periods of
1891 time. Over the lifetime of a patent for biologics

1892 manufacturing technology will surely improve making it much
1893 easier for companies delivering bio-similars to enter the
1894 market. These companies will gain really at the innovators
1895 significant expense. And isn't that an argument for some
1896 period of exclusivity to be sure that innovators will still
1897 be willing to take the up front risks to develop these
1898 incredible medicines?

1899 Mr. {Wroblewski.} You know, those technologies that
1900 they are going to be developing actually would be applicable
1901 to the pioneer as well, so the pioneer actually can benefit
1902 from the increase in technological advancement. For example,
1903 if a follow-on develops a better manufacturing process, that
1904 manufacturing process can be then imported or be used by the
1905 pioneer as well, and so that competition to improve
1906 innovation benefits not only follow-on but can benefit the
1907 pioneer as well.

1908 Mr. {Pallone.} Okay. Mr. Murphy. I am sorry. Mr.
1909 Buyer.

1910 Mr. {Buyer.} Thank you very much.

1911 Mr. {Pallone.} Before you start, let me just mention he
1912 will be the last speaker before we break for the votes, and
1913 then we will come back right after.

1914 Mr. {Buyer.} I would like to know who asked you to do
1915 this report. Who asked you to do this report?

1916 Ms. {Harbour.} Thank you for that question. Before I
1917 answer that, there is a lot of commonality in this room
1918 although it may not--

1919 Mr. {Buyer.} That is not answering my question. Answer
1920 my question.

1921 Ms. {Harbour.} I did.

1922 Mr. {Buyer.} Were you contacted or encouraged by any
1923 member of the House and Senate or staff--

1924 Ms. {Harbour.} May I answer your question, sir?

1925 Mr. {Buyer.} Yes.

1926 Ms. {Harbour.} In 2003, I read the Commission's IP
1927 report. I was a new commissioner. I read it, and there was
1928 a footnote that talked about generic biologics they called it
1929 then and how there was a great debate and a lot of
1930 controversy about this issue and how it was keeping
1931 potentially life-saving drug products from the American
1932 consumer. So as a commissioner, I went to my staff and I
1933 said this is an issue that is very important to the American
1934 people. And I know that my staff is very expert in these
1935 areas. I said can we take a look at this and see if we can
1936 add to the debate. That is how this issue came to the fore.

1937 Mr. {Buyer.} So you did this on your own?

1938 Ms. {Harbour.} No. It was with the approval of the
1939 other commissioners, but I did see this issue back in 2004.

1940 Mr. {Buyer.} Do you see yourself as an expert in
1941 promoting competition in U.S. markets?

1942 Ms. {Harbour.} No, I do not. No. I see myself as an
1943 expert on the American consumer and trying to be a champion
1944 of the American consumer much as most of Congress is.

1945 Mr. {Buyer.} Since you are eager to sit at the table
1946 and discuss health, would you be equally as eager to turn to
1947 your commissioners and ask that the FTC consider studying the
1948 effects of the proposed public health plan options on
1949 competition in the health insurance market?

1950 Ms. {Harbour.} First of all, I was summoned to the
1951 table. I am not eager to sit here, but I am happy to sit
1952 here.

1953 Mr. {Buyer.} I am going to just ask you to answer the
1954 question that I have asked.

1955 Ms. {Harbour.} Would you repeat it, please?

1956 Mr. {Buyer.} Would the FTC consider studying the
1957 effects of the proposed public health plan options on the
1958 competition in our health insurance market?

1959 Ms. {Harbour.} If we are directed to study anything by
1960 Congress--

1961 Mr. {Buyer.} Well, you weren't directed to do this
1962 study and give it to us. You did this on your initiative you
1963 said with pride.

1964 Ms. {Harbour.} Yes, and we do a lot of things on our
1965 own initiative at the Federal Trade Commission.

1966 Mr. {Buyer.} Would you on your own initiative consider
1967 the public option plan discussed by the President and its
1968 impact on competition in the insurance market?

1969 Ms. {Harbour.} If we were asked to do so we--

1970 Mr. {Buyer.} You are asked to do so. All right? I ask
1971 you to do so.

1972 Ms. {Harbour.} But we would have to vote on that and it
1973 would have to be decided by a majority of the Commission.

1974 Mr. {Buyer.} Right. Okay. Oh, wonderful. I will even
1975 put it in writing to you. I will ask you to do that, and
1976 then you can consider with the other commissioners. Would
1977 that be okay?

1978 Ms. {Harbour.} Sir, you may do whatever you like and we
1979 will--

1980 Mr. {Buyer.} Well, you have just done whatever you
1981 like, right, on your own initiative. Let me just do this.
1982 If you are willing to--now you are willing to consider the
1983 public plan options in the insurance markets impact on
1984 competition because you are so concerned about the consumer.
1985 Number 2, I am going to ask you for another report. Here in
1986 the House, we just passed a tobacco bill. The Senate is
1987 about to pass a tobacco bill that locks down the tobacco

1988 market, as a matter of fact, almost eliminates competition
1989 because we don't even have harm reduction anymore, and so I
1990 am going to ask for a second report for you also to consider,
1991 the impact of tobacco legislation and competition in the
1992 marketplace. I am going to ask you for 2 reports, okay?

1993 Now the other question I have is I noted in a footnote
1994 that you had sent a letter to Chairman Pallone outlining
1995 preliminary views on the likely effects of the regulatory
1996 approval pathway. That is great. That wasn't shared with
1997 any of us. If this had been done back in May of 2008, this
1998 is a hearing, Mr. Chairman, that should have happened some
1999 time ago, so I appeal to you that this not be our only
2000 hearing that we have--

2001 Ms. {Harbour.} Sir, I believe that letter is on the
2002 public--

2003 Mr. {Buyer.} Ma'am, I am not asking any question of
2004 you.

2005 Ms. {Harbour.} It is in the public record.

2006 Mr. {Buyer.} Ma'am, I am not asking any question of
2007 you.

2008 Mr. {Pallone.} If you are asking me the question--

2009 Ms. {Harbour.} The letter is on the public record.

2010 Mr. {Pallone.} Let me just cover it. Is the gentleman
2011 yielding to me?

2012 Mr. {Buyer.} My point is, this is my personal opinion,
2013 this is a hearing that we should have had later--at an
2014 earlier time, not now, and so my appeal to you is, Mr.
2015 Chairman, that we bring the FDA in so we can look at--

2016 Ms. {Harbour.} And CC'ed.

2017 Mr. {Buyer.} Pardon?

2018 Mr. {Pallone.} Wait a minute. Let us please--

2019 Mr. {Buyer.} Ma'am, I am not asking you any question.

2020 Mr. {Pallone.} Mr. Buyer, look, it is a little unclear
2021 who you are asking the question of. It may not be obvious to
2022 you but it is increasingly to the 2 of us that we are not
2023 sure. The question is to me at this point?

2024 Mr. {Buyer.} All right. My appeal is that you bring
2025 the FDA in so we can get into the efficacy and safety issues.
2026 That is my appeal to you.

2027 Mr. {Pallone.} Okay.

2028 Mr. {Buyer.} So I am not asking any questions of this
2029 witness.

2030 Mr. {Pallone.} Let me just--if you would yield. Well,
2031 we are out of time anyway. But let me answer the question.
2032 First of all, the letter you mentioned, it is my
2033 understanding that that letter was posted on the web site for
2034 the committee and circulated almost a year ago, the one that
2035 you mentioned that was sent to me. And as far as the second

2036 question, I have already stated that we are going to have
2037 additional hearings and this is just the first one so I just
2038 want to make that clear again.

2039 Mr. {Buyer.} All right. I have a unanimous consent
2040 request.

2041 Mr. {Pallone.} You have a unanimous consent request?

2042 Mr. {Buyer.} Yes.

2043 Mr. {Pallone.} Go ahead.

2044 Mr. {Buyer.} I have a letter from the Association of
2045 American Universities, which includes the leading research
2046 universities, not only researchers in Indiana and Purdue, but
2047 over 60 in the country, and I would ask unanimous consent
2048 that the Association of American Universities letter be
2049 inserted into the record. Obviously, they are seeking
2050 providing 12 years of data exclusivity, and I don't believe
2051 it is very clear from the FTC report that they include the
2052 nation's leading academic researchers and what their opinions
2053 are.

2054 Mr. {Pallone.} Without objection, so ordered.

2055 [The information follows:]

2056 ***** COMMITTEE INSERT *****

|
2057 Mr. {Pallone.} And the committee is going to now recess
2058 until we have the conclusion of these 2 votes and then we
2059 will come right back. Thank you.

2060 [Recess.]

2061 Mr. {Pallone.} The subcommittee will reconvene. Thank
2062 you for still being here. And we go to the gentlewoman from
2063 the Virgin Islands, Ms. Christensen.

2064 Ms. {Christensen.} Thank you, Mr. Chairman, and again
2065 thank you for holding this hearing and welcome to the
2066 commissioner, Commissioner Harbour. The report makes several
2067 statements to support its conclusion that a 12 to 14 data
2068 exclusivity period is unnecessary. One statement is that
2069 there is no evidence that patents claiming a biologic drug
2070 product have been designed around more frequently than those
2071 claiming small molecules. And the other is that because
2072 there is no evidence about the lack of patentability of new
2073 biologic products nor that market forces have been
2074 insufficient incentivize development the Commission has not
2075 recommended a specific length for exclusivity period. If
2076 there are no bio-similar pathways that exist, how could there
2077 be any evidence as to how patents could we worked around?
2078 Isn't the whole point that in a bio-similar world
2079 patentability changes because the approval standard has been

2080 reduced from sameness to similarity?

2081 Ms. {Harbour.} Let me just say that in this market we
2082 know that the follow-on biologic will resemble brand to brand
2083 competition. And we know that the patents are strong on
2084 biologic drugs. Now your question was rather long, so I
2085 didn't get all of it but I am going to let Mr. Wroblewski
2086 answer what he heard, and then I will come back.

2087 Mr. {Wroblewski.} Okay. Sure. Your question was to
2088 the extent that if there is no follow-on biologic how can
2089 there be--if there is no pathway yet how can there be any
2090 evidence. What we looked at is the existing brand
2091 competition because these markets are very large, and so
2092 there is plenty of opportunity for another branded competitor
2093 to come into the market, duplicate all the clinical and
2094 safety efficacy data, get a full new drug, and then compete,
2095 but we found that the patents have been so strong in so many
2096 of these markets that it has even kept out a branded
2097 competitor from doing just that.

2098 Ms. {Christensen.} So from creating a similar product
2099 that comes through a different pathway?

2100 Mr. {Wroblewski.} If you create the similar product
2101 what you are doing is you are saying to the FOB you don't
2102 have to do as much clinical testing but you are still going
2103 to have to do some in order to be approved and you can rely

2104 on the FDA's previous findings about the innovator drug that
2105 it is safe and effective and you won't have to do as much.
2106 But if the patents have been strong to keep out the branded
2107 competitors they are going to be equally as strong to keep
2108 out the follow-on competitors who have to be similar.

2109 Ms. {Christensen.} I guess you don't really make a
2110 recommendation as to what the period of exclusivity is, but
2111 just given the trends and the complexity of the drugs, and
2112 all of the other factors, the length of time that the very
2113 specific processes that have to take place that may not be
2114 able to be duplicated, the amount of investment that has to
2115 be made, can you just explain to me again why we would not
2116 provide for a longer period. It just seems, I mean as a
2117 physician I know that I would have a lot of difficulty. I
2118 would have to adjust myself to generics period to begin with
2119 because my patients, some of them wouldn't accept them even
2120 if I did. But because there may be immune differences in how
2121 a person reacts immunologically and the medication, why
2122 wouldn't you give these complex molecules with all the other
2123 factors a longer period of exclusivity?

2124 Ms. {Harbour.} Let me take a stab at that. We feel
2125 that the patent protection and market-based pricing is
2126 enough. Why? First of all, the rationale for 12 to 14-year
2127 branded exclusivity period basically would be to compensate

2128 for any perceived failures of the patent system to reward and
2129 protect and to incentivize biologic drug innovation, but our
2130 report has not found any perceived failure. Therefore, we
2131 found that branded exclusivity was not necessary because the
2132 branded biologic manufacturers are likely to enter the market
2133 and earn substantial revenues even after follow-on entry.

2134 And the follow-on biologics are unlikely when they do
2135 enter the market against the pioneer manufacturers, they are
2136 unlikely to price discount more than 10 to 30 percent. That
2137 means that the branded pioneer manufacturers are likely to
2138 maintain their advantage. They will still retain 70 to 90
2139 percent of their market share after the follow-on biologic
2140 enters. They are still making very excellent profits and the
2141 biologic product has already, as I said, been incentivized
2142 through patent protection and market-based pricing.

2143 Ms. {Christensen.} Well, my time is up. If there is
2144 another round, I may come back.

2145 Mr. {Pallone.} Just to know, we are not going to have
2146 another round but thank you. Mr. Murphy.

2147 Mr. {Murphy of Pennsylvania.} Thank you, Mr. Chairman.
2148 Some quick questions here. The comment that you just made
2149 about 70 to 90 percent, they will maintain 70 to 90 percent
2150 of their market share, and they will likely continue to reap
2151 substantial profits. What is the basis of that statement?

2152 Likely, what does likely mean?

2153 Mr. {Wroblewski.} The basis of the statement is the
2154 experience that we have seen so far in Europe in terms of how
2155 they have priced and then with the limited experience that we
2156 have seen with the one example with Humatrope here in the
2157 U.S. It is a biologic drug but happens to be approved under
2158 the Federal Food, Drug, and Cosmetic Act so it is an
2159 exception. So when we looked at those, but then it is also
2160 based on the Commission conducted a workshop in which we had
2161 the biotech industry. We had the potential FOB competitors.
2162 We had the payors, the PBMs, and the--

2163 Mr. {Murphy of Pennsylvania.} Did you have the
2164 companies that actually do the research and development in
2165 the room? Did you have the companies that actually developed
2166 the new drugs in the room?

2167 Mr. {Wroblewski.} Oh, yes. Oh, yes.

2168 Mr. {Murphy of Pennsylvania.} And did they say that
2169 they thought it was maintaining at 70 percent--

2170 Mr. {Wroblewski.} Yes.

2171 Mr. {Murphy of Pennsylvania.} Did they say maintaining
2172 70 percent market share they could continue to--

2173 Mr. {Pallone.} I couldn't even hear some of the
2174 comments you made. I don't know if the reporter could.
2175 Maybe don't repeat it now but just stay close to that mike.

2176 Mr. {Wroblewski.} Okay. I am almost swallowing it.

2177 Mr. {Murphy of Pennsylvania.} I understand that nearly
2178 90 percent of biotech companies have remained unprofitable.
2179 In 2008, a third of them had less than 6 months cash on hand.
2180 They have to go out and get venture capital for these things,
2181 and if we say to the venture capitalists who are investing
2182 that we are going to reduce that by several years of return
2183 on investment here that to have someone come through--I
2184 wasn't in this room when everybody met. Let us take out the
2185 payors. Let us take out the FOBs who is going to benefit
2186 from this. Just the companies, they said, yes, it is fine
2187 with us, cut us down to 5 years and we can make do with this?

2188 Mr. {Wroblewski.} No. No.

2189 Mr. {Murphy of Pennsylvania.} Okay. What did they
2190 agree to?

2191 Mr. {Wroblewski.} They agreed to what the market effect
2192 would be of FOB entry.

2193 Mr. {Murphy of Pennsylvania.} They are fine with it?

2194 Mr. {Wroblewski.} It was their research that--

2195 Mr. {Murphy of Pennsylvania.} Down to what level, down
2196 to how many years exclusivity?

2197 Mr. {Wroblewski.} Say that again.

2198 Mr. {Murphy of Pennsylvania.} Down to how many years of
2199 exclusivity are they fine with?

2200 Mr. {Wroblewski.} What we were trying to do was analyze
2201 how competition was likely to develop.

2202 Mr. {Murphy of Pennsylvania.} But down to how many
2203 years exclusivity, did they comment on that?

2204 Mr. {Wroblewski.} They have strenuously advocated for a
2205 12 to 14-year period of exclusivity.

2206 Mr. {Murphy of Pennsylvania.} So they are okay if it
2207 stays 12 to 14 years and to have competition into the market
2208 there, is that what they said, they can still--

2209 Mr. {Wroblewski.} Say the last piece again. And the--

2210 Mr. {Murphy of Pennsylvania.} The 70 to 90 percent of
2211 their market share but it is at 70 to 90 percent of their
2212 market share so let FOBs come in, but would that also still
2213 maintain some exclusivity for that 12 to 14 years?

2214 Mr. {Wroblewski.} What we had tried to do was to see
2215 how the competition was likely to develop to determine
2216 whether--

2217 Mr. {Murphy of Pennsylvania.} I only have 2 minutes
2218 left. I just need an answer. Does that--are they agreeing,
2219 yes, we are okay with competition if we can keep the 12 to
2220 14-year exclusivity, and that allows us to raise enough money
2221 in an unprofitable time to do research on new drugs?

2222 Mr. {Wroblewski.} I don't think they ever agreed that
2223 they would be able to keep 70 to 90 percent. It is just what

2224 the experience has shown that they would--

2225 Mr. {Murphy of Pennsylvania.} Well, I am confused
2226 because I thought you said that they all met together and
2227 they told you they were supportive.

2228 Mr. {Wroblewski.} Everybody predicts that the effect of
2229 a follow-on biologic will be--that they will come in at a 10
2230 to 30 percent discount, and if they do that the brand or the
2231 pioneer is likely to retain 70 to 90 percent of its market
2232 share.

2233 Mr. {Murphy of Pennsylvania.} Okay, but I thought you
2234 said--

2235 Mr. {Wroblewski.} We looked at what that implication
2236 was.

2237 Mr. {Murphy of Pennsylvania.} I need an answer here. I
2238 am really not trying to be funny, but I don't want to dance
2239 around this because I want to make sure we have plenty of
2240 money to continue to develop life-saving drugs. That is what
2241 I want. Cheap drugs that don't cure anything are worthless.
2242 Expensive drugs that no one can afford are worthless. So I
2243 need to know. You talked about some people sat around and
2244 they agreed to something. What the heck did they agree to,
2245 and if they didn't, don't tell me they did. Are they saying
2246 that this 12 to 14-year exclusivity remains, are they saying
2247 they are okay with competition, are they saying they are okay

2248 with making it 5-year exclusivity? What specifically did
2249 they say in 3 words or less? I just need an answer quickly.

2250 Mr. {Wroblewski.} They agreed that competition would be
2251 like a branded competitor and we have ways to deal with
2252 branded competitors now.

2253 Mr. {Murphy of Pennsylvania.} Did they comment at all
2254 on the years of exclusivity or is your report not touching on
2255 today?

2256 Mr. {Wroblewski.} No. It describes completely that
2257 they have put forth a model that shows that they need 12 to
2258 14 years.

2259 Mr. {Murphy of Pennsylvania.} Okay. One other thing I
2260 want to ask real quick. The issue of similarity so a
2261 molecule may change its large molecule. A molecule may
2262 change. We are not going to require the FDA to do testing on
2263 those?

2264 Mr. {Wroblewski.} We took it as a given that the FDA
2265 would approve a safe and effective product, whatever that
2266 required.

2267 Mr. {Murphy of Pennsylvania.} So the FDA may still
2268 require additional testing of some of these drugs?

2269 Mr. {Wroblewski.} And that is the reason why it is
2270 going to be so expensive to bring in an FOB.

2271 Mr. {Murphy of Pennsylvania.} Okay. So just changing a

2272 molecule on something, I mean you could change one molecule
2273 in an H2O formula and make something that is toxic versus
2274 something that is necessary so I hope that that is an
2275 important part of this whole report. If that is something we
2276 have discussed more perhaps you can elaborate on this for me
2277 because it is something you made reference to in writing and
2278 also in your testimony here. I really would like to know
2279 what that means because that is going to be very important to
2280 understand how we can have a competitive marketplace and also
2281 make sure there is sufficient funding in here that we can
2282 keep moving forward in developing these new drugs. I would
2283 be grateful for that. The procedure will be to let the
2284 chairman know and we will go on from there. Thank you so
2285 much.

2286 Mr. {Pallone.} Let me mention to you and to the
2287 members, and obviously as always you will be able to pose
2288 questions in writing that we would ask you to respond to
2289 after the hearing. The gentlewoman from California, Ms.
2290 Eshoo.

2291 Ms. {Eshoo.} Thank you, Mr. Chairman. The first thing
2292 I would like to start out with is to ask for unanimous
2293 consent to place in the record the comprehensive responses to
2294 every question raised by the subcommittee from the chief
2295 scientist of the FDA, Dr. Frank Torti, which was peer

2296 reviewed, and, second, the exhaustive economic analysis of
2297 data exclusivity of biologics by Henry Grabowski, whose name
2298 has been mentioned several times by several members on both
2299 sides of the aisle today. He is the director of the Program
2300 of Pharmaceuticals and Health Economics at Duke University.
2301 So I would ask that these be placed in the record.

2302 Mr. {Pallone.} Let me just ask, these are the comments
2303 by the FDA under the Bush Administration, is that what they
2304 are?

2305 Ms. {Eshoo.} Well, the FDA is the FDA regardless of
2306 what Administration it is under.

2307 Mr. {Pallone.} No, no, I just want to make sure because
2308 I know we have asked--I am only asking because I know that we
2309 have asked the FDA, the current FDA, too, but these are the
2310 ones from the previous, right? Let me see them.

2311 Ms. {Eshoo.} You know what, Mr. Chairman, I think you
2312 know what I asked. I am just asking for unanimous consent to
2313 place this in the record. If people want to read it, they
2314 will have access to it. If they think it is garbage, they
2315 can throw it out. It doesn't force anyone. It is a very
2316 simple request.

2317 Mr. {Pallone.} No, no, I agree. I am just trying to
2318 verify what it is.

2319 Ms. {Eshoo.} Read it and then you will see. Is there

2320 unanimous consent to it?

2321 Mr. {Pallone.} Well, normally I like to know what it is
2322 before I agree.

2323 Ms. {Eshoo.} I just read it into the record.

2324 Mr. {Pallone.} Tell me again. It is the FDA--

2325 Ms. {Eshoo.} These are the comprehensive responses to
2326 the questions that the members of the subcommittee almost 2
2327 years ago before we had the meeting--

2328 Mr. {Pallone.} Right, but we have also asked them--
2329 these are the ones from the previous Administration. We have
2330 asked them again in the current Administration.

2331 Ms. {Eshoo.} You don't agree with what the FDA
2332 responded, but I still would like that in the record.

2333 Mr. {Pallone.} No, I just want to make sure that they
2334 are the ones from the previous Administration. That is what
2335 we are talking about, right?

2336 Ms. {Eshoo.} What is the date on it? It is September
2337 18, 2008.

2338 Mr. {Pallone.} Okay.

2339 Ms. {Eshoo.} So it is just before my candidate for
2340 President won.

2341 Mr. {Pallone.} All right. So ordered.

2342 [The information follows:]

2343 ***** COMMITTEE INSERT *****

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2344 Ms. {Eshoo.} In trying to read the report, digest it,
2345 and then analyze it in the unfair time frame that was
2346 established either by the FTC or by the committee, I don't
2347 know which it is, there is something that stood out to me,
2348 and that is throughout the report, throughout your report you
2349 base the--you talk about obviously the generics that are the
2350 result of Hatch-Waxman, which we all celebrate, and this new
2351 attempt to use that framework, very broad framework, and
2352 apply it to biologics. But what you, I think, fail to state
2353 and then develop in the report is that under Hatch-Waxman the
2354 compounds, the pharmaceuticals must be identical. That is by
2355 law. Biologics, bio-similars, think of the 2 parts of that
2356 word, will be similar. They cannot be identical. I don't
2357 know what scientists you brought in to instruct you on this,
2358 but I have to say that to base your report, as I read it, I
2359 think it is deeply flawed because you base your outcome and
2360 your analysis of bio-similars on the previous regimen and the
2361 previous law, which is very different.

2362 I don't see where you have taken into consideration the
2363 differences between the two which is what makes this case
2364 very complex. We have a regulatory framework today in which
2365 any new biologic will receive, and I want to move on, because
2366 I want to ask my questions but that is an observation, any

2367 new biologic would receive 20 years of patent protection and
2368 no potential for bio-similar competition. Innovators and
2369 investors are assured that as long as their patents are in
2370 force, there is no possibility of a competitor going to the
2371 FDA using the innovator's safety and efficacy record and
2372 taking a shortcut to the market to compete against them.

2373 Now we are proposing to move to a policy in which
2374 patents will remain in force but competitors will be able to
2375 come to market to compete against an innovative product
2376 without going through a full-blown FDA review. As you point
2377 out in the report, this will cost a bio-similar manufacturer
2378 about a tenth of the cost for an innovator or a non bio-
2379 similar competitor to bring a product to market. Now how can
2380 this not possibly change? How can this--because you say in
2381 your report that investment incentives won't change. How can
2382 this not possibly change the investment incentives in bio-
2383 technology? If a venture capitalist or a drug company is
2384 contemplating a new product for development, won't this
2385 fundamentally alter their rise/reward calculation? This has
2386 to have an examination. I don't know where you leap frog to.
2387 It is almost as if this doesn't exist or that if we don't
2388 talk about, we don't have to deal with it, therefore, it
2389 doesn't exist.

2390 So I think you need to answer that. And I want to bring

2391 out my next question as well. Your report states that a 12
2392 to 14-year exclusivity period, this is quote, ``is
2393 unnecessary to promote innovation by pioneer biologic
2394 manufacturers.'' This position is based on your assumptions
2395 that patent workarounds will be no easier to accomplish for
2396 biologics than they have been for small molecule generic
2397 drugs. You also state that data exclusivity is only
2398 justified for products that are unpatentable, but I see no
2399 substantiation at all for these positions in your report.
2400 That is why I question whether past or present information
2401 about small molecule generics is a reliable predictor for
2402 biologics, and that is why I question the basis for your
2403 assumptions.

2404 We have absolutely no experience, and I want to repeat
2405 that. We have absolutely no experience with the similarity
2406 standard that will be used for biologics for the approval of
2407 bio-similars, so how can you be sure that a new and untested
2408 standard would not facilitate a path for patent workarounds
2409 for biologics? How can you be sure that the different nature
2410 of biologic patents in conjunction with the similarity
2411 standard would not facilitate patent workarounds? How can
2412 you be sure? And, you know what, guessing in this is not
2413 going to be good enough. I would challenge you to ingest
2414 what comes out without the kind of scrutiny of the FDA and

2415 comparing one with the other as if they are the same as if it
2416 is apples and pears. It is not. How can you be sure that
2417 today's science and the scientific advances in the future
2418 would not make it easier for bio-similar companies to work
2419 around biologic patent claims?

2420 I think that this is a real chink in the armor of the
2421 report or just in the report, which I have to tell you at
2422 quarter to 1:00 this morning, I thought really suggested a
2423 lot of guesswork on the part of the FTC. And let me hold
2424 something up, and I don't know if you had anyone come in and
2425 show you this. This is a regular drug, small molecule
2426 compound. This is tamoxifen. Look at it. It is all the
2427 same. This is herceptin. This is herceptin. This is
2428 herceptin. If this picture doesn't speak a thousand words
2429 where you use the model throughout your report based on the
2430 generics of the small molecules and apply it to this, I want
2431 to tell you something, patients are going to be in big
2432 trouble in this country. Patients are going to be in big
2433 trouble in this country.

2434 And if efficacy of this movement is not taken into
2435 consideration, God help us. Now there is something else that
2436 has gone around in the committee for those that are opposed
2437 to my viewpoint, and they have every right to oppose it. But
2438 I want to--and there are other members that have touched on

2439 this. We cannot take for granted those that innovate to
2440 pursue the cure of these deadly diseases. The FDA is not
2441 going to do it, the Energy and Commerce Committee is not
2442 going to do it. We have a private sector that does it. Yes,
2443 there need to be new rules of the road because we want lower
2444 costs and safe products. But that role cannot be diminished,
2445 and, I don't know, I looked at the back of your report. Did
2446 you have any people that do the investing in this come and be
2447 part of your round table? If they were law firms, I didn't
2448 recognize them.

2449 Mr. {Pallone.} Let me just--we are like twice the time
2450 so I am just going to ask you to--I know you can't respond to
2451 everything but--

2452 Ms. {Eshoo.} Well, there was an assertion, Mr.
2453 Chairman.

2454 Mr. {Pallone.} But if you could just respond as quickly
2455 as you can because we need to move on.

2456 Ms. {Harbour.} I will. There were just a number of
2457 assumptions. First of all, let me just apologize to you for
2458 the lack of time you had to read the report.

2459 Ms. {Eshoo.} Well, why did that happen to begin with?
2460 Were you told--how long have you been working on this?

2461 Ms. {Harbour.} The commissioners received the report at
2462 4:00 on Tuesday evening.

2463 Ms. {Eshoo.} No, no. How long has the FTC been working
2464 on this report?

2465 Mr. {Wroblewski.} We announced our workshop because we
2466 had a public hearing in August of last year.

2467 Ms. {Eshoo.} How long have you been working on it?

2468 Mr. {Wroblewski.} Ten months.

2469 Ms. {Eshoo.} Ten months.

2470 Ms. {Harbour.} And it was finished on Tuesday.

2471 Ms. {Eshoo.} And you notified the committee that it was
2472 complete when?

2473 Mr. {Wroblewski.} I notified the--the beginning of last
2474 week that it would be ready.

2475 Ms. {Harbour.} And it was ready Tuesday at 4:00.

2476 Ms. {Eshoo.} And did the FTC--was it the FTC that
2477 refused to put the report out to members and only after
2478 cajoling that we finally got it and that some of us took it
2479 home to read last night?

2480 Ms. {Harbour.} Let me be really clear. The report was
2481 finished Tuesday at 4:00 p.m. The commissioners of the
2482 Federal Trade Commission voted this Tuesday, this week, at
2483 4:00 p.m. on the report. There were embargoed copies that
2484 went probably before we even voted on it, but it went to the
2485 full committee the very next day.

2486 Ms. {Eshoo.} You know what, let us get to the--

2487 Mr. {Pallone.} All right, but we have to move on.

2488 Ms. {Eshoo.} I would like you to answer the questions
2489 that I posed.

2490 Ms. {Harbour.} Okay. There was an assumption that was
2491 made, you said that the report applied the Hatch-Waxman
2492 framework in this context. It doesn't--

2493 Ms. {Eshoo.} Similarities. I am sorry. The identical
2494 standard and use it and apply it to the similar standard.

2495 Ms. {Harbour.} The report actually did not say that.
2496 In fact, the approval pathway for biologics will be very
2497 different than the Hatch-Waxman approval process, and that is
2498 why I started by apologizing that you didn't get a chance to
2499 read the full report because it doesn't say that the approval
2500 process is similar. It is not. In fact, we are advocating
2501 that a Hatch-Waxman approval process would not be appropriate
2502 in the case of follow-on biologics. And the reason we say
2503 that is because it mimics brand-to-brand competition.

2504 Ms. {Eshoo.} I am not talking about the approval
2505 process. I am talking about the investment incentive. You
2506 all are the ones that are in charge of competition. That is
2507 why, I guess, you got involved in this whole issue and that
2508 is why I think--

2509 Mr. {Pallone.} If you would just answer that, and then
2510 we have to move on. I am just going to have to move to the

2511 next person.

2512 Mr. {Wroblewski.} What we did is we looked at--we did
2513 look at the investment incentives for the biologics and
2514 compared them to the investment incentives for a small
2515 molecule drug, the Hatch-Waxman type drug, and the research
2516 that we have that is out there, and I provided to your staff
2517 earlier, was that the actual time and the cost to develop a
2518 pioneer biologic drug versus a pioneer small molecule drug
2519 are the same.

2520 Mr. {Pallone.} All right. I have to go. Ms. Capps is
2521 the next for questions.

2522 Ms. {Capps.} Thank you. Thank you, Honorable
2523 Commissioner, for being here for this long. One of the
2524 reasons, I have 3 different questions to ask, one of the
2525 reasons that has been given for a 12 to 14-year exclusivity
2526 period is that without such a lengthy period start-up biotech
2527 companies will not be able to interest venture capitalists in
2528 investing in their companies, and without venture capital
2529 these companies cannot survive. Some believe that this
2530 specific number of years is very difficult to evaluate.
2531 Before Congress makes a determination on exclusivity periods,
2532 this hearing is because we feel a duty to determine whether
2533 there is adequate evidence to support arguments in its favor.
2534 First question, did the evidence gathered by the FTC in the

2535 course of its investigation support the claims that venture
2536 capitalists will no longer invest in start-up biotech
2537 companies without this 12 to 14 years of exclusivity?

2538 Mr. {Wroblewski.} We believe that patent protection
2539 will still provide those incentives. Patent protection plus
2540 market-based pricing will still provide those incentives for
2541 venture capitalists to invest in start-up biotech ventures.

2542 Ms. {Capps.} I know you have mentioned this already. I
2543 just wanted to get it clearer from my perspective as well.
2544 Next question, is there evidence that start-up biotech
2545 companies will still be able to recruit venture capital in
2546 during like a 5-year period comparable to what the
2547 traditional drugs have or the small molecule drugs have?

2548 Mr. {Wroblewski.} Yes, because patent rights are still
2549 going to be strong.

2550 Ms. {Capps.} Do you have evidence that this is the
2551 case?

2552 Ms. {Harbour.} Well, we have seen if you take a look at
2553 the stock market in the biotech market the stock prices only
2554 went down 15 percent compared with the general market indices
2555 went down 30 percent.

2556 Ms. {Capps.} But you are using that as one method of
2557 your valuation?

2558 Ms. {Harbour.} There are probably more as well, but

2559 that is what comes to mind.

2560 Ms. {Capps.} Are there others?

2561 Mr. {Wroblewski.} The only thing I was going to add was
2562 the venture capital that has come into the biotech industry
2563 in the past quarter has actually been very robust.

2564 Ms. {Capps.} And right now there is no 12 to 14-year
2565 exclusivity because that is what we are debating, so right
2566 now they have nothing--pardon?

2567 Mr. {Wroblewski.} That is true, there is no 12 to 14-
2568 year exclusivity.

2569 Ms. {Capps.} There is the same as small molecule.
2570 Finally, another kind of tact, the FTC report concludes, as
2571 you just mentioned, that 12 to 14 years of exclusivity is
2572 unnecessary because patents and market-based pricing
2573 available under current law provides sufficient incentives
2574 for innovation. I am particularly interested in one of your
2575 conclusions that given an excessive period of exclusivity may
2576 in itself have negative consequences, and that may actually
2577 harm patients. This is a piece that I would like you to
2578 spell out. What are some of these negative consequences,
2579 particularly how the length of exclusivity might decrease the
2580 number of medical breakthroughs but also the particular--I
2581 know many people hang on to the hope that something is going
2582 to be available to them for their own life-saving needs, and

2583 so these 2 aspects. Additional breakthroughs, follow-on
2584 behind some new discovery, often times they do, and then the
2585 part that relates to the patient's own survivability.

2586 Ms. {Harbour.} I would say that the 12 to 14-year
2587 exclusivity period could in fact slow the pace of innovation
2588 so new--

2589 Ms. {Capps.} So other companies will know they just
2590 can't even do anything for that long a time so they won't
2591 try?

2592 Ms. {Harbour.} That is right, and ultimately that is
2593 not good for the American consumer because you are not
2594 getting new drug products in the market as quickly.

2595 Ms. {Capps.} Right. I know especially because there
2596 are different criteria in other countries that sometimes
2597 people see availabilities in other places that they can't
2598 make available to themselves here, which creates quite a
2599 possible tragic situation at least from their points of view
2600 although to be sure we want to make sure that our standards
2601 are ones that we set ourselves. Is there any evidence on the
2602 previous--since I have just a few seconds left, that a long
2603 length of time of exclusivity would have this sort of
2604 chilling effect on additional innovations to that particular
2605 so upgrading it or making it better or doing something
2606 different along the side of it, sometimes different outcomes

2607 based on something that is set up in a particular--and they
2608 are very complex and they will spin off into some other kind
2609 of breakthrough?

2610 Mr. {Wroblewski.} We have seen in other areas that
2611 whenever the exclusivity ends that that is when the
2612 innovation occurs, and so to the extent that the follow-on
2613 pathway that you are establishing still keeps intact those
2614 very robust incentives of patent protection and market-based
2615 pricing then you will have the threat of competition coming
2616 from behind acting it is almost like carrots and sticks.
2617 With the carrot you have the ability to price at market
2618 whatever the market will bear for that period of time for
2619 your patent. And then you have the competition can come on
2620 and hasten the development. That is win-win for the
2621 consumers.

2622 Ms. {Harbour.} And one thing I want to add. The
2623 exclusivity is really additional protection over and above
2624 what the patent system provides and the original rationale
2625 for the 12 to 14-year branded exclusivity period under Hatch-
2626 Waxman was to compensate for a perceived failure of the
2627 patent system. We haven't perceived that failure here with
2628 biologics and follow-ons.

2629 Ms. {Capps.} Thank you. I yield back.

2630 Mr. {Pallone.} Thank you. The gentleman from Utah, Mr.

2631 Matheson.

2632 Mr. {Matheson.} Thank you, Mr. Chairman. In my opening
2633 statement, I mentioned that 80 percent of the biotech
2634 industry right now remain unprofitable. Is that consistent
2635 with what you have heard as well?

2636 Mr. {Wroblewski.} We have seen the same statistics.

2637 Mr. {Matheson.} In the previous round of questions, you
2638 were asked for evidence about ability to attract capital.
2639 You mentioned recent stock performance and quarterly
2640 investment from venture funds. Do you think that short-term
2641 window of the last few months is really the best evidence you
2642 got for telling us that the investment incentives are right
2643 because I got to tell you that doesn't sell me.

2644 Mr. {Wroblewski.} Sure. We can certainly provide you
2645 all the evidence. We would be more than happy to give you
2646 the evidence.

2647 Mr. {Matheson.} Mr. Chairman, I think it would be real
2648 helpful again at future hearings, let us get some folks in
2649 the venture capital industry and let us get some other folks
2650 in here so we can have a broad discussion about what is
2651 really going on here because I do think we want to make sure
2652 when we are setting policy that we do set an environment that
2653 encourages that private sector investment in these areas. I
2654 think that would be a useful tool. I want to ask a question.

2655 Right now in Europe, you have heard, and a number of people
2656 said this in their opening statements, that it is 10 to 11
2657 years of data exclusivity. Have you in your analysis thought
2658 about how an exclusivity period in the United States would be
2659 lower than the European model, how that would affect U.S.
2660 competitiveness in this industry?

2661 Mr. {Wroblewski.} The European model is very different
2662 for 2 reasons that we mentioned earlier. One was that the
2663 scope of the patent system is different in that they have
2664 regulated prices in Europe, so with a 10-year period of
2665 exclusivity and only the ability to charge a regulated price
2666 as opposed to a price that the market would bear, and if they
2667 have developed a monopoly, it is a monopoly price, that that
2668 market necessarily isn't--that model isn't necessarily as
2669 translatable here to the U.S.

2670 Mr. {Matheson.} Have you in your analysis, have you
2671 seen where a biotech industry is moving away from Europe and
2672 coming to the United States in previous years?

2673 Mr. {Wroblewski.} I think what we saw throughout the
2674 entire analysis was that biotech in many ways is a global
2675 industry, but that here in the United States it is locally
2676 centered, so because of the strong collaborative efforts
2677 between universities, between start-ups that have talent to
2678 manage projects that you have a collaboration, and so that is

2679 why you have in Wisconsin, you have a biotech industry--

2680 Mr. {Matheson.} Let me ask you, in your analysis did
2681 you look at why--in terms of looking why the Europeans set
2682 this data exclusivity at 10 to 11 years, you have mentioned
2683 your issue about market pricing, did you analyze other
2684 reasons why they set that exclusivity period where they did,
2685 and in fact was not one of the reasons because industries
2686 were leaving Europe and coming to this country?

2687 Mr. {Wroblewski.} When we spoke with the European
2688 regulators they explained that their system was kind of a
2689 different system because they were incorporating not only
2690 biologics but small molecule drugs too in that whole system
2691 and that it was a different dynamic than what I think we are
2692 facing here.

2693 Mr. {Matheson.} Let me ask you this question.
2694 Obviously, the committee is looking at different bills that
2695 look at data exclusivity. What are the factors you think we
2696 ought to be taking into consideration as a committee in terms
2697 of how we determine an appropriate length of exclusivity?

2698 Mr. {Wroblewski.} I think there are a couple of things
2699 that we should look at, one, to see if there is a failing in
2700 the patent system because drugs are unpatentable, that is a
2701 serious flaw for all drug development, and there should be
2702 some type of mechanism to recoup and to encourage people or

2703 firms to engage in that clinical testing.

2704 Mr. {Matheson.} So are you suggesting it is more of a
2705 patent reform issue and not data exclusivity, is that what
2706 you are saying?

2707 Mr. {Wroblewski.} Yes.

2708 Mr. {Murphy.} And you are saying that the fact the
2709 biologic industry maybe faces a different set of dynamics
2710 than conventional prescription drug industry that this
2711 exclusivity issue is not an appropriate tool for us to
2712 acknowledge the challenges in the biotech industry?

2713 Mr. {Wroblewski.} We didn't see that the tools that we
2714 currently used to incentivize innovation, basically patents
2715 and the fact that you can price up the market somehow would
2716 fail and with a bio-similar that wouldn't have nearly the
2717 dramatic market impact that a small molecule generic drug
2718 would have.

2719 Mr. {Matheson.} If you think that the intent is that we
2720 want to set up an appropriate opportunity for the private
2721 sector to recoup its R&D cost to develop one of these, are
2722 you telling me data exclusivity is not an appropriate tool
2723 for us to be looking at?

2724 Mr. {Wroblewski.} I think it is an appropriate tool to
2725 look at if the other 2 tools which have been wildly
2726 successful are broken.

2727 Mr. {Matheson.} And you are suggesting they are broken?

2728 Mr. {Wroblewski.} Quite the opposite. I am suggesting
2729 that they seem very strong.

2730 Mr. {Matheson.} I see my time has expired, Mr.
2731 Chairman, but I guess I will reiterate what a number of folks
2732 have said. I think it would be helpful to bring some other
2733 folks in before this committee to get some other points of
2734 view, and I will yield back my time.

2735 Mr. {Pallone.} Thank you. Before I ask Mr. Inslee, I
2736 know that my colleague from Georgia has a request.

2737 Mr. {Deal.} Yes, Mr. Chairman. I have a unanimous
2738 consent request that a report from Alex M. Brill, who is a
2739 fellow at the American Enterprise Institute, and a report
2740 from Lawrence L. Kotlikoff, Professor of Economics at Boston
2741 University, and a report from the ARP Public Policy Institute
2742 on biologics, that they be included in the record.

2743 Mr. {Pallone.} Without objection, so ordered.

2744 [The information follows:]

2745 ***** COMMITTEE INSERT *****

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2746 Mr. {Pallone.} Mr. Inslee.

2747 Mr. {Inslee.} Thank you, Mr. Chairman. Thanks for
2748 allowing me to participate in this very important hearing,
2749 and I hope there are others on this line. This is a complex
2750 area, but there is one conclusion of this report that is so,
2751 in my view, fantastically unrelated to the realities of the
2752 marketplace. I really got to question it. On page 7 of your
2753 executive report, I will read you what it says. It says,
2754 ``Central to each of these exclusivities is a public policy
2755 trade-off, a restriction on competition is provided in return
2756 for the development of a new drug product or new use of an
2757 existing product. A 12 or 14-year exclusivity period departs
2758 sharply from this trade-off because it does not spur the
2759 creation of a new biologic drug or indication. The drug has
2760 already been incentivized through patent protection and
2761 market-based pricing.''

2762 Now that statement is so fantastically unrelated to
2763 reality suggesting that the removal of the exclusivity period
2764 will help incentivize further investment in new drugs to cure
2765 new diseases. Right now if a drug company wants to go out
2766 there and develop a new drug that will cure leukemia, they
2767 have an incentive to investment in part because of data
2768 exclusivity, and yet you have turned that upside down and

2769 suggest by removing that data exclusivity somehow you will
2770 create an additional incentive for investment of a new drug.
2771 Now a biologically similar drug is not going to cure a
2772 disease that hasn't already been dealt with by the original
2773 product, and I just cannot fathom how you make this argument
2774 that removing data protection is going to create greater
2775 incentive for investors to put money into products that will
2776 truly respond to this condition in a new way. I just think
2777 you have turned reality on its head in that regard. So I
2778 will give you a chance to respond to that. I can't imagine
2779 what it would be but take a shot.

2780 Ms. {Harbour.} Let me take a shot first. Your question
2781 seems to presume that the patent system is not strong enough
2782 to protect patents. Basically, exclusivity is additional
2783 protection above and beyond what the patent system provides.

2784 Mr. {Inslee.} But let me just ask you this. Don't you
2785 agree that data exclusivity is one of the things that
2786 investors take into consideration when they decide to plunk
2787 down several million dollars on something that may take a
2788 decade, that may or may not work? Don't you think that is an
2789 incentive for investment in truly new drugs that truly treat
2790 conditions in a new way, which is the original patent that we
2791 are talking about here? Don't you agree with that?

2792 Ms. {Harbour.} No, only if there is truly a perceived

2793 failure with the patent system.

2794 Mr. {Inslee.} Well, then you do not have any, and with
2795 all due respect, any recognition of the investment climate in
2796 the United States if you do not recognize this as critical to
2797 inspiring investment in these truly new drugs. So let me ask
2798 you about that. Did your study of valuing the impact on the
2799 investment in new products, truly new products, what will
2800 approach these conditions in a new way, did you evaluate how
2801 that would affect investment in these new products, and I
2802 mean new. That is not follow-on biologics. Did you?

2803 Mr. {Wroblewski.} We did not evaluate that in
2804 particular, and I will tell you why. It is because patent
2805 protection has been very, very strong. We have suggested
2806 though in the executive summary that one way to--

2807 Mr. {Inslee.} I have got limited time. I think if you
2808 would answer my question, I would appreciate it, but the
2809 point I want to make is you assumed for purposes of this
2810 study that there is no impact. That is an assumption we
2811 can't make because if you make that assumption and it is
2812 wrong, which I believe it is wholeheartedly wrong, you will
2813 cut off the development of new drugs because investments will
2814 not be made in them. So let me ask you a further question.
2815 Madam Commissioner, you told us you consider yourself an
2816 expert on consumers. I will give you a hypothetical

2817 consumer. Let us take parents of a 10-year old kid with
2818 leukemia, and we are now evaluating risks when we consider
2819 this legislation. One of the risks is that we would continue
2820 data exclusivity and the parents might have a 10 to 30
2821 percent increased cost of a drug that might cure leukemia.
2822 Let us assume that there is one right now. The other risk is
2823 that a drug would never be created to cure leukemia because
2824 by removing data exclusivity the investment never gets made
2825 to provide that life-saving drug. As an expert in consumer
2826 behavior, what do you think is more important in the bigger
2827 risk to those parents of that kid?

2828 Ms. {Harbour.} First of all, if I said I was an expert
2829 on consumers, I misspoke but let me--

2830 Mr. {Inslee.} I think that was the direct quote I could
2831 find.

2832 Ms. {Harbour.} I am an expert on protecting the
2833 American--

2834 Mr. {Inslee.} Okay. As an expert in protecting the
2835 consumer, what do you think would be a greater risk in the
2836 minds of the parents of that child, the risk that they would
2837 have a 10 to 30 percent higher cost for the drug or the risk
2838 that this drug that could cure their child would never be
2839 created?

2840 Ms. {Harbour.} You are assuming that data exclusivity

2841 is the only way that one would invest in a drug, and that is
2842 what I am pushing back against. I don't think that
2843 assumption is correct. There are exceptions though where if
2844 you have a small patient population or if you are bringing
2845 drugs on the Orphan Drug Act where exclusivity would be
2846 necessary because there is a perceived market value, in that
2847 circumstance exclusivity would be absolutely appropriate.

2848 Mr. {Inslee.} And the unfortunate limitation of your
2849 study, according to what was just testified--

2850 Mr. {Pallone.} I just have to ask the gentleman--

2851 Mr. {Inslee.} Thank you, Mr. Chair. I appreciate your
2852 cooperation.

2853 Mr. {Pallone.} Okay. The gentleman from Texas, Mr.
2854 Burgess.

2855 Mr. {Burgess.} Thank you, Mr. Chairman. Let me just
2856 follow along that discussion that you were just having. Now
2857 within the Federal Trade Commission, have you constructed a
2858 matrix that will give you a cost benefit analysis, some of
2859 the newer compounds, for example, that inhibit some small
2860 blood vessel growth that may be used in treating more
2861 advanced cancers? Do you look at the number of hospital days
2862 that might be saved by using one of these advanced biologics
2863 and considering the cost? Yes, they are expensive but the
2864 disease that they are treating also has expensive

2865 consequences associated with it, so that if we avoid a
2866 surgery, if we avoid a week in the hospital, there are
2867 additional savings, not just the base line of the drug but
2868 there are other things to consider. So is there a matrix or
2869 a simulation or program that you use to help make those
2870 evaluations or is this simply data that is derived from the
2871 price tag on the bottle or box that the drug comes in?

2872 Ms. {Harbour.} Those sort of questions sound like they
2873 are within the expertise of the FDA. We are looking at the--

2874 Mr. {Burgess.} I am so glad you brought that up because
2875 Mr. Chairman, we should be having this discussion with the
2876 FDA.

2877 Ms. {Harbour.} And perhaps you will. We are your
2878 beginning act here, and we are talking about the competitive
2879 consequences of this sort of follow on. I believe there will
2880 be more hearings and discussions on these issues.

2881 Mr. {Burgess.} Now you and the FDA, are you aligned on
2882 your definition of things like bio-similar and bio-generic?
2883 Do you mean the same thing when you say those terms?

2884 Mr. {Wroblewski.} Yes.

2885 Mr. {Burgess.} It seems like the FDA has hinted that it
2886 might be otherwise, but you feel that currently there is a
2887 scientific basis for determining interchangeability of
2888 biologics from different and unrelated manufacturers?

2889 Mr. {Wroblewski.} What we tried to do was to say if
2890 there is an abbreviated pathway where the follow-on does not
2891 have to duplicate findings of safety and effectiveness
2892 because it can rely on the FDA's approval of the pioneer drug
2893 if that is allowed.

2894 Mr. {Burgess.} That is such a crucial question because
2895 the safety question can be very, very difficult to answer.
2896 And again just as an aside a week ago I was visiting the FDA
2897 and Dr. Hamberg and getting a tour with her through the new
2898 facility that they are occupying out there. One of the
2899 researchers just passing in the halls said what a difficult
2900 time they were having because of the viruses that might
2901 infect the cell cultures that are going to create these
2902 monoclonal antibodies that might be useful in the treatment
2903 of prevention of Alzheimer's in the future. Well, that is a
2904 pretty important arm or branch of that research. I don't
2905 know that he knows or would be interested if he could tell us
2906 that is this something that is so standard and so settled
2907 that you could do this in Dallas as well as Denver as well as
2908 Beijing and get the same result.

2909 Ms. {Harbour.} That is very important, and that
2910 certainly would be for the FDA, not the FTC, to determine the
2911 safety and efficacy of these follow-on biologics.

2912 Mr. {Burgess.} Again, we are hitting on a recurrent

2913 theme, Mr. Chairman. We need to have a hearing that involves
2914 the FDA and many of us have been asking for that for some
2915 time. Again, I will just emphasize that I have not aligned
2916 myself with either of the 2 bills that are out there. I am
2917 really in an information gathering mode and safety had to be
2918 paramount for a doctor that picks up the pen and writes the
2919 prescription and rips it off and puts it in the patient's
2920 hand and counsels them as to the risks and benefits. We have
2921 got to be able to provide them the best data. And it isn't
2922 always just the price tag on the box or the bottle that the
2923 medication is going to be delivered in.

2924 What about, because this would come up all the time when
2925 I was a doctor, and I was in practice for years. There were
2926 some classes of medicines, and these were not biologics,
2927 these were just regular things, but there was some class of
2928 medicines there you just really didn't want to make a change
2929 and you didn't want a generic to be substituted and some of
2930 those things might be some of the cardiac drugs, certainly
2931 some of the diuretics that treat congestive heart disease,
2932 and in my practice estrogens from different manufacturers
2933 actually seemed to have a different biologic behavior. And I
2934 don't know whether it was the bio availability or the vehicle
2935 or what it was, but how are we going to address that? A
2936 doctor has got a patient who is on a very stable regimen, a

2937 patient with a serious and significant disease, and now a new
2938 bio-similar becomes available, how are we going to govern
2939 that because in the generic world it became harder and harder
2940 for me to control that, and often times I would have to pick
2941 up the phone and call 1-800 California and stay on hold for a
2942 long time to get my point across.

2943 Mr. {Wroblewski.} We couldn't agree with you more that
2944 those types of switching are going to be very difficult to do
2945 in the bio-similar environment, and that is one of the
2946 foundations that drew our conclusions that when a follow-on
2947 comes on to the market that its market impact is going to be
2948 substantially different than a generic drug, the market
2949 impact that a generic drug has.

2950 Mr. {Burgess.} Under the Waxman-Hatch, whatever it was,
2951 we lost the ability to--the provider, the doctor, lost the
2952 ability to control that, and again you had to really
2953 intervene on your patient's behalf if you didn't want to have
2954 a substitution.

2955 Mr. {Wroblewski.} And there is no similar type
2956 mechanism in--

2957 Mr. {Burgess.} Well, I think we heard that discussed
2958 this morning that there would have to be ways of directing
2959 this behavior because you couldn't always trust doctors to do
2960 the right thing, imagine that. Just one last point I will

2961 make. We heard the heparin tragedy a year ago in this very
2962 hearing room. The fact that often times the act of
2963 pharmaceutical ingredient, we only manufacture the compounds
2964 in this country but actually the active pharmaceutical
2965 ingredient may come from overseas, and the ability of the FDA
2966 to monitor those manufacturing facilities that are overseas,
2967 and again we saw a tragedy with heparin which is not a
2968 complex molecule. It is a little bit more complex than
2969 aspirin but it would not fall into this category. And we saw
2970 what happened with the intrusion of a foreign substance into
2971 that active pharmaceutical ingredient. It just seems to me
2972 that this manufacturing process which is fraught with much
2973 more peril, you got to be much more precise. You don't just
2974 line up the amino acids and say, there, I have made the
2975 protein. It is the folding, the unfolding, the sulphide
2976 bonza, hydrogen bonza, all those things are going to be
2977 critical to the biologic action of that product, and, again,
2978 all of which can be affected by the humidity, the atmospheric
2979 pressure, and goodness knows what else.

2980 We have an obligation to protect--you say you are the
2981 advocate for the consumer. I think our first obligation has
2982 to be for the safety of that consumer, which is both the
2983 physician and the patient in that scenario.

2984 Ms. {Harbour.} And as an advocate for consumers, I

2985 think it is a good thing to discuss all of these issues. We
2986 are here discussing the competitive implications. Obviously,
2987 the safety implications are paramount. You can't pass go if
2988 there aren't safety implications. There needs to be a
2989 hearing on this potentially as well, but here we can't opine
2990 on those. We don't have the expertise to opine on the
2991 safety. The FDA would have to do that.

2992 Mr. {Burgess.} Thank you for your testimony. Mr.
2993 Chairman, did you get that, we need to have a hearing with
2994 the FDA?

2995 Mr. {Pallone.} I have repeatedly said that we are
2996 having more hearings so no one is disagreeing with that
2997 notion, and I think it is pretty obvious that we have a lot
2998 of disagreements here and we need further hearings. Let me
2999 just thank both of you for being here. This has not been
3000 easy for you, but I appreciate your bearing with us. And, as
3001 I mentioned before, we will undoubtedly have members asking
3002 in writing for you to respond to questions. Normally that is
3003 about 10 days, and the clerk will notify you within the next
3004 10 days of any written questions that the members would have.
3005 But I cannot stress enough that I think that this report was
3006 really informative for me and the other members, and
3007 appreciate your bearing with us today. Thank you very much.
3008 And without further adieu, this subcommittee hearing is

3009 adjourned.

3010 [Whereupon, at 1:45 p.m., the subcommittee was

3011 adjourned.]