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2 HIF090.170

3 HEARING ON H.R. 1706, THE PROTECTING CONSUMER ACCESS TO

4 GENERIC DRUGS ACT OF 2009

5 TUESDAY, MARCH 31, 2009

6 House of Representatives,

7 Subcommittee on Commerce, Trade, and Consumer Protection

8 Committee on Energy and Commerce

9 Washington, D.C.

10 The subcommittee met, pursuant to call, at 11:12 a.m.,
11 in Room 2123 of the Rayburn House Office Building, Hon. Bobby
12 L. Rush (chairman) presiding.

13 Members present: Rush, Schakowsky, Sarbanes, Sutton,
14 Stupak, Barrow, Space, Dingell, Waxman (ex officio),
15 Radanovich, Stearns, Whitfield, Pitts, Terry, Gingrey,
16 Scalise, and Barton (ex officio).

17 Staff present: Christian Tamotsu Fjeld, Counsel; Anna
18 Laitin, Professional Staff; Michelle Ash, Counsel; Valerie

- 19 Baron, Legislative Clerk; Shannon Weinberg, Minority Counsel;
20 Will Carty, Minority Professional Staff; and Brian
21 McCullough, Minority Senior Professional Staff.

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22 Mr. {Rush.} Good morning, everyone. I want to thank
23 you for coming to today's hearing. I will begin this hearing
24 by recognizing myself for 5 minutes for the purposes of an
25 opening statement. This hearing is on the bill H.R. 1706,
26 Protecting Consumer Access to Generic Drug Act of 2009.

27 Today's legislative hearing is on a bill that Chairman
28 Waxman and I introduced last Congress, and this subcommittee
29 held a legislative hearing on our bill on May 2, 2007. We
30 have introduced the bill again with the intent that it
31 becomes law. H.R. 1706 bans what are known as exclusion
32 payments, reverse payments or reverse consideration in patent
33 settlements between name brand and generic drug companies.
34 This is a practice in which the brand name company pays or
35 provides value to the generic company, and the generic
36 company agrees to delay the marketing of its generic drug
37 product.

38 First the bill is fully supported on a bipartisan basis
39 by the FTC. The commission believes that a legislative fix
40 is needed because the courts have thwarted their enforcement
41 efforts. Both Republican and Democratic chairman and
42 commissioners have historically supported congressional
43 action cracking down on these uncompetitive settlements.
44 This is not a partisan issue.

45 Second, the bill does not ban all settlements in all
46 patent cases. Quite the contrary. H.R. 1706 only bans
47 exclusion payments and legal settlements. Brand name and
48 generic companies are still free to settle their differences.
49 In fact, before the court invalidated the FTC's enforcement
50 efforts, drug companies were selling their patent disputes
51 without any exclusion payments. It wasn't until the courts
52 struck down the FTC's enforcement action in 2005 that these
53 very unique type of settlements came back from the dead.

54 Third, these types of settlements were completely unique
55 to the drug industry. They do not appear in any kind of
56 patent dispute other than this drug industry. In all other
57 patent disputes, the litigants settle in two ways. One, they
58 enforce or the accused pays a patent holder a royalty to
59 market its products. Or two, the parties agree to an early
60 entry date.

61 Only in the drug industry do we see the unusual behavior
62 of a patent holder, which is the brand name company, suing
63 the accused infringer, the generic company, and then settle
64 by paying the infringer to stay off the market. These unique
65 settlements are the result of the equally unique regulatory
66 framework of Hatch-Waxman.

67 I don't believe that the drug companies are acting in
68 bad faith. I believe that they are perfectly logical under

69 their fiduciary duty to their shareholders. They are being
70 responsible, and they are simply responding to the incentives
71 they face under Hatch-Waxman.

72 Lastly, H.R. 1706 will save taxpayers, businesses, and
73 consumers tens of billions of dollars. That is the ultimate
74 purpose of this bill. Congress is currently considering ways
75 to save money in order to provide affordable health insurance
76 to all Americans. I believe that H.R. 1706 can play an
77 important role in reducing prescription drugs costs in our
78 economy.

79 We cannot afford to do nothing on this unique
80 uncompetitive way of doing business that costs consumers
81 millions of dollars. I want to thank our witnesses for
82 appearing before this committee in this first step in the
83 legislative process.

84 [The prepared statement of Mr. Rush follows:]

85 ***** COMMITTEE INSERT *****

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86 [The information follows:]

87 ***** INSERTS A, B *****

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88 Mr. {Rush.} And I will now yield back the balance of my
89 time, and now I want to recognize the ranking member of this
90 subcommittee, my friend Mr. Stearns from Florida.

91 Mr. {Stearns.} Good morning, and thank you, Mr.
92 Chairman. I am glad we are having this hearing on H.R. 1706,
93 Protecting Consumers' Access to Generic Drugs Act. On this
94 side of the aisle we perhaps see this bill a little
95 differently. We see it as a solution looking for a problem.
96 The Hatch-Waxman Act of 1984 we think is working, and we are
97 not sure. Maybe a little bit of steering might be implied
98 but not necessarily eliminating with a brand new bill with
99 this H.R. 1706.

100 You know when you look at the history of the
101 availability of generic drugs over the past 25 years, which
102 have helped millions of people live healthier lives and most
103 importantly reduce the cost of health care, in the face of
104 ever increasing health care costs for families, I asked my
105 staff to pull up some statistics. And since the Hatch-Waxman
106 passage, the generic industry share of the prescription drug
107 market has jumped from around 19 percent to over 70 percent
108 today. So again I say let us be careful. Do no harm.

109 It is clear that the Hatch-Waxman Act and current
110 practices have been successful in bringing low-cost

111 alternatives to families and to the market. So I do have a
112 few concerns which I will outline here. This bill addresses
113 two facets of the generic pharmaceutical trade: reverse-
114 payment settlement, which I am going to use the word payment
115 settlement. I notice the chairman used the words exclusion
116 payments and reverse payments, but I think the actual term
117 which is payment settlements. And the other issue is the
118 180-day exclusivity period granted to first filers under the
119 Hatch-Waxman Act.

120 This latter consideration is really there as a incentive
121 for generic drugs who take the risk to sue. So I am not sure
122 that it should be changed. Now, opponents of the payment
123 settlement argue that this practice delays the introduction
124 of generic drugs to market and permit drug innovators to
125 continue their patent protection and market exclusivity, even
126 if it is for a shorter period of time than the patent allows.

127 In reality though, the opposite is true. These
128 settlements often bring drugs to market sooner than would
129 otherwise be permitted by the completion of the brand drug's
130 patents.

131 Critics also argue these settlements encourage patent
132 challengers to abandon their claims in litigation when an
133 alleged 70 to 80 percent of challenges succeed. This
134 statistic can be misleading and does not take into account

135 that while a challenger may win on four out of five claims,
136 it is the invalidation of just one of those challenges that
137 is necessary to prevent the launch of a generic drug.

138 Now, according to recent studies, the success rate of
139 challenges that lead to the early introduction of a generic
140 drug is actually closer to 45 percent, not the 70 percent
141 that people talk about. Furthermore, patent litigation is
142 expensive, unpredictable, and can last for many years. The
143 emphasis in patent litigation, as in any other litigation
144 area, is to settle. In many cases, it is a win-win
145 situation. The brand company wins by saving money on
146 protecting its patent. The generic company wins by saving
147 money on litigation expenses and gaining earlier market
148 entry. And the consumer wins with early access to a less
149 expensive generic product.

150 Now, unfortunately this legislation that we are talking
151 about this morning would outlaw anything of value to be
152 exchanged in a patent settlement. Therefore, an innovative
153 drug company would have no incentive to do anything but
154 defend its patent until expiration, inadvertently creating a
155 chilling effect on early generic drugs introductions which
156 the consumers would enjoy.

157 Given this reality, generic companies could be
158 discouraged from investing capital in patent prosecutions

159 until it is assured of a success, a virtual impossibility in
160 any patent litigation scenario. If longer, drawn-out
161 litigation was not enough of a disincentive to challenge a
162 patent, eliminating a generic company's ability to recover
163 its litigation costs to the 180-day exclusivity period is
164 enough to put the final nail in the casket of generic
165 challenges.

166 As a carrot to encourage patent challenges, the Hatch-
167 Waxman Act provides the first filer 180 days of exclusivity
168 as the only generic drug permitted on the market, simply
169 enabling a successful generic company challenger to recoup
170 its significant litigation costs. It is this reward that
171 encourages the risk of challenging a patent. If this
172 exclusivity is no longer granted, the result will be the
173 opposite of what this bill intends. Fewer drugs patients
174 will be challenged, and consumers will have to wait much
175 longer until patents expire or litigation come to conclusion
176 before cheaper generic drugs can be made available.

177 So I look forward to the testimony of our witnesses
178 today, and thank you again, Mr. Chairman, for having this
179 hearing.

180 [The prepared statement of Mr. Stearns follows:]

181 ***** COMMITTEE INSERT *****

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182 Mr. {Rush.} The chair thanks the gentleman. The chair
183 now recognizes the chairman of the full committee, the
184 gentleman from California, Mr. Waxman, for five minutes for
185 the purposes of opening statement.

186 The {Chairman.} Thank you very much, Mr. Chairman. I
187 want to thank you for holding this important hearing. This
188 year is the 25th anniversary of the Drug Price Competition
189 and Patent Term Restoration Act, commonly known as Hatch-
190 Waxman or Waxman-Hatch, and that law established our generic
191 drug approval system.

192 Generic drugs play a critical role in promoting public
193 health where they are available. They promote competition,
194 which in turn lowers prices. Lowering drug prices reduces
195 overall health care bills. More importantly though, lower
196 drug prices mean access to important medications for many
197 patients who might not otherwise be able to afford them.

198 Today in the U.S. a remarkable 67 percent of
199 prescriptions are filled with generic medicines, saving
200 consumers and the federal and state governments tens of
201 billion dollars annually. Unfortunately in recent years, we
202 have seen that the vibrant competition we envisioned has not
203 flourished as well as we had hoped.

204 The Federal Trade Commission has highlighted a

205 significant cause of this problem. Generic and brand name
206 drug companies have increasingly been entering into patent
207 settlement agreements that have an anti-competitive effect.
208 These settlement arrangements frequently involve agreements
209 in which the generic drug makers stay out of the market in
210 exchange for some form of compensation from the brand-name
211 drug makers.

212 These settlements are beneficial to both the brand-name
213 company and the generic challenger. The brand gets
214 additional time to sell its drug at monopoly prices. The
215 generic gets payments without any need to make or market the
216 drug. Both the brand and generic firms profit, but they do
217 so at the expense of the consumers who much continue to pay
218 monopoly prices. This is the last thing Congress intended
219 when we enacted Waxman-Hatch.

220 The law was intended to give consumers access to
221 generics at the earliest possible opportunity, not to line
222 the pockets of generic and brand-name drug companies. Some
223 courts have erroneously concluded that these agreements were
224 condoned by Hatch-Waxman. These courts are sorely mistaken.
225 The use of our law to prevent generic competition is contrary
226 to intent of that law.

227 Now Congress must act to prevent the continued erosion
228 of these principles, the Protecting Consumer Access to

229 Generic Drugs Act of 2009, the bill under discussion today,
230 is a sensible solution that will help put an end to the
231 practice of paying generic drug companies to stay out of the
232 market. I recognize we need to proceed with care. Some
233 patent settlement agreements can provide benefits across the
234 board. Settlements can allow the parties involved to avoid
235 expensive protracted litigation. Consumers can sometimes
236 gain access to generic drugs that might otherwise have been
237 deferred by litigation.

238 This legislation recognizes that reality and permits
239 settlements in which nothing more than the date of entry is
240 negotiated. And if FTC decides that other exceptions need to
241 be made to enhance competition and benefit consumers, then
242 FTC can implement those changes through rule making.

243 In effect, it is designed to rid us of the bad
244 settlements and leave us with the good ones. I look forward
245 to the testimony of the witnesses today and working with all
246 the members of the committee to get this bill enacted into
247 law. Thank you, Mr. Chairman.

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

249 ***** COMMITTEE INSERT *****

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250 Mr. {Rush.} The chair thanks the chairman of the full
251 committee. Now the chair recognizes the gentleman from
252 Kentucky, Mr. Whitfield, for the purposes of opening
253 statement for 2 minutes.

254 Mr. {Whitfield.} Mr. Chairman, thank you very much. We
255 look forward to this hearing on H.R. 1706, Protecting
256 Consumer Access to Generic Drugs Act. I think this
257 legislation has the very best intents, and obviously we want
258 to protect all sides in this debate. We want to be sure that
259 innovative drug companies continue to spend money and
260 research and developments come through with drugs that help
261 curtail disease. We also want the consumer to be able to get
262 generic drugs as soon as possible at a less cost to improve
263 health care.

264 And one of the issues that I am going to be interested
265 in today is that it was my understanding that in all the
266 legal actions filed by the FTC about these exclusion
267 agreements that they had lost all of the lawsuits. But then
268 in reading the memorandum, I see that in the Sixth Circuit
269 Court of Appeals held that such agreements are per se
270 violations of the Federal Anti-Trust Law. But in the Second
271 and the Eleventh Circuit Court of Appeals, they have ruled
272 that agreements do not violate anti-trust laws and merely

273 reflect the give and take of legal settlements.

274 So I hope that as we proceed with our witnesses today
275 that we can certainly get some clarification on that issue as
276 well as others. And I yield back the balance of my time.

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

278 ***** COMMITTEE INSERT *****

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279 Mr. {Rush.} The chair thanks the gentleman. The chair
280 now recognizes the gentleman from Maryland, Mr. Sarbanes, for
281 2 minutes for the purposes of opening statements.

282 Mr. {Sarbanes.} Thank you, Mr. Chairman. I am looking
283 forward to the testimony today and anxious to see this
284 proposal move forward, which I think is a very common sense
285 solution to the distortion in the regime that has occurred as
286 a result of the court conclusion that the FTC didn't have
287 authority to regulate here and tries to remedy that.

288 It is particularly important as we embark on looking at
289 how to apply similar regimes to other arenas, which of course
290 is a discussion that is going on now, we got to make sure we
291 fix this one. Businesses and lawyers are clever in finding
292 ways to get around impediments. That is what they have done
293 here. And to use the vernacular, we just need to be cleverer
294 and try to fix this. And that is what this legislation
295 intends to do.

296 So I look forward to the discussion today, and I yield
297 back my time.

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

299 ***** COMMITTEE INSERT *****

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300 Mr. {Rush.} The chair thanks the gentleman from
301 Maryland. It is my pleasure to allow Mr. Pitts from Florida-
302 -I am sorry, from Pennsylvania to allocate 2 minutes to him
303 for the purposes of opening statement.

304 Mr. {Pitts.} Thank you, Mr. Chairman. I would like to
305 thank you for convening a hearing on this bill. I think we
306 all agree that our goal should be to make generic drugs
307 available to the consumers who need them. I am somewhat
308 concerned that the legislation will have a chilling effect on
309 patent challenges by generic drug companies resulting in
310 longer waiting periods for generic drugs for consumers who
311 depend on them.

312 This bill would place a total ban on all patent
313 settlements in which the company that holds the patent on the
314 brand-name drug gives anything of value to the generic
315 company challenging the patent except for an early entry date
316 into the market. What will the results be? With no
317 incentive to settle, cases will be litigated to the very end
318 as brand drug companies fight to hold onto their authorized
319 monopoly on the drug, the only way they have to recoup the
320 millions of dollars they have put into developing and testing
321 new drugs.

322 With millions of dollars of legal fees on the line,

323 generic companies will only challenge a patent if they are
324 virtually assured of a successful outcome. This goes
325 completely against the incentives for generics to challenges
326 patents that are built into Hatch-Waxman.

327 Finally, since 2003, Congress has required that
328 litigants notify federal anti-trust authorities of their
329 pharmaceutical patent settlements. DOF and FTC are already
330 notified of all patent settlements, and they can sue if they
331 believe the outcome of a case is anticompetitive.

332 FTC has filed suit in a number of cases, and in the vast
333 majority, the courts have found these settlements acceptable
334 and refused to strike them down. So, Mr. Chairman, the
335 system is working. These settlements should be reviewed on a
336 case-by-case basis, and to ban these settlements will only
337 keep generics off the market for a longer period of time,
338 hardly a pro-consumer outcome.

339 I would like to thank all of our witnesses for coming to
340 testify today, and I yield back the balance of my time.

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

342 ***** COMMITTEE INSERT *****

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343 Mr. {Rush.} The chair thanks the gentleman. The chair
344 now will recognize the chairman emeritus of the full
345 committee, my friend from Houston, Mr. Dingell, for 5 minutes
346 for the purpose of an opening statement.

347 Mr. {Dingell.} Mr. Chairman, thank you, and I want to
348 commend you for your leadership and for holding this hearing.
349 At issue before the committee today is the very fundamental
350 question of fairness. Should pharmaceutical companies be
351 able to continue to enjoy the right to collude the legal
352 settlements in order to stifle consumer access to generic
353 drugs?

354 As the cost of health care continues to increase, mainly
355 due to the cost of drugs, we must dispose of this question
356 with a view towards providing consumers with a greater choice
357 and lower prices while at the same time preserving for the
358 industry the inviolability of intellectual property rights
359 for manufacturers of pharmaceuticals.

360 At the root of this debate lie the Hatch-Waxman's
361 amendments to the Federal Food, Drug, and Cosmetic Act, whose
362 intent it is to promote the aggressive entry of generic drugs
363 into the marketplace to benefit consumers. Curiously, this
364 has not occurred. This intent has been undermined of late by
365 the growing practices of the pharmaceutical industry in

366 settling patent disputes by the so-called practice of
367 ``exclusion payments'' in which a patent holder pays a
368 generic challenger in exchange for delay in the generic
369 drug's entry into the market.

370 Who gets screwed here? The consumer. In my view,
371 should a generic challenger prove its product does not
372 infringe upon the patent held by a brand-name pharmaceutical
373 manufacturer secretive agreements of a legal character
374 between private parties should not prevent the generic drug's
375 introduction into commerce.

376 Clearly this goes well against the intent of the
377 committee and the Congress when we passed Hatch-Waxman. This
378 in mind, the exclusion payments strike me as a counter to the
379 interests of consumers and more pointedly, an unfair method
380 of competition, which would otherwise be prohibited under
381 section five of the Trade Commission Act.

382 At this juncture, I would like to note that prohibiting
383 exclusion payments may have a beneficial effect for state
384 budgets and indeed for the federal government because the
385 budget of Medicare, Medicaid and S-CHIP roles are going to be
386 stressed by both the depression that we now undergo and the
387 awful situation we confront of the increased need of people
388 from groups that were formerly benefited by health coverage
389 which they had lost. So we have a very serious problem of

390 widespread economic displacement that is increasing these
391 costs.

392 By acting proscribed uncompetitive practices like
393 exclusion payments, we could reduce the strain on the states
394 of providing their citizens with health care, something which
395 I believe is a fundamental right of all Americans. I look
396 forward to working with you, Mr. Chairman, to seeing this
397 legislation through and to make it become law. And I urge my
398 colleagues to be of assistance in this great undertaking.
399 Thank you, Mr. Chairman. I yield back the balance of my
400 time.

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

402 ***** COMMITTEE INSERT *****

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403 Mr. {Rush.} The chair thanks the chairman emeritus.
404 And now it is my pleasure to recognize the gentleman from
405 Nebraska. I am sorry--recognize my friend--I didn't see him
406 down there--my friend from Texas, the ranking member of the
407 full committee, Mr. Barton, for 5 minutes for an opening
408 statement.

409 Mr. {Barton.} Thank you, Mr. Chairman, and I look
410 forward to the day we have a hearing on your bill and my bill
411 to reform the BCS football championship series.

412 Mr. {Rush.} Will the gentleman yield for a moment?

413 Mr. {Barton.} I would be happy to yield.

414 Mr. {Rush.} I talked about our bill this morning. I
415 want you to know.

416 Mr. {Barton.} Very good. Well, the Senate is beginning
417 to steal our thunder, Mr. Chairman, so we--

418 Mr. {Rush.} We can't let that happen.

419 Mr. {Barton.} --don't let that happen.

420 Mr. {Rush.} They wouldn't know what to do with it.

421 Mr. {Barton.} But I do want to thank you, Mr. Chairman,
422 for this hearing on generic drugs, which is part of this
423 committee and this subcommittee's jurisdiction. Access to
424 lower cost drugs has not only helped Americans beat diseases,
425 it has been a boon for health care in a world that depends on

426 the drugs that we, the United States, manufacture. We need
427 to recognize that it won't be all good news if we don't weigh
428 the pros and cons of generics competing with brand names.

429 Sick people depend on affordable drugs, but they also
430 depend on innovation and research to create the drugs that
431 they need. Without adequate reward, innovation fades,
432 research declines, and life-saving medicine doesn't happen.
433 The framers got it right in Article 1, Section 8 of the
434 Constitution, and I quote ``promote the progress of science
435 by securing for a limited time the exclusive right to
436 discoveries.'' We should heed Section 8. It has worked well
437 for over 200 years.

438 American innovation is a cornerstone of intellectual
439 property rights, and we need to ensure that our domestic
440 industry continues to get the benefits of these property
441 rights, especially in dealing with our trading partners
442 overseas.

443 Pharmaceutical companies should have the opportunity to
444 pursue constitutionally protected inventions. We should not
445 diminish the incentive to undertake the substantial risk
446 involved. As everybody here knows, the risk associated with
447 new drug approvals are significant. First comes the R&D
448 component, followed by a lengthy FDA approval process, both
449 of which require large amounts of money, which may not be

450 recouped if the R&D falters or the FDA approval doesn't
451 happen. At no point does anybody guarantee any drug
452 innovator that the competition won't invent a similar drug
453 first and get to the market first.

454 I believe that when a new drug successfully makes it to
455 market, we need to provide the innovator with intellectual
456 property protection. It is important to get the balance
457 right. In that spirit, Congress has always recognized the
458 necessity of providing these protections. We have also
459 recognized obviously the benefits of generic drug competition
460 in the marketplace, which lowers cost and increases access.

461 Congress made the wise decision 20 years ago when we
462 passed Hatch-Waxman. I started to say Waxman-Hatch. I have
463 always supported this concept of providing a balanced
464 incentive for both sides of the industry because it works.
465 Inevitably, however, patent disputes arise between generic
466 firms and brand manufacturers. Litigation can and often does
467 take years to reach a final verdict.

468 However, both sides decide sometimes to settle a case
469 when the outcome isn't certain and the parties have a
470 negotiated settlement based on the possible benefits and the
471 probabilities of winning the case outright. To be very
472 clear, consumers should have the best drugs available at the
473 cheapest possible price. But I think the best way to achieve

474 that is to provide innovators with their strong intellectual
475 property protection while providing a clear path for generics
476 to enter the market.

477 I have a serious concern about imposing a ban on the
478 exchange of anything of value in a private patent litigation
479 settlement. Limiting the options of private litigants to
480 settle out of court should be avoided if at all possible.
481 The right to defend or challenge patents should be preserved.

482 Unfortunately, Mr. Chairman, I think the bill that you
483 have introduced, H.R. 1706, would remove incentives parties
484 have to settle, could force many more cases into lengthy
485 litigation where years may elapse before a decision is
486 reached.

487 Forcing drug companies down this path probably would
488 erode any benefit to the consumer. Since the FTC seems to me
489 to have adequate authority to challenge these improper
490 settlements in court, I am anxious to hear from the witnesses
491 as to why the judicial system is not the appropriate venue to
492 resolve these issues.

493 Finally, Mr. Chairman, as I said almost two years ago at
494 our last hearing on this issue, I am very interested in the
495 economics of the industry and whether changing the structure
496 of incentives and rewards, including some of the changes
497 contemplated by your bill, will ultimately benefit consumers

498 in the long run.

499 I want to hear from the witnesses their views of this
500 issue and also whether they feel that there are anti-trust
501 concerns with these settlements, given the fact that the
502 courts and the federal anti-trust authorities don't seem to
503 agree on the issue.

504 But in any event, Mr. Chairman, this is an important
505 hearing. I am very pleased that you are holding it, and I
506 look forward to hearing from the witnesses and also the
507 questions from our distinguished members of the subcommittee.
508 And I yield back.

509 [The prepared statement of Mr. Barton follows:]

510 ***** COMMITTEE INSERT *****

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511 Mr. {Rush.} The chair thanks the ranking member, and
512 now it is my pleasure to recognize the gentleman from
513 Michigan, Mr. Stupak, for 2 minutes for the purposes of an
514 opening statement.

515 Mr. {Stupak.} Mr. Chairman, I am supportive of the
516 bill, and I will waive my 2 minutes. And I will ask that it
517 be added on for questioning later.

518 [The prepared statement of Mr. Stupak follows:]

519 ***** COMMITTEE INSERT *****

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520 Mr. {Rush.} The chair thanks the gentleman. Now, the
521 chair recognizes my friend from Ohio, Mr. Space, for 2
522 minutes for the purposes of an opening statement.

523 Mr. {Space.} Thank you, Mr. Chairman, for holding this
524 important hearing on an issue that, at its core, is designed
525 to provide inexpensive and effective prescriptive medications
526 to the people that we serve.

527 I think in addressing this issue, like so many other
528 issues that affect the pharmaceutical world, we have to walk
529 a delicate line between fostering innovation and providing
530 inexpensive access to constituents. Particularly the latter
531 issue becomes important in light of the fact that so many
532 people are hurting financially right now and actually making
533 conscious decisions between purchasing prescription
534 medication and buying food.

535 I hope that we will consider these issues of
536 intellectual property and patent settlements in a very
537 deliberate process, being very careful and mindful to
538 maintain that balance between fostering innovation while
539 protecting consumers. And I am hopeful that today's
540 testimony will shed some important light on this topic. I
541 yield back.

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

543 ***** COMMITTEE INSERT *****

|
544 Mr. {Rush.} The chair thanks the gentleman. Now for
545 the second time now the chair recognizes the gentleman from
546 Nebraska, Mr. Terry, for 2 minutes for the purposes of
547 opening statement.

548 Mr. {Terry.} Well, I appreciate you asking me twice.

549 Mr. {Rush.} I am trying to get to you.

550 Mr. {Terry.} I will waive.

551 [The prepared statement of Mr. Terry follows:]

552 ***** COMMITTEE INSERT *****

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553 Mr. {Rush.} All right, the chair thanks the gentleman.
554 Now it is my pleasure to recognize the gentleman from
555 Louisiana, Mr. Scalise, for 2 minutes for the purposes of an
556 opening statement.

557 Mr. {Scalise.} Thank you, Mr. Chairman. I will waive
558 as well and hold that time for questioning.

559 [The prepared statement of Mr. Scalise follows:]

560 ***** COMMITTEE INSERT *****

|
561 Mr. {Rush.} Well, we thank you. Now, it is my pleasure
562 to recognize the gentleman from Georgia, Mr. Gingrey--Dr.
563 Gingrey for 2 minutes for the purposes of an opening
564 statement.

565 Mr. {Gingrey.} Mr. Chairman, the third time is the
566 charm. I want to thank you for calling this hearing today on
567 H.R. 1706, The Protecting Consumer Access to Generic Drugs
568 Act of 2009. I believe that it goes without saying how
569 valuable generic drugs have been for consumers in the
570 prescription drug market. And this hearing will pick up
571 where the subcommittee left this issue back in 2007 when I
572 was not a member.

573 As a physician for nearly 30 years and a member of this
574 health subcommittee, I know that access to generic drugs
575 provides proven medical remedies and improvements to the
576 quality of life and often at a much lower cost. As this
577 subcommittee examines such an important issue for consumers
578 across the country, we must act in a way that preserves and
579 bolsters access to generic drugs.

580 However, Mr. Chairman, despite the intent of H.R. 1706
581 to expedite the process by which generic drugs get to the
582 consumer, I am concerned that this legislation may indeed
583 have unintended consequences causing consumers to wait even

584 longer to get access to generic versions of brand-name drugs.
585 At the very heart of this legislation is the legitimacy of an
586 out-of-court settlement between a drug company holding a
587 patent on a drug and one seeking to create the generic
588 version.

589 Mr. Chairman, patent law in this area is very unique.
590 When companies are able to settle their disputes out of
591 court, consumers are the ultimate winners. Unfortunately
592 H.R. 1706 would prohibit the practice, thus reducing the
593 incentive for a generic company to take on financial burden
594 of challenging patents and potentially delaying some generics
595 from actually coming to the market.

596 Mr. Chairman, for the sake of all health care consumers,
597 I urge we use the utmost caution and care as we move forward
598 on this legislation. I certainly look forward to hearing the
599 thoughts of our panel this morning on such an important
600 issue, and I yield back the remaining 30 seconds.

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

602 ***** COMMITTEE INSERT *****

|
603 Mr. {Rush.} The chair thanks the gentleman. Now, the
604 chair recognized my friend from Georgia, Mr. Barrow, for 2
605 minutes for the purposes of an opening statement.

606 Mr. {Barrow.} I thank the chair. In the interest of
607 time, I will waive an opening.

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

609 ***** COMMITTEE INSERT *****

|
610 Mr. {Rush.} Thank you very much. Now the chair
611 recognizes my friend from Illinois, Ms. Schakowsky, the vice
612 chair of the subcommittee for 2 minutes for the purposes of
613 an opening statement.

614 Ms. {Schakowsky.} Thank you, Mr. Chairman. I am an
615 original cosponsor of H.R. 1706, the Protecting Consumer
616 Access to Generic Drugs Act of 2009, because I believe that
617 the availability of generic drugs is a critical component to
618 lowering health care costs for the consumer, for businesses,
619 for the taxpayer.

620 The legislation would prohibit patent settlements in
621 which a brand-name drug maker pays off a generic drug maker
622 to prevent the generic medicine from entering the market.
623 These payments are known as reverse or exclusion payments,
624 and it strikes me as incredibly disingenuous that those who
625 would tout the importance of free markets and competition
626 would also take exclusive action to prevent fair competition
627 in the case of necessary and sometimes lifesaving
628 prescription medications.

629 Settlements that include exclusion payments may be good
630 for the brand-name manufacturer that gets to keep its
631 monopoly, and it may be a good thing for the generic company
632 that gets paid not to produce a drug, but such settlements

633 are a bad deal for consumers.

634 My state of Illinois has joined others in successfully
635 taking on anti-trust actions by brand-name drug companies.
636 In 2003, Illinois was part of a multi-state settlement of an
637 action against Aventis for entering into an exclusion payment
638 settlement with a generic challenger which delayed
639 competition with its heart drug Cardizem.

640 However, the Cardizem case predated recent circuit court
641 decisions that have made it more difficult for anti-trust
642 enforcers to challenge reverse payments. The case which
643 garnered millions of dollars for Illinois consumers might not
644 have been successful in the current environment.

645 According to a 2004 FDA analysis, the average patient
646 taking several medications could save 14 to 16 percent on
647 drug costs if they can replace some of their prescriptions
648 with generics. If they were taking medications that could be
649 completely replaced with generics, their prescription drug
650 costs could be reduced by 52 percent.

651 I think that ensuring lower cost generics on the market
652 is a key component of reigning in health care spending, and I
653 believe that setting the bar any lower would be irresponsible
654 on the part of this Congress. Thank you, Mr. Chairman.

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

656 ***** COMMITTEE INSERT *****

|

657 Mr. {Rush.} The chair thanks the gentlelady. Now, the
658 chair wants to exercise a moment of personal privilege this
659 morning by recognizing the chairman of the Federal Trade
660 Commission who has come here to be with us this morning. I
661 am not sure, Mr. Chairman, how long you will be able to stay,
662 but you are always welcome here. We want you to know any
663 time you want to drop in, just drop in, all right. Mr. John
664 Lebowitz is recognized. We thank you so much for your
665 presence.

666 And now we would like to welcome our expert and esteemed
667 panel that have come. I want you to know that you are the
668 finest panel that have ever assembled before us this morning,
669 all right. And we recognize you so much, and we thank you so
670 much for being here with us.

671 I want to recognize from my left to right, beginning
672 with the Honorable J. Thomas Rosch, who is the commissioner
673 of the Federal Trade Commission. And I want to recognize
674 you, Commissioner Rosch. I think that is how you pronounce
675 your last name. Thank you so much.

676 Next to him is Mr. Scott Hemphill, who is an associate
677 professor of law at Columbia University. Welcome, Mr.
678 Hemphill. Next to Mr. Hemphill will be Ms. Joanne Handy.
679 She is a board member of an organization I just recently

680 joined, AARP. Welcome, Ms. Handy.

681 Next to her is Ms. Diane Bieri. She is a general
682 counsel for PhRMA. Welcome, Ms. Bieri. And next to Ms.
683 Bieri is Dr. Barry Sherman, who is a chief executive officer
684 for Apotex Incorporated. Dr. Sherman, you have been here
685 before and you are familiar. And we welcome you once again.

686 And next to Dr. Sherman is Mr. Ted Whitehouse of the
687 firm Willkie Farr and Gallagher, who has been before the
688 committee before. And he is here on behalf of Teva
689 Pharmaceuticals. We certainly want to again welcome each and
690 every one of you and thank you for taking out moments of your
691 important day to be here with us.

692 And now we will recognize Commissioner Rosch for 5
693 minutes for the purposes of an opening statement.

|
694 ^STATEMENTS OF J. THOMAS ROSCH, COMMISSIONER, FEDERAL TRADE
695 COMMISSION; SCOTT HEMPHILL, ASSOCIATE PROFESSOR OF LAW,
696 COLUMBIA UNIVERSITY; JOANNE HANDY, BOARD MEMBER, AARP; DIANE
697 BIERI, GENERAL COUNSEL, PHARMACEUTICAL RESEARCH AND
698 MANUFACTURERS OF AMERICA; BARRY SHERMAN, CHIEF EXECUTIVE
699 OFFICER, APOTEX, INC.; AND TED WHITEHOUSE, WILLKIE FARR AND
700 GALLAGHER, ON BEHALF OF TEVA PHARMACEUTICALS

|
701 ^STATEMENT OF J. THOMAS ROSCH

702 } Mr. {Rosch.} Thank you, Chairman Rosch, Congressman
703 Stearns, and members of the subcommittee.

704 Mr. {Rush.} Turn the mike on please. Pull it closer to
705 you.

706 Mr. {Rosch.} Okay, I appreciate the chance to appear
707 before you today. The written statement that we submitted
708 represents the views of the commission as a whole. My oral
709 testimony is my own, and it doesn't necessarily reflect the
710 views of any other commissioner.

711 There are several compelling reasons why it is
712 imperative that Congress enact legislation in this area.
713 Reverse payment agreements strike at the heart of the special
714 statutory framework Congress created in the Hatch-Waxman Act.

715 That framework was designed to balance two policy goals that
716 are critically important to the pharmaceutical industry.

717 Hatch-Waxman gave branded companies a longer patent
718 life. The tradeoff was the generic companies were given a
719 strong incentive to challenge questionable brand patents and
720 start competing with the branded companies if they win. And
721 that tradeoff was 180 days of generic exclusivity. In that
722 way, generic companies were supposed to protect consumers
723 from unwarranted patent monopoly pricing by branded
724 companies.

725 But reverse payment settlements frustrate the purpose of
726 Hatch-Waxman in two ways. First, the settlements incentivize
727 the generic to abandon the patent challenge, leaving a
728 suspect patent intact for the entire extended patent period.

729 Second, they can incentivize the generic to challenge
730 patents that shouldn't be challenged in hopes of getting paid
731 off for settlement. In other words, the anticompetitive
732 settlements have ended up vesiating the incentives for
733 generics to protect consumers and instead can result in
734 generics feathering their own nests. By virtue of the
735 reverse payment settlement agreement, the brand stops the
736 generic's challenge and so it doesn't lose its patent
737 monopoly even if its patent is invalid or not infringed.

738 The generic meanwhile gets a share of the brand's

739 monopoly profit in the form of the reverse payment, but the
740 consumer, including the federal government as has been
741 pointed out, ends up being a huge loser since consumers
742 continue to pay monopoly profits until the generic starts to
743 compete.

744 This is demonstrated by the pie chart on page 12 of the
745 commission's written remarks, and a good example is our
746 Cephalon case where the CEO of the brand boasted that his
747 deals generated an additional \$4 billion in sales. Most of
748 the profits from those sales will come from consumers
749 pockets. Now, imagine if there are 10, 15 or even more of
750 these settlements each year.

751 Beyond that, on their face reverse payment agreements
752 are market division agreements between potential competitors.
753 That is why the Sixth Circuit in the Cardizem case held that
754 they were per se illegal, and that holding is consistent with
755 the 1990 Supreme Court Palmer decision, which held that
756 market division agreements between potential competitors are
757 per se illegal. So reverse payment agreements not only
758 violate the purpose of Hatch-Waxman but also seemingly
759 violate the Palmer holding.

760 So why am I here supporting congressional legislation?
761 Well, recent circuit court decisions have ignored Palmer and
762 Cardizem, substituting their own judicial policy judgments.

763 The market division agreements should be permissible to
764 settle patent litigation.

765 For example, the 11th Circuit's Schering decision in
766 which the circuit court declined to follow Palmer or Cardizem
767 emphasized that its decision was based on ``policy.'' But
768 Congress is the body with the responsibility to set patent
769 policy.

770 In short, the courts have disturbed the balance that
771 Congress struck in Hatch-Waxman by permitting reverse payment
772 settlement agreements and Congress should correct that
773 imbalance. Congress shouldn't wait for the Supreme Court to
774 review these erroneous judicial decisions either. There is
775 no reason to think that the court will set things right any
776 time soon. It has decided to review both Schering and
777 Tamoxifen, which followed Schering. That is the Second
778 Circuit decision and the petition currently before the case
779 in the Cipro case, the most recent of these decisions.

780 In that petition, the petitioner actually suggests that
781 the Supreme Court defer ruling on the petition until the
782 parties file a petition in a parallel action.

783 More important, however, Cipro represents the extreme
784 case. It holds that reverse payment settlements are in
785 effect per se legal, not illegal, but per se legal. Even if
786 the court concludes that Cipro is wrong and that reverse

787 payment agreements are not per se legal, that still leaves
788 open the question of whether, as Schering and Tamoxifen held,
789 the strength of the patent is a threshold issue that has to
790 be litigated before the public or private plaintiff can
791 litigate the anti-trust merits.

792 I have said publicly, Mr. Chairman, that litigating the
793 strength of the patent may be one way to avoid Schering and
794 Tamoxifen, but I will be the first to admit that that may be
795 costly and duplicative. Hatch-Waxman contemplated that the
796 generic would litigate the strength of the patent.

797 Mr. {Rush.} Mr. Rosch, would you please bring your
798 comments to a close? You are a minute and 47 seconds over
799 your time.

800 Mr. {Rosch.} Okay, can I just conclude by saying--

801 Mr. {Rush.} Please.

802 Mr. {Rosch.} --Mr. Chairman that at the commission at
803 least, this is not a partisan issue. Eleven members of the
804 commission over the years that this has been at issue, all
805 the Republicans, all of the Democrats have joined in these
806 cases, and all four of us, two Republicans and two Democrats
807 who are currently on the commission, strongly support the
808 legislation that is before the committee. Thank you.

809 [The prepared statement of Mr. Rosch follows:]

810 ***** INSERTS 1, 1A *****

|
811 Mr. {Rush.} Thank you very much. Now the chair
812 recognizes the gentleman, Mr. Scott Hemphill, for 5 minutes
813 or thereabouts for purposes of an opening statement.

|
814 ^STATEMENT OF SCOTT HEMPHILL

815 } Mr. {Hemphill.} Thank you. Chairman Rush, Congressman
816 Stearns, and members of the subcommittee, I am Scott
817 Hemphill, an associate professor at Columbia Law School. My
818 scholarship and teaching focus on the balance between
819 innovation and competition, established by anti-trust law,
820 intellectual property and regulation.

821 I thank you for the opportunity to testify today about
822 anti-competitive, pay-for-delay agreements between brand name
823 drugs makers and their generic rivals. These remarks draw
824 upon my ongoing academic research into the economic effects
825 of these settlements and their appropriate legal treatment.
826 Most recently an article forthcoming in the ``Columbia Law
827 Review''--I hope these articles might be included in the
828 hearing record.

829 Mr. {Rush.} So ordered.

830 Mr. {Hemphill.} Advise the Federal Trade Commission on
831 the anti-trust issues raised by pay-for-delay settlements,
832 but the views I express today are mine alone.

833 For 25 years, the Hatch-Waxman Act has provided a way
834 for generic drug makers to introduce a competing version of
835 the patented brand name drug even before the relevant patent

836 or patents expire by arguing that the patent is invalid or
837 not infringed. The generic firm has a large incentive to do
838 this: 180 days of exclusive sales free from generic
839 competition when it later enters the market. Usually the
840 brand name firm files a patent infringement suit in response.
841 Often, the generic firm wins the suit, and when it does, drug
842 prices fall.

843 But sometimes the brand name firm, instead of taking
844 that chance, decides to settle the suit. The parties
845 dismiss the suit and agree on a particular date when the
846 generic firm can enter the market. That date is the result
847 of a hard bargain between the two companies. The brand name
848 firm pushes for as late a date as possible, arguing that it
849 is likely to win the case at trial if put to the test. The
850 more persuasive that argument is, the later the entry date.

851 Now, such a settlement which rests solely upon the
852 inherent strength of the patent is properly permitted, but
853 now think what happens when a brand name firm instead makes a
854 payment to the generic firm, rather than relying solely on
855 its prospects at trial. In that case, the payment secures a
856 later date than is warranted by the likely validity of the
857 patent alone. That payment to a rival made to secure
858 additional delay in the generic entry ought to be prohibited.

859 This pay-for-delay settlement problem is growing. To

860 get a better sense of the problem, I collected a data set
861 using public information of 143 brand generic settlements
862 between 1984 and August 2008. Of these, 60 settlements
863 raised pay-for-delay issues. Settlements as to just 10
864 drugs, whose form is particularly troubling and which
865 currently block generic entry, account for U.S. sales of
866 about \$17 billion each year.

867 The problem is not just growing worse. It is also
868 getting harder. In the early days of pay-for-delay
869 settlements, the brand name paid cash, a couple hundred
870 million dollars in the case of the antibiotic Cipro. These
871 deals are, relatively speaking, easy to understand. But
872 today firms also pay by making contemporaneous side deals
873 that help to disguise the payment, and they can even use the
874 180-day period I mentioned a moment ago as a source of
875 payment.

876 Let me explain. A generic firm gets 180 days if it
877 fights the patent and wins. It loses 180 days if it fights
878 the patent and loses. But what if it settles? In that case,
879 it keeps the 180 days. Now, this is important because it
880 means that a brand name firm can approach the generic and say
881 let me keep my patent and in exchange, I will let you have
882 the 180 days, just much later.

883 For a blockbuster drug such as Lipitor, such forbearance

884 is worth hundreds of millions of dollars to a generic firm.
885 The current approach to pay-for-delay settlement is just not
886 working. H.R. 1706 is an important step forward in
887 identifying and determining pay-for-delay settlement.
888 Section 2A of the bill prohibits a settling brand name firm
889 from providing a generic firm with ``anything of value beyond
890 a negotiated entry date'' and with a few specified
891 exceptions.

892 It is important that the subcommittee recognize that
893 anything of value, properly understood, includes all forms of
894 compensation that induce delay, including effective
895 guarantees of exclusivity. The subcommittee might wish to
896 make this point explicit in the bill.

897 To conclude, the pay-for-delay problem is getting worse
898 as new deals are made and as deal structures become more and
899 more complicated. Congress can help by prohibiting these
900 anti-competitive arrangements. Thanks are due to the
901 subcommittee for taking a leadership role on this important
902 issue. I look forward to hearing your questions and
903 concerns.

904 [The prepared statement of Mr. Hemphill follows:]

905 ***** INSERTS 2, 2A, 2B *****

|
906 Mr. {Rush.} The chair thanks the gentleman. Now, the
907 chair recognizes Ms. Joanne Handy for 5 minutes for the
908 purposes of an opening statement.

|
909 ^STATEMENT OF JOANNE HANDY

910 } Ms. {Handy.} Mr. Chairman, members of the subcommittee,
911 I am, as you know, Joanne Handy, a member of the AARP board,
912 also a nurse and a health care provider. On behalf of our
913 more than 40 million members, thank you for the chance to
914 testify about H.R. 1706. AARP has endorsed this legislation,
915 and we call on Congress to enact this legislation this year.

916 Older Americans, as has been referred to several times
917 by members of the subcommittee, use prescription drugs more
918 than any other segment of the U.S. population. Unfortunately
919 the cost for brand name drug products continue to rise at
920 rates that far exceed inflation, causing a strain on the
921 budgets of both consumers and other health care payers,
922 including the government.

923 Spiraling drug costs are particularly for older adults
924 who are disproportionately affected by chronic disease and
925 more likely to need multiple medications. When faced with
926 higher drug costs, they frequently skip doses, reduce doses,
927 and let prescriptions go unfilled. The result is preventable
928 and expensive hospitalizations and adverse health outcomes.

929 This occurs far less often for those taking generic
930 drugs, which have proven to be one of the safest and most

931 effective ways for consumers to lower their prescription drug
932 costs. AARP encourages its members to use generic drugs
933 whenever possible. AARP strongly supports efforts that
934 provide timely market entry of generic drugs. We are
935 concerned, however, about the recent trends in reverse
936 payments, which occurs when generic manufacturers receive
937 anything of value in exchange for agreeing not to research,
938 develop, manufacture, or sell its generic products.

939 These reverse payments delay market entry of new generic
940 drugs, and thus increase the odds that older Americans will
941 be forced to cut back or go without needed medicines because
942 of the rising cost. AARP believes that H.R. 1706 is an
943 appropriate remedy to end the problem of reverse payments.
944 This legislation is needed because when brand and generic
945 pharmaceutical companies engage in conduct that delays market
946 entry of generic drugs, consumers and other health care
947 payers pay higher prices. And as a result, older Americans
948 are more likely to go without the drugs they need because of
949 the higher costs.

950 Stopping or delaying market entry of the first generic
951 drug prevents all the other generic drugs from competing and
952 ultimately extends the brand name manufacturer's market
953 exclusivity. This creates a powerful incentive for companies
954 to negotiate, to collude with the first to file generic

955 manufacturer to delay market entry of the generic product.

956 Legislation is necessary because, as you have heard,
957 there have been recent court decisions that have held that
958 reverse payment agreements do not violate the antitrust laws.
959 These decisions have unquestionably lead to an increase of
960 such agreements and hampered the Federal Trade Commission's
961 ability to prevent these abuses.

962 In fact, the FTC has reported a marked increase in the
963 number of questionable settlements. 50 percent of the 2006
964 settlement agreements between brand and generic manufacturers
965 included some form of payment as well as an agreement to
966 delay market entry. Ending these costly patient abuses is
967 one essential component in our efforts to reduce skyrocketing
968 brand name drugs prices and provide affordable comprehensive
969 health care options to all Americans.

970 Again AARP strongly supports H.R. 1706. We are pleased
971 to see the committee and members from both houses of Congress
972 and both sides of the aisle moving forward on this issue.
973 Thank you for inviting us to be here.

974 [The prepared statement of Ms. Handy follows:]

975 ***** INSERT 3 *****

|
976 Mr. {Rush.} Thank you. Now, the chair recognizes Ms.
977 Diane Bieri who is the general counsel for PhRMA for 5
978 minutes for the purposes of opening statement. Welcome.

|
979 ^STATEMENT OF DIANE BIERI

980 } Ms. {Bieri.} Thank you. Chairman Rush, Congressman
981 Stearns, and members of the subcommittee, thank you for the
982 invitation to participate in today's hearing on legislation
983 that could have a significant impact on pharmaceutical
984 company settlements of patent disputes. My name is Diane
985 Bieri, and I am the executive vice president and general
986 counsel of PhRMA.

987 In 2008 alone, PhRMA members including both large and
988 small biotech and pharmaceutical companies invested more than
989 \$50 billion in discovering and developing new medicines.
990 What is more, roughly 70 percent of this research was made
991 right here in the United States, representing a significant
992 number of American jobs and other contributions to the
993 economy.

994 In the past 10 years, over 300 new medicines have made
995 it through the increasingly complex FDA review process and
996 into the hands of physicians and patients. These new
997 medicines are increasing life expectancy, decreasing
998 disability, and providing hope to patients and their loved
999 ones who are fighting life-threatening and debilitating
1000 diseases such as cancer, cardiovascular disease, diabetes,

1001 rheumatoid arthritis, and many others.

1002 America's biopharmaceutical companies are facing more
1003 challenges than ever in terms of bringing new medicines to
1004 market. It takes on average 10 to 15 years and more than \$1
1005 billion to bring one new medicine to patients. That is why
1006 research-based companies and their investors need to be
1007 confident that the law will respect and uphold the critical
1008 role of intellectual property, including patents, in
1009 providing the opportunity to recoup these substantial
1010 investments.

1011 Patent protection is the engine that allows America's
1012 research-based biopharmaceutical companies to take risks and
1013 strive to develop the next generation of life-saving and
1014 life-enhancing treatments.

1015 Of course, it is important to remember that
1016 pharmaceutical products effectively have a shorter period of
1017 patent life than other types of products. Pharmaceutical
1018 companies must obtain FDA approval before marketing their
1019 products, and much of the patent term is spent before the
1020 medicine actually comes to market. Recognizing these
1021 challenges, the Hatch-Waxman Act of 1984 attempted to balance
1022 the interests of both innovative and generic companies.

1023 The law made it easier for generics to come to market
1024 but also restored to innovators some of the patent time lost

1025 during the clinical research and regulatory review process.
1026 But even after Hatch-Waxman, the useful patent life of a
1027 pharmaceutical product is limited. For example, one study
1028 showed that for medicine whose generic competitors entered
1029 the market between 2002 and 2005, the average time on the
1030 market before generic competition was only 11.2 years.

1031 In addition, you have to look at the tremendous increase
1032 in competition between brand medicines, but particularly
1033 between brand medicines and generics. Since passage of
1034 Hatch-Waxman, the generic industry share of the prescription
1035 drug market has jumped from less than 20 percent to over 71
1036 percent today. This is, of course, due in part to the fact
1037 that Hatch-Waxman has spawned more patent challenges as it
1038 was meant to do.

1039 Hatch-Waxman gives generic companies incentives to
1040 challenge patents as soon as four years after the brand
1041 medicine receives FDA approval, without requiring the generic
1042 to take the risk of actually marketing the product before the
1043 patent challenge is resolved.

1044 Given this construct, patent challenges have become
1045 commonplace, but patent litigation is still lengthy,
1046 expensive, and risky for all concerned. Generic companies do
1047 not have perfect information when they bring challenges, and
1048 brand companies cannot be sure their view of the strength of

1049 their patents will carry the day at trial.

1050 The rapid expansion in generic utilization has been
1051 fueled, in part, by the fact that innovators and generics
1052 have had the flexibility to resolve some of these patent
1053 suits in fair and appropriate ways without taking every case
1054 the whole way through trial and appeal.

1055 There is no doubt that H.R. 1706 would significantly
1056 reduce that flexibility. Courts and experts tell us that
1057 patents settlements between brand and generic companies, even
1058 those that include some payment from the brand to the
1059 generic, can benefit consumers. Yet H.R. 1706 would prohibit
1060 a wide variety of patent settlements just because the brand
1061 company transfers something of value to the generic.

1062 This kind of broad ban would chill all patent
1063 settlements and is likely to reduce innovation and also
1064 reduce the number of patent challenges filed. Broad limits
1065 on options for patent settlements would force both sides to
1066 spend valuable resources litigating rather than developing
1067 new medicines or bringing generic versions to market.
1068 Statistics from recent years show that innovators are likely
1069 to win over 50 percent of the cases litigated through appeal,
1070 which means that generic entry in those cases could not come
1071 until the patent expires.

1072 In contrast, a settlement might include provisions

1073 allowing a generic product to come to market well before the
1074 patent expires and could produce other collateral benefits
1075 such as licenses for generics to market products unrelated to
1076 the patent dispute. Instead of a blanket rule banning
1077 certain types of patent settlements, enforcement agencies and
1078 courts should continue to evaluate settlements on a case-by-
1079 case basis to determine whether on the whole they benefit
1080 consumers.

1081 The Medicare Drug Improvement and Modernization Act of
1082 2003 enhanced the FTC and Department of Justice's ability to
1083 make those determinations. The approach preserves the
1084 delicate balance between intellectual property protection
1085 that fosters innovation and competition principles that
1086 encourage access to generic medicines and a strong healthy
1087 generic industry.

1088 I look forward to answering any questions you may have,
1089 and PhRMA looks forward to working with you on this
1090 legislation. Thank you again for your attention to these
1091 important policy issues.

1092 [The prepared statement of Ms. Bieri follows:]

1093 ***** INSERT 4 *****

|
1094 Mr. {Rush.} The chair thanks Ms. Bieri, and it is now
1095 my honor to introduce and to allow Dr. Barry Sullivan 5
1096 minutes for the purposes of opening--Sherman, I am sorry--
1097 Sherman 5 minutes for the purposes of opening statement. Dr.
1098 Sherman, you are recognized for 5 minutes.

|
1099 ^STATEMENT OF BARRY SHERMAN

1100 } Mr. {Sherman.} Okay, Nr. Chairman, members of the
1101 subcommittee, thank you for the opportunity to testify again
1102 today. Apotex Inc. is very eager to do its jobs of
1103 challenging weak patents and bringing to the market products
1104 as quickly as possible for the benefit of our customers, who
1105 are the pharmacy industry of America and through them to
1106 American consumers.

1107 We are therefore eager to help elucidate the fundamental
1108 problem that is blocking generic entry, and that, in our
1109 view, is settlements by first filers that whereby they accept
1110 unduly late, very late entry dates, cheap their exclusivity
1111 and thereby block market entry to others such as us who would
1112 continue to fight and thereby gain much earlier market entry.

1113 And the cost to the American consumer is enormous.
1114 Billions of dollars for individual products and certainly
1115 many tens of billions of dollars in total. One example is
1116 the drug Modafanil whereby the Cephalon settled with four
1117 generic suppliers challengers some years ago and thereby got
1118 delayed generic entry until the year 2012. The patent is
1119 very weak. We would be prepared to launch the product now if
1120 we could, and indeed, in Canada, we have already succeeded in

1121 the patent challenge. And the product is on the market in
1122 Canada as a generic sold by Apotex. So the problem is quite
1123 enormous.

1124 There have been legislative initiatives including this
1125 one to address the problem by trying to prohibit reverse
1126 payments, settlements that include reverse payments. In our
1127 view, reverse payments per se are not the problem. They are
1128 simply a symptom of a problem.

1129 Why are brand companies prepared to make large payments?
1130 It is not because they are fair payments to the particular
1131 company with whom they are settling. It is because when they
1132 settle with the first filer, they know the first filer
1133 retains the exclusivity and blocks all others. So they are
1134 paying not to get the one settlement, to get the entire block
1135 of the market until near patent expiry, and that is the
1136 fundamental problem.

1137 In our view, there are two flaws that need to be
1138 addressed and can easily be addressed. The first is that the
1139 first filer who settles and doesn't do what was intended by
1140 the Hatch-Waxman gets to keep that exclusivity to block all
1141 others.

1142 And the second problem is that these agreements almost
1143 always contain poison pill provisions whereby if a subsequent
1144 filer does succeed to get early entry, the settler simply

1145 accelerates entry and takes away the benefit to the
1146 subsequent filer who actually succeeded.

1147 One example that brings the point home is the case of
1148 Altace Ramapril. The first filer was Cobalt. They settled
1149 for very late entry, but in 2007, Lupin won--even though they
1150 were not the first filer, won in the court of appeal. What
1151 then happened? Cobalt used its poison pill provision to
1152 accelerate its entry, launch the product, and Lupin could not
1153 launch even though they were the ones who invested and won.
1154 So all of the benefit went to Cobalt, who had settled. None
1155 of the benefit went to the successful litigant who was not
1156 the first filer.

1157 The message from that case is clear to all who would
1158 subsequently challenge a patent. Don't do it. It isn't
1159 worth it. You can't succeed. So the effect is that the
1160 litigation by those who would actually fight to win is
1161 paralyzed.

1162 In our view, there are two simple amendments that are
1163 needed to fix this problem. The first amendment is to give a
1164 shared exclusivity to a subsequent filer who does fight and
1165 wins. And the second provision that is needed is to override
1166 the poison pill provisions which would, in essence, provide
1167 that if a first filer settles for very late entry, FDA can
1168 then not give final approval to that first filer until that

1169 date. And that date can then not be accelerated by reason of
1170 a subsequent win by a subsequent filer.

1171 These two provisions would accomplish two very important
1172 things. Number one, it would give--when there is an
1173 anticompetitive settlement whereby a first filer has agreed
1174 to defer to a very late entry date, it would given an
1175 incentive to a subsequent filer to pick up the battle,
1176 challenge the patent and win and get earlier entry.

1177 And the second effect would be that it would eliminate
1178 the anticompetitive settlements because if these provisions
1179 were enacted, a brand company would no longer make a reverse
1180 payment to a first filer because it wouldn't have the effect
1181 of blocking all challengers. It would only block the one,
1182 and therefore there would be no reason to make that big
1183 payment.

1184 And secondly, it would tell the first filer they
1185 couldn't settle for too late a date because if it does, it
1186 will be stuck with that date. And then we will lose the
1187 opportunity launch if a second filer, subsequent filer, wins
1188 an earlier entry date.

1189 So in our view, the attacking or trying to eliminate
1190 reverse payments really will not solve the problem.
1191 Anticompetitive settlements will continue with the same
1192 anticompetitive effect only without the reverse payments.

1193 And what is necessary to address the problem is to give
1194 shared exclusivity to a subsequent filer who does take up the
1195 battle and wins and to eliminate the poison pill provisions
1196 whereby a first filer who agrees to late market entry can
1197 then accelerate that entry on the basis of an earlier win by
1198 someone who does invest in the challenge and wins.

1199 We very much urge the committee, subcommittee, to
1200 consider our suggestions because we have been at this a very
1201 long time. We understand what the issues are. We are
1202 fighting the battles every day. We are most eager to do the
1203 job, which the Hatch-Waxman provisions incentivized used to
1204 do, to fight, to win, to bring our products to market early.

1205 We are blocked by these anticompetitive settlements, and
1206 these are the challenged that we are convinced are needed to
1207 solve the problem. Thank you very much.

1208 [The prepared statement of Mr. Sherman follows:]

1209 ***** INSERT 5 *****

|
1210 Mr. {Rush.} The chair thanks the gentleman. Now the
1211 last witness, the chair recognizes for 5 minutes Mr.
1212 Whitehouse. You are recognized now for 5 minutes for the
1213 purposes of opening statement.

|
1214 ^STATEMENT OF TED WHITEHOUSE

1215 } Mr. {Whitehouse.} Thank you. Chairman Rush and
1216 Congressman Stearns and members of the subcommittee, good
1217 morning. I am Ted Whitehouse. Now it is good afternoon. I
1218 am a partner at Willkie Farr and Gallagher and appearing
1219 today on behalf of Teva Pharmaceuticals, which, as you know,
1220 is the leading pharmaceutical company that participates both
1221 on the generic and the brand sides of the industry. Teva and
1222 I appreciate the opportunity to appear and be heard on these
1223 important issues.

1224 As I think you know, Teva has been an active participant
1225 in the last Congress and in the current Congress in the
1226 deliberations on the matters at issue in this hearing. We
1227 hope it has been apparent to everyone that Teva is very
1228 concerned about this and similar legislative proposals but
1229 also very willing to work constructively with Congress and
1230 the FTC in an effort to ensure that the concerns being raised
1231 here are addressed without doing harm to the vital concerns
1232 and incentives at the heart of Hatch-Waxman.

1233 Teva believes that the intricately crafted Hatch-Waxman
1234 process that Congress put in place 25 years ago has worked
1235 and is working very well. Teva's basic position is that no

1236 new legislation is needed. Teva is therefore opposed to H.R.
1237 1706. Teva believes the ability to reach reasonable, timely
1238 and pro-consumer settlements in Hatch-Waxman paragraph four
1239 litigations is absolutely essential to Teva's efforts to
1240 bring low-cost generic drugs to market as soon as possible.
1241 And that is Teva's fundamental business, to work to bring
1242 products to market as soon as possible.

1243 From the perspectives of consumers, settlements that
1244 result in bringing products to market sooner with more
1245 certainty than might otherwise be the case are a very good
1246 thing. Teva believes that the members and staff should give
1247 particular attention to a recent paper written by three
1248 prominent economists including Dr. Laura D'Andrea Tyson, a
1249 professor of economics at Berkeley who served as a chair of
1250 the counsel of economic advisors and is director of the
1251 National Economic Counsel in the Clinton Administration. She
1252 is joining the Obama Administration to advise on tax policy
1253 as we understand it.

1254 This paper, copies of which we believe have been
1255 distributed to all members and their staff, confirms on the
1256 basis of economic analysis and theory some of the conclusions
1257 that Teva reached from this practical experience. First,
1258 that settlements can be good for consumers. Second, that
1259 reasonable settlements are more likely to be achieved is

1260 parties have more than one or two issues over which to
1261 bargain. And third the paper emphasized the importance of
1262 case-by-case analysis of settlements rather than a blanket
1263 ban on particular terms.

1264 As Dr. Tyson's coauthor said in a letter sent yesterday
1265 the chair and ranking member ``a broad ban on certain types
1266 of patent settlements, such as that considered in the
1267 proposed legislation, will likely make Americans consumers
1268 worse off.''

1269 Teva does not contend that all Hatch-Waxman settlements
1270 are necessarily good for consumers, but it takes strong issue
1271 with the legislation that would have prevented Teva from
1272 engaging in any of the recent settlements that Teva reached
1273 that produced real benefits for consumers. For example, 10
1274 settlements entered into by Teva between 1999 and 2007 took
1275 approximately 80 years of the lives of the patents at issue
1276 and will end up saving consumers more than \$67 billion.

1277 Teva believes that more serious considerations should be
1278 given to legislative alternatives that were extensively
1279 discussed in the last Congress, such as mandatory expedited
1280 review by the courts or a more formal expedited FTC pre-
1281 effective review process. If the subcommittee determines to
1282 proceed with the approach embodied in H.R. 1706, Teva
1283 strongly urges that the exceptions or carveouts in the bill

1284 be broadened to make clear that at least the kinds of terms
1285 that Teva has successfully employed in the past to reach
1286 settlements that produced real benefits for consumers remain
1287 permissible.

1288 And those provisions include, among other things, early
1289 generic entry on other products in addition to the one in
1290 suit, a full release for damages and a covenant not to sue on
1291 all patents on the generic products involved in the
1292 settlement, a limited exclusive license, and case-by-case
1293 authority for the FTC.

1294 Now, most of H.R. 1706 is directed to patent
1295 settlements; however, section four addresses a different set
1296 of issues not tied or limited to patent settlements.
1297 Essentially section four would broaden the circumstanced
1298 under which the first generic company to challenge a brand
1299 company's patents could lose or forfeit the 180 days of
1300 marketing exclusivity provided to first filers under Hatch-
1301 Waxman.

1302 As you have heard today, there are people in the
1303 industry who don't like the 180-day exclusivity provisions,
1304 but it is important to be very clear that those provisions
1305 have been in Hatch-Waxman from the start and are absolutely
1306 essential to the incentive structure that has brought this
1307 country the vibrantly competitive and publicly beneficial

1308 generic drug industry from which consumers, third-party
1309 payers, and the federal and state governments benefit every
1310 day.

1311 I respectfully invite your attention to my written
1312 statement for a full explanation of Teva's concerns relating
1313 to these complex provisions in section four. But very
1314 briefly, by way of example, as written, subsection CC would
1315 result in forfeitures of exclusivity before anyone has been
1316 cleared to enter the market. Proposed subsection DD, we
1317 believe, is confusingly unclear and potentially very
1318 overbroad.

1319 On all of these issues, Teva hopes to continue an active
1320 and constructive dialogue with members of Congress and their
1321 staff and with FTC commissioners and the FTC staff, all with
1322 a view of trying to address any legitimate concerns while
1323 carefully preserving all that is good and necessary about the
1324 existing and highly successful Hatch-Waxman process.

1325 Thank you very much, and I would be pleased to answer
1326 any questions that you may have.

1327 [The prepared statement of Mr. Whitehouse follows:]

1328 ***** INSERTS 6, 6A *****

|
1329 Mr. {Rush.} The chair thanks Mr. Whitehouse, and now
1330 the chair will begin the round of questioning by recognizing
1331 himself for 5 minutes for the purposes of questioning the
1332 witnesses. And I just want to ask the witnesses if we need
1333 to go into a second round of questions, the chair is willing
1334 to do that if the witnesses can make themselves available for
1335 an additional round of questioning from the members of the
1336 subcommittee.

1337 Chair recognizes himself for 5 minutes. Exclusion
1338 payment settlements are unique to the pharmaceutical
1339 industry. In all other industries, as I stated in my opening
1340 statement, patents are usually settled in two ways. One, the
1341 accused infringement pays a royalty to the patent holder or
1342 two, the two parties agree to an early entry date. It is my
1343 belief and has been stated earlier that only in the
1344 pharmaceutical industry do we see a very unusual behavior of
1345 a patent holder, which the brand name drug company suing the
1346 accused infringer, the generic company, and then paying the
1347 accused infringer to stay off the market. Only in the
1348 pharmaceutical industry.

1349 I am going to ask Commissioner Rosch, do these types of
1350 settlements happen in any other sector? And while you are
1351 answering that, think about this question: why are these

1352 settlements unique to the drug industry? And what keeps them
1353 from occurring in other industries or commercial sectors?
1354 And how does the framework of Hatch-Waxman impede or enhances
1355 this kind of activity? Those are the questions I have for
1356 you.

1357 Mr. {Rosch.} Thank you, Mr. Chairman. Let me take them
1358 up one by one. First of all, yes I do believe that these
1359 kinds of settlements, that is to say the kinds of settlements
1360 with which this legislation is concerned, are unique to the
1361 pharmaceutical industry.

1362 I think I take issue with characterizing them as payment
1363 settlements. They are not that. They are reverse payment
1364 settlements. They are settlements in which the holder of the
1365 patent actually pays the person who is alleging infringement
1366 some money or other thing of value. We do not frankly see
1367 that kind of settlement in any other industry. So that is
1368 the answer to the first question.

1369 Second, why don't we see it in any other industry? It
1370 is not because we consider either the branded or the generics
1371 to be nefarious. It is simply a matter of economics. Now
1372 what am I talking about in terms of economics? First, state
1373 substitution laws as well as various kinds of formularies
1374 very much encourage switching, switching to a lower cost drug
1375 from a branded drug that is under patent.

1376 Second, because of that encouragement, generic drugs are
1377 inclined and incentivized to switch their drugs as quickly as
1378 possible. And to do that, they are willing to actually take
1379 a haircut on their prices, well below that that the brand
1380 charges because the brand is able to charge monopoly prices.

1381 Third, that threatens however the brand tremendously
1382 because the brand's drug is still under patent, and it is
1383 able to avail itself of monopoly pricing, brand monopoly
1384 pricing, as well as brand monopoly profits.

1385 Fourth, because it is so threatened, the brand is
1386 willing and incentivized to go ahead and share some of those
1387 profits with the generic. And that is what happens when it
1388 offers a reverse payment. It is, in fact, a sharing some of
1389 those profits with the generic.

1390 So finally, the reverse payment settlement is a win-win
1391 proposition for both the brand and the generic. It helps the
1392 brand on the one hand maintain its patent monopoly. And
1393 secondly however what it does is to incentivize the generic
1394 to abandon its challenge to the patent monopoly and therefore
1395 to eschew the kind of pro-consumer activity that the Hatch-
1396 Waxman Act was originally designed to encourage.

1397 There is nothing wrong with the original Hatch-Waxman
1398 Act. To the contrary, its incentives were perfectly aligned.
1399 It gave the brands something. It gave the generics something

1400 for challenging the brands. The problem is not with the Act.
1401 The problem is with the court decisions, which have ignored
1402 the teaching of the Supreme Court as well as what the framers
1403 of the Act had in mind in enacting the Act to begin with.

1404 Mr. {Rush.} The chairman's time has ended, and now the
1405 chair recognizes my friend from Florida, Mr. Stearns, for 5
1406 minutes for the purpose--

1407 Mr. {Stearns.} Thank you, Mr. Chairman. I ask
1408 unanimous consent that the letter that was sent to you and
1409 Mr. Radanovich, the academic study that draws reference by--
1410 that Mr. Whitehouse mentioned, draws out the complexity of
1411 determining whether reverse payment settlements are anti-
1412 consumer and demonstrate that these settlements are actually
1413 pro-consumer in most cases be made part of the record.

1414 Mr. {Rush.} Hearing no objection, so ordered.

1415 [The statement follows:]

1416 ***** COMMITTEE INSERT *****

|
1417 Mr. {Stearns.} This is an interesting hearing, Mr.
1418 Chairman. You have the pharmaceutical industry, and as I
1419 understand it, the generic drug industry is aligned together.
1420 It is the most unlikely alliance here. Mr. Whitehead and
1421 others I represent--I mean as I understand it from my staff,
1422 Dr. Sherman, that you are alone here. That most of the
1423 generics--isn't that true, Dr. Sherman, that most of the
1424 generics are supporting--are not supporting this bill. Is
1425 that true, Mr. Whitehead? Most of the generic companies are
1426 not supporting this bill?

1427 Mr. {Whitehouse.} That is correct.

1428 Mr. {Stearns.} Okay, and then the pharmaceuticals
1429 obviously, Ms. Bieri, do not support it. So I say to Mr.
1430 Rosch, you have here the pharmaceuticals against the bill,
1431 the generics against the bill in this case, you pointed out,
1432 pretty in detail how the courts have ruled that the Hatch-
1433 Waxman bill is working and that these reverse payments that
1434 you use--you don't like my term the settlement payment--that
1435 they actually are acceptable legal remedy and they are not
1436 anticompetitive. Isn't that true, Mr. Rosch?

1437 Mr. {Rosch.} Some of the courts have done that.

1438 Mr. {Stearns.} No, but in general, didn't all the
1439 courts show that these agreements are not anticompetitive?

1440 Mr. {Rosch.} No, that is not correct. The Sixth
1441 Circuit in the Cardizem case held that they were in fact per
1442 se illegal. The Eleventh Circuit and the Second Circuit
1443 however have held otherwise as a matter of policy. And as I
1444 said before, I think it is Congress's authority to make
1445 policy, not--

1446 Mr. {Stearns.} Did you say the Supreme Court wouldn't
1447 even rule on this because it was decided by the lower courts?

1448 Mr. {Rosch.} No, the Supreme Court did not rule on it
1449 because, as you know, the Supreme Court doesn't take--doesn't
1450 review all circuit court decisions.

1451 Mr. {Stearns.} Well, wouldn't you say the majority of
1452 courts have ruled that this is not anticompetitive?

1453 Mr. {Rosch.} Two to one, you are correct.

1454 Mr. {Stearns.} Two to one, okay. So we establish two
1455 to one the courts. So what this bill is trying to do is
1456 circumvent the courts where the courts have heard legal
1457 arguments on both sides and a two-to-one majority have said
1458 that this reverse payment that you use, which I say is a
1459 settlement payment, is not anticompetitive. Is that a true
1460 statement?

1461 Mr. {Rosch.} No, it is not correct. First of all,
1462 because the Supreme Court has held in other contexts, that is
1463 to say when they are not part of a settlement, that exactly--

1464 Mr. {Stearns.} But not in this context?

1465 Mr. {Rosch.} No, the Supreme Court has not addressed
1466 this--

1467 Mr. {Stearns.} That is what I am saying, okay. You
1468 know I think when you look at the statistics that before the
1469 Hatch-Waxman only 19 percent of the generic industry share
1470 the prescription drug benefit was only 19 percent. After the
1471 Hatch-Waxman, it went up to 70 percent. So that would show
1472 that it is working. I hear no evidence that if we pass this
1473 bill that you are going to go from 70 to 80 to 90 percent.
1474 In fact, you might go lower. And, Mr. Whitehead, if this
1475 bill pass, the statistics I just gave you before the Hatch-
1476 Waxman went to 70 percent, do think the statistics will go
1477 lower if this bill is passed?

1478 Mr. {Whitehouse.} We believe it is documented in this
1479 economic study that--

1480 Mr. {Stearns.} Yeah.

1481 Mr. {Whitehouse.} --there is a very real risk that
1482 there will be disincentive to the generic companies.

1483 Mr. {Stearns.} So why would we want to do harm then
1484 with something that the court says is not anticompetitive?
1485 We have both people involved have indicated they don't want
1486 it to happen, and we have a study to say the overwhelming
1487 statistic that it is going up to 70 percent is working. And

1488 we have a study that says in fact, if you pass this bill,
1489 that consumers will have less choice. And so it is a little
1490 interesting to me. Mr. Rosch, here is a question for you.

1491 Mr. {Rosch.} Thank you.

1492 Mr. {Stearns.} When you have statistics where it says
1493 that a study claims that in all patent litigation initiated
1494 between 1992 and 2000, the generic prevailed in 73 percent of
1495 the challenged drug products. But I don't think that is
1496 telling the whole story. How many of these wins resulted in
1497 actual generic products coming on the market?

1498 Mr. {Rosch.} Well, let us assume that it is 45 percent
1499 as--

1500 Mr. {Stearns.} No, let us just take 73 percent as the--

1501 Mr. {Rosch.} Okay.

1502 Mr. {Stearns.} --statistic that is used. Of that 73
1503 percent, how many of those resulted in actual products being
1504 put on--

1505 Mr. {Rosch.} I can't--

1506 Mr. {Stearns.} You know what? I can tell you it is
1507 probably low because if a product consists of color, shape,
1508 compound, and dissolution, and they might win three of the
1509 cases. They say okay, we won on color, shape and
1510 dissolution, dissipation let us say, but the actual content
1511 of that, the compound itself they lose on, they can't do

1512 anything.

1513 Mr. {Rosch.} Well, let us assume it is 45 percent as
1514 you suggested earlier.

1515 Mr. {Stearns.} Okay.

1516 Mr. {Rosch.} Let us assume it is 45 percent. That
1517 means that in 45 percent of the cases, these reverse payments
1518 are actually operating to hurt consumers. If it is--

1519 Mr. {Stearns.} No, well ultimately with reverse
1520 payment, settlement payment, my terms, with that means that
1521 generic drug finally comes on. Otherwise, it would be, I
1522 think you mentioned, 80 years or somebody in the panel said
1523 it would take 80 years of litigation. So you suddenly have
1524 this litigation abruptly stopped. You have in six months the
1525 possibility of generic coming on the market, and this whole
1526 litigation process ends.

1527 Mr. {Rosch.} Well, there is nothing in the bill that
1528 would chill settlements at all. There were lots of
1529 settlements that were made before the court ruled. And
1530 Schering, there have been a number of settlements recently.

1531 Mr. {Stearns.} Okay, I just want--there is no evidence
1532 of reverse settlements have actually reduced cost.

1533 Mr. {Rush.} The time of the gentleman has ended. The
1534 chair now recognizes Mr. Stupak for 7 minutes for the
1535 purposes of questioning the witnesses.

1536 Mr. {Stupak.} Thank you, Mr. Chairman. Dr. Sherman,
1537 let me ask you this question. In June of 2008, Pfizer
1538 reached a settlement with Ranbaxi concerning Lipitor, the
1539 world's top selling drug. According to press reports, the
1540 settlement delayed the entry of generic here in the United
1541 States until November of 2011, up to 20 months later than
1542 many analysts had been anticipating.

1543 The settlement of litigation here in the United States
1544 was part of a global settlement in which Pfizer granted
1545 licenses to Ranbaxi authorizing Ranbaxi to sell generic
1546 Lipitor in seven other pharmaceutical markets, Australia,
1547 Canada, Belgium, Germany, Italy, the Netherlands, and Sweden.
1548 The deal is reported to allow Ranbaxi to sell generic in
1549 those seven countries two to four months earlier than the
1550 patents expire. It was also reported that the deal would
1551 make generic Lipitor available in Canada earlier than in the
1552 U.S.

1553 Pfizer also dropped its challenge to Ranbaxi's current
1554 sale of generic Lipitor in four countries, Brunei, Malaysia,
1555 Peru, and Vietnam. Both Pfizer and Ranbaxi said the
1556 agreement did not involve any payments. It seems to me that
1557 this global deal was full of payments. Under the settlement,
1558 market entry for Lipitor appears to have been permitted
1559 earlier in a host of countries than here in the United

1560 States, which coincidentally happens to be the largest market
1561 in the world.

1562 So I have three questions if I may. If we pass
1563 legislation solely banning reverse payments, will we see more
1564 arrangements like this where delayed entry in United States
1565 is tied to settlement of litigation permitting earlier access
1566 to generic in markets outside the United States? Secondly,
1567 won't companies attempt to evade the payment ban by taking
1568 the position that settlements outside the United States are
1569 not subject to U.S. requirements that settlement reported to
1570 the Federal Trade Commission? And third, that the Federal
1571 Trade Commission prosecutes them for any such effort, won't
1572 the length of time it takes to do so be so long that any
1573 opportunity for savings from generic competition really be
1574 lost?

1575 Mr. {Sherman.} Yes, I have to say that--

1576 Mr. {Stupak.} I would ask you to turn on your mike
1577 please.

1578 Mr. {Sherman.} I am sorry. My concern is not only that
1579 reverse payments are not the fundamental problem. It is the
1580 ability to block other generics by reason of keeping the
1581 exclusivity. That is the fundamental problem. But there is
1582 no question in my mind that no matter how one tries to stop
1583 reverse payments by legislation, not only is it--even if it

1584 worked, it wouldn't have the significant effect.

1585 But it can't work because the creative minds of thieves
1586 are without limit, and there is no question that deals can be
1587 simultaneously done outside of the United States, and Lipitor
1588 is not the only example. For example, Ben Lefaxine, Effexor
1589 XR is another example. Some years ago, Teva settled with
1590 Wyeth and agreed to a very late entry in the United States.
1591 And at the same time, they settled the Canadian litigation
1592 allowed them on the market in Canada through their Nova Pharm
1593 division. So Canadian consumers have had low-cost generic
1594 Effexor XR for years, where it is delayed in the United
1595 States under two agreements that were entered simultaneously,
1596 one outside of the United States. And that probably is
1597 beyond the purview of the American courts because the
1598 American courts don't have jurisdiction over foreign
1599 countries operating abroad. And there is no way to stop
1600 simultaneous signature of agreements that appear to be
1601 unrelated or that can be said to be unrelated.

1602 Also attempts to block anticompetitive agreements by the
1603 FTC taking action will be futile because they will become
1604 mute by the time it is decided. It may be decided five years
1605 after an agreement is signed that it is improper, but in the
1606 meantime, there is no other generic firm because that
1607 agreement is there, able to justify investing to challenge

1608 the patent or bring the product to market. So even if a
1609 challenge to an agreement were to work, it would be moot by
1610 the time it happened.

1611 So the concern that we have is not only that attempts to
1612 block anticompetitive deals by banning reverse payments won't
1613 be affected, but it is not really addressing the fundamental
1614 problem. That is not the payment itself but the fact that
1615 these deals, whereby the subsequent filers who would fight,
1616 can't fight because they can't get on the market. That is
1617 the problem that has to be addressed. Give shared
1618 exclusivity with subsequent filer who wins. That solves the
1619 whole problem. The problem disappears, and consumers will
1620 get the benefit.

1621 Mr. {Stupak.} Well, let me ask this one. I am going to
1622 ask Professor Hemphill if he could answer this one. H.R.
1623 1706 only prohibits a very specific type of provision
1624 exclusive payments in drug patent settlements. That is the
1625 bill only prohibits the brand name drug from paying or
1626 providing value to the generic company in exchange for the
1627 generic company delaying market entry.

1628 The bill does not ban legal settlements in general.
1629 History has shown us that drug companies are perfectly
1630 capable of settling their patent disputes without exclusion
1631 payments. When the Federal Trade Commission and states crack

1632 down on these types of settlements in 2000, they disappeared,
1633 and drug companies settled their cases just like any other
1634 companies do in other industries. However, when the courts
1635 then invalidated the FTC's enforcement efforts in 2005,
1636 exclusion payment settlements came back with a vengeance.

1637 So, Professor, doesn't this show that drug companies are
1638 perfectly capable of settling their patent disputes like any
1639 other company? And is there any evidence from the
1640 settlements from 2000 to 2005 which did not contain reverse
1641 payments, were they any more costly or difficult to achieve
1642 than settlements with reverse payments?

1643 Mr. {Hemphill.} That is a terrific question. It is
1644 difficult to get to the very bottom of the question using
1645 publicly available information, though based on the work that
1646 I have done as to settlements--with respect to information
1647 that it is the public domain, the answer does seem to be yes,
1648 that is, just as you have suggested, drug companies during
1649 that interregnum when the FTC rules seem to be in effect did
1650 seem able to settle, just not able to settle in a
1651 anticompetitive manner.

1652 Mr. {Stupak.} Right, okay. Commissioner Rosch, did you
1653 care to--did you find the settlements during this period to
1654 be more costly or more difficult to achieve by drug companies
1655 during that 2000/2005 period when your enforcement mechanism

1656 was there?

1657 Mr. {Rosch.} No, we did not.

1658 Mr. {Stupak.} Anyone else care to comment on that? Ms.
1659 Bieri, did your companies find it more difficult or more
1660 costly to sell when we did not have that five-year period of
1661 time?

1662 Ms. {Bieri.} Thank you, Congressman. I would just say
1663 that I think Mr. Hemphill is right, that the publicly
1664 available data aren't sufficient to show that for a fact.
1665 And I would--

1666 Mr. {Stupak.} How about your internal data on behalf of
1667 PhRMA? You must track that, do you not?

1668 Ms. {Bieri.} No, we do not track the number of
1669 settlements each year.

1670 Mr. {Stupak.} Okay.

1671 Mr. {Rush.} The gentleman's time has ended.

1672 Mr. {Stupak.} Thank you, Mr. Chairman.

1673 Mr. {Rush.} The chair now recognizes the gentleman from
1674 Nebraska, Mr. Terry, for 5 minutes.

1675 Mr. {Terry.} Thank you, Mr. Chairman. I am one of the,
1676 I think, maybe two or three trial attorneys on this side of
1677 the aisle. Omaha, you are right. I knew there was something
1678 I liked about you. And settled hundreds of cases, wrote,
1679 read settlement agreements. But I got to tell you this one

1680 is a little out of the box for me, so I am going to have to
1681 kind of take some small steps and ask you some generic
1682 questions, pun intended. That is as good as it gets up here,
1683 folks, so--

1684 Mr. Rosch, just so I understand the scope of things, how
1685 many--just take in the last five years, how many of these
1686 reverse settlements have occurred? 5, 10, 500?

1687 Mr. {Rosch.} At least 103 that I know about,
1688 Congressman. Our staff reviewed that many at least,
1689 including, I should add, reverse payment settlements in which
1690 there were side deals plus a date certain for entry. So they
1691 were not always just payments of money, but there were 103 of
1692 them. And our staff found that all but a couple of them were
1693 very suspect.

1694 Mr. {Terry.} Now, I am sorry, out of the 103, you found
1695 that 103 of them were suspect?

1696 Mr. {Rosch.} No, two of them were not suspect.

1697 Mr. {Terry.} Were not? So 101 of them--

1698 Mr. {Rosch.} Were.

1699 Mr. {Terry.} --fell into the category of being suspect?

1700 Mr. {Rosch.} I guess that is why I have some problems
1701 with Teva's thesis because they would like to exempt a lot of
1702 side agreements.

1703 Mr. {Terry.} Okay, now as I understand, when the brand

1704 name files their patent, I mean there is a date certain there
1705 of when that patent ceases to exist and a generic can come
1706 in. I mean that is very easy to find that information,
1707 right?

1708 Mr. {Rosch.} Yes, but--

1709 Mr. {Terry.} Okay, what is the but?

1710 Mr. {Rosch.} The but is that there is also provision in
1711 the statute that, for a certain period of time after the
1712 brand is entered, it will basically get a free pass.
1713 Normally, that is five years, but it can go up to seven years
1714 in the case of some pediatric drugs where there are
1715 relatively few sales.

1716 In addition to that, they get something that you and I
1717 never saw in our lifetimes as litigators, and that is that
1718 they get a certain period of stay time with respect to an
1719 automatic, if you will preliminary injunction. And there is
1720 nothing like that--

1721 Mr. {Terry.} How long--

1722 Mr. {Rosch.} --in any other patent--

1723 Mr. {Terry.} --would that stay time average?

1724 Mr. {Rosch.} I believe--

1725 Mr. {Terry.} And who gives that stay time? That is not
1726 statutory.

1727 Mr. {Rosch.} It is statutory.

1728 Mr. {Terry.} That is statutory?

1729 Mr. {Rosch.} That is.

1730 Mr. {Terry.} So statutorily, they get an extra amount
1731 of time because of--

1732 Mr. {Rosch.} It is 30 months.

1733 Mr. {Terry.} Thirty months. So I guess is there then
1734 not clarity on when the dates that the patent runs out that
1735 the generic can just jump into the market without legal
1736 issue?

1737 Mr. {Rosch.} No, again this is a matter of the statute.
1738 The statute allows what is called the first filer--

1739 Mr. {Terry.} Right.

1740 Mr. {Rosch.} --who goes to the FDA first, and certifies
1741 that it is not infringing or that the patent is invalid.

1742 Mr. {Terry.} That is where--can I interrupt there?

1743 Mr. {Rosch.} Yes.

1744 Mr. {Terry.} Because that is where part of my confusion
1745 is coming in. If the date for the patent has run out, why do
1746 they have to declare or somehow adjudicate that there is
1747 something wrong with the patent?

1748 Mr. {Rosch.} Because the statute contemplates that
1749 before the patent runs out the generic will be incentivized
1750 to challenge patents which are not valid or infringed or in
1751 which validity or infringement is questioned.

1752 Mr. {Terry.} Well, even though they may be incentive,
1753 they still have to find something wrong with the patent.

1754 Mr. {Rosch.} Correct.

1755 Mr. {Terry.} Unless they want to wait until the end of
1756 the patent date. So it seems to me that if they are
1757 incentivized to attack the validity of the patent because we
1758 want to have a policy that gets those generics out there
1759 sooner than the end date.

1760 Mr. {Rosch.} Yes.

1761 Mr. {Terry.} I am not sure if I would agree with the
1762 premise that these are reverse payments. Out of the 103
1763 then, let me just jump to my conclusion for my--I am out of
1764 time but--

1765 Mr. {Rosch.} Surely.

1766 Mr. {Terry.} --let me ask this question. How many out
1767 of the 101 nefarious reverse settlements actually made the
1768 date that the generic got to the market sooner than the clear
1769 date that the name brand patent ran out?

1770 Mr. {Rosch.} The answer is, I believe, in almost all of
1771 those cases, it was sooner, but I would suggest most
1772 respectfully that that is not the question. Brand names do
1773 not pay tens or hundreds of millions of dollars in reverse
1774 payments to generics in order to accelerate their entry into
1775 the market. They don't do that. What instead they are doing

1776 is they are paying to keep that--to skew if you will the
1777 incentives of the generic to prevent the generic from
1778 actually challenging a patent that should be challenged. So
1779 that is the pernicious part.

1780 There is nothing wrong--I want to emphasize that. There
1781 is nothing wrong with the incentives created by Hatch-Waxman.
1782 The problem is created by the reverse payment settlement.

1783 Mr. {Rush.} The gentleman's time has expired. The
1784 chair now recognizes the gentlelady from Illinois, Ms.
1785 Schakowsky, for five minutes.

1786 Ms. {Schakowsky.} Let me just say that over 30 years
1787 ago, I was involved in, because I was a direct of a senior
1788 citizen organization, working to get the state of Illinois to
1789 pass generic drug legislation in the hopes that it would
1790 reduce the cost, which has proven to be true. My colleague
1791 and friend Mr. Stearns was talking about how incredible it
1792 was that the generic drug, or at least the first filers
1793 anyway, and the pharmaceutical companies were on the same
1794 side.

1795 Obviously the problem is that they are because both are
1796 benefiting to the detriment, it seems, of the consumers. Mr.
1797 Whitehouse, you were probably citing this study, and you
1798 certainly didn't mean to imply that because Laura Tyson was
1799 an author that the Obama Administration is supporting this

1800 point of view, did you?

1801 Mr. {Whitehouse.} Not at all. I--

1802 Ms. {Schakowsky.} Okay, and who paid for this study?

1803 Mr. {Whitehouse.} My understanding is that it was--

1804 funding was provided by Ms. Bieri's association, PhRMA.

1805 Ms. {Schakowsky.} PhRMA.

1806 Mr. {Whitehouse.} But they make clear that they express

1807 their independent views.

1808 Ms. {Schakowsky.} I just think that is important to

1809 note for the record, that the study that is being cited was

1810 paid for by the pharmaceutical industry. Let me ask the

1811 commissioner, Rosch--is it Rosch, I am sorry?

1812 Mr. {Rosch.} That is perfectly fine.

1813 Ms. {Schakowsky.} What is it really though?

1814 Mr. {Rosch.} Rosch.

1815 Ms. {Schakowsky.} Okay, Rosch.

1816 Mr. {Rosch.} Like the chairman's.

1817 Ms. {Schakowsky.} No, you should accept your real name.

1818 Okay, sorry. That the suggestions made by Dr. Sherman, he

1819 proposed that maybe we would consider two amendments to the

1820 legislation. Do you--or Mr. Hemphill, if you want to comment

1821 on that--think that would improve the legislation and why?

1822 Mr. {Rosch.} Well, again I am just speaking for myself,

1823 Congresswoman, but I am very reluctant to reduce the 180-day

1824 exclusivity period or to water it down at all or to dilute it
1825 at all because I think that is the carrot. That is the
1826 incentive for the generic to challenge.

1827 Ms. {Schakowsky.} Yeah, but if this first filer makes a
1828 deal and then the second filer--well, maybe you can explain
1829 it better--

1830 Mr. {Rosch.} That is why I don't want--that is why I
1831 want to ban reverse payments because that--

1832 Ms. {Schakowsky.} Period?

1833 Mr. {Rosch.} Period.

1834 Ms. {Schakowsky.} Okay. Well, why is your suggestion
1835 preferable then, Dr. Sherman?

1836 Mr. {Sherman.} We are not suggesting that the 180 days
1837 be reduced. We are suggesting that it go to or be shared by
1838 the person who actually earns it, the one who actually
1839 carries the challenge and succeeds in invalidating the
1840 patent. Right now, the first filer can settle and keeps the
1841 180 exclusivity, which is a huge reward, for doing nothing,
1842 for agreeing not to challenge a patent and for agreeing with
1843 the brand company to defer generic entry until just before
1844 patent expires at enormous cost to consumer. They are not
1845 earning it.

1846 So we are saying in a case where a first filer has
1847 settled, it is not entitled to that exclusivity, but let them

1848 keep it anyway. Let us just give a shared exclusivity to the
1849 person who then picks up the challenge, does what Congress
1850 intended, invests in challenging the patent, and succeeds.
1851 If you don't do that, there is no incentive for anybody to
1852 pick up the challenge and to get early entry into the market
1853 in the face of a settlement by a first filer who has agreed
1854 to undermine the system and accept very late--

1855 Ms. {Schakowsky.} Okay, Mr. Hemphill, does that make
1856 any sense?

1857 Mr. {Hemphill.} So the underlying policy concern is a
1858 real one that a first filer could settle, retain the
1859 exclusivity, and that that would create public policy
1860 problems. Perhaps a simpler solution, a solution actually
1861 suggested by Apotex two years ago would be that upon
1862 settlement, the exclusivity is simply forfeited.

1863 My concern about adding a new layer of exclusivity in
1864 addition to the possibly of diluting existing incentives is
1865 this is an extremely complicated scheme as it is. A lot of
1866 the problems result from manipulation of the 180 days.
1867 Doubling the set of possible--or multiplying the set of
1868 possible holders of exclusivity, I think, promises some
1869 confusion and complexity.

1870 To forfeit your alternative, which Apotex in the past
1871 suggested in response to the same policy concerns, strikes me

1872 as a simpler and maybe easier to implement alternative.

1873 Ms. {Schakowsky.} Okay.

1874 Mr. {Sherman.} May I answer that? We did propose that
1875 two years ago, and it certainly would be better than what we
1876 have now, simply a forfeiture of exclusivity. But the
1877 problem there is then there is no incentive for a subsequent
1878 filer to take up the advantage, to take up the battle. And
1879 that is the very thing that the full regime is intended to
1880 incentivize. So giving a shared exclusivity to a subsequent
1881 who does take up the battle is better because then you are
1882 going to have someone investing to do it, and that will
1883 result in earlier entry into the market for generics. It is
1884 very--

1885 Ms. {Schakowsky.} Okay, I appreciate this back and
1886 forth. Thank you.

1887 Mr. {Rush.} The chair now will recognize the ranking
1888 member of the subcommittee, Mr. Radanovich, for 5 minutes for
1889 questions.

1890 Mr. {Radanovich.} Thank you so much, Mr. Chairman, and
1891 I beg the forgiveness of the committee. I had a prior
1892 constituent water issue that needed to be addressed. I am a
1893 little bit late to this hearing. But I want to thank the
1894 panel for being here. I do have a couple of quick questions.

1895 First of all, to the honorable Mr. Rosch, Ms. Handy

1896 testified that H.R. 1706 creates two safe harbors. The first
1897 that the only value allowed for a generic is the right to
1898 market a drug prior to patent expiration. Second, the
1899 generic cannot be sued for infringement, thereby insulating
1900 them from any damages. A settlement is usually an agreement
1901 where both parties receive consider. However, it seems that
1902 the considerations are entirely one-sided. What would be the
1903 benefit to the brand company to settle in this situation,
1904 number one? And number two, why would a brand company ever
1905 choose not to prosecute their patent to the fullest to see
1906 litigation through to the bitter end?

1907 Mr. {Rosch.} Well, with respect to the first issue, I
1908 think it really goes to whether or not side agreements should
1909 be or are covered by this legislation. And the answer is, as
1910 I indicated earlier, based on our own studies internally,
1911 side agreements can indeed end up being a part of the
1912 problem. So that is the answer to the first part of the
1913 question.

1914 The answer to the second part of the question really
1915 goes to the extent to which you want to incentivize--it seems
1916 to me you want to incentivize the generic to actually
1917 challenge what may be an invalid or a patent that is not
1918 being infringed. And again my view is that you want to give
1919 the--my own personal view is you want to give the generic the

1920 broadest possible incentive in that regard, which is what I
1921 think you do with the 180 days.

1922 Mr. {Radanovich.} Um-hum, thank you very much. Ms.
1923 Bieri, is it? Ms. Bieri?

1924 Ms. {Bieri.} Yes.

1925 Mr. {Radanovich.} Thank you. Why is it so important
1926 for innovative pharmaceutical companies to retain the ability
1927 to settle patent litigation with generic companies?

1928 Ms. {Bieri.} Thank you, Congressman. Litigation is
1929 risky and expensive, and to--it incurs significant cost for
1930 both the brand companies and the generic companies.
1931 Companies have to have a way to resolve their disputes
1932 without taking them the whole way to trial. And so for both
1933 parties to this litigation, it is important to have the
1934 flexibility to be able to come to mutual arrangements that
1935 are still within the scope of the patent and therefore
1936 beneficial to consumers and ultimately which will bring these
1937 medicines, generic medicines, to the market before the patent
1938 expires but still be a fair arrangement for both parties to
1939 the settlement.

1940 Mr. {Radanovich.} Wouldn't the brand companies be
1941 better off if they successfully defended their patents in
1942 court?

1943 Ms. {Bieri.} That would be true if, in fact, the

1944 outcome of litigation were always certain. But litigation is
1945 risky, expensive, and uncertain. And businesses like
1946 certainty as you well know. So it is often better for the
1947 brand company to, within the scope of its patent, have a date
1948 certain by which it knows that the generic will come on the
1949 market.

1950 Mr. {Radanovich.} I see. Yeah. Question for the
1951 panel, anybody who cares to respond. Our government and our
1952 American companies engage in daily fights against
1953 intellectual property theft. It seems, however, that a
1954 number of our witnesses are arguing for less stringent IP
1955 protections when it comes to pharmaceuticals. I think that
1956 we could agree that life-saving innovation must be
1957 encouraged, but it seems, however, that you are arguing that
1958 the IP rights of some innovators are less worthy of
1959 protection afforded by the law than perhaps Hollywood or
1960 Silicon Valley or Nashville.

1961 Many can defensively disagree, but I would like to hear
1962 any of your thoughts on the issues of intellectual property
1963 in general. Mr. Hemphill?

1964 Mr. {Hemphill.} Yeah, I guess just to start, I think it
1965 is not true at all that the proposed bill here runs any risk
1966 of treating pharmaceutical companies, brand or generic as
1967 second class citizens. As the matters stand, we have a very

1968 complicated regime that is already very different from what
1969 anybody else gets. Commissioner Rosch mentioned a few
1970 moments ago the special 30-month stay granted to a brand name
1971 firm, even if the patent is extremely trivial. A patent term
1972 extension, of course, is another example.

1973 There are examples on the other side, but to think of
1974 this as an example of second class citizenship for PhRMA
1975 companies, I think, is far from the fact here.

1976 Mr. {Radanovich.} Okay, anybody else care to comment?
1977 Dr. Sherman?

1978 Mr. {Sherman.} Yes, what distinguishes pharmaceuticals
1979 from other industries is this unique provision whereby the
1980 first filer has exclusivity to block others. So what you
1981 have when you have, under this regime, a brand company and
1982 the first filer negotiating, the parties that are not at the
1983 table are the public and the other generic firms who would be
1984 prepared to continue to fight. And the settlement to which
1985 they are not a party, affects them because it precludes the
1986 other generics from fighting to win because they are blocked
1987 by the continuing exclusivity. And the consumers aren't at
1988 the table, and they are the ones who are paying the billions
1989 of dollars of extra money as a result of the settlement.

1990 So sure, this bill would treat pharmaceutical
1991 differently because it would ban reverse payments, but the

1992 question that should be asked is why are they happening in
1993 this industry? And it is happening because the present
1994 regime permits a first filer to settle on behalf of all of
1995 the generic industries and consumers who are not at the
1996 table.

1997 So the way to fix it is not to have special provisions
1998 that bar reverse payments but to stop--to fix the regime so
1999 that a first filer who settles is settling only for himself
2000 and is not blocking another generic who would, in fact,
2001 continue to invest and fight for earlier entry.

2002 Mr. {Radanovich.} Thank you.

2003 Mr. {Rush.} The gentleman's time has concluded.

2004 Mr. {Radanovich.} Thank you, Mr. Chairman.

2005 Mr. {Rush.} The chair now recognizes the gentleman from
2006 Louisiana, Mr. Scalise, for 5 minutes.

2007 Mr. {Scalise.} Thank you, Mr. Chairman. The first
2008 question just open up to the whole panel. If you can explain
2009 or give an example of a case where Congress has actually
2010 specified that a certain industry specific private settlement
2011 would be illegal. Start with Mr. Whitehouse and work down.

2012 Mr. {Whitehouse.} We are certainly not aware of any,
2013 and we think in fact it is important to recognize and these
2014 economic papers do point out, make the important point, that
2015 this isn't unique to PhRMA, that every settlement and any

2016 litigation, as any litigator will tell you, involves some
2017 mutuality of consideration, or there wouldn't be a deal. And
2018 so it is the technicality of how the money or the
2019 compensation moves in any particular transaction. It is an
2020 artifact, but it is in the end of any interest because a
2021 settlement is not going to happen unless both sides are
2022 getting something out of it.

2023 Mr. {Scalise.} Mr. Sherman?

2024 Mr. {Sherman.} Well, again, the problem is that this
2025 industry is unique because the first filer in this case who
2026 settles is settling on behalf of everybody and entering into
2027 an agreement which blocks all others from getting to market.
2028 That is what distinguishes this industry, and that is what is
2029 wrong. That is what should be fixed.

2030 Mr. {Scalise.} Do you know of any other cases in other
2031 industries where this type of proposal that is brought
2032 forward is--

2033 Mr. {Sherman.} No, because there is no other industry
2034 where somebody gets an exclusivity by reason of doing a
2035 challenge and can block all others. That is the problem.

2036 Mr. {Scalise.} Not sure that that is the case, but Ms.
2037 Bieri?

2038 Ms. {Bieri.} Congressman, I am not aware of any other
2039 industry in which a bill target settlements of a particular

2040 type. I would say that the courts, when they look at these,
2041 and to some extent the agencies, have approached these on a
2042 case-by-case basis so that they start from the proposition
2043 that settlements are pro-competitive if, in fact, they would
2044 allow the generic to enter prior to the expiration of the
2045 patent. And if in fact they don't, then they may be
2046 anticompetitive. So they pursue a case-by-case analysis
2047 which to us is more sensible than a per se ban.

2048 Mr. {Scalise.} Ms. Handy.

2049 Ms. {Handy.} Respectfully, Congressman, I don't know
2050 the answer, but I think whether or not it occurs, the issue
2051 is whether it is good for consumers.

2052 Mr. {Scalise.} And we will get into that later in the
2053 questioning. Thanks. Mr. Hemphill.

2054 Mr. {Hemphill.} Yeah, the litigation, the settlements,
2055 and the proposed fix are all industry specific and unusual.

2056 Mr. {Scalise.} Unusual. Thank you. Mr. Rosch?

2057 Mr. {Rosch.} That is correct.

2058 Mr. {Scalise.} All right. Well, thank you.

2059 Mr. {Rosch.} But the--

2060 Mr. {Scalise.} First round. Well, let me ask Mr. Rosch
2061 and then--

2062 Mr. {Rosch.} As has been pointed out, however,
2063 Congressman, this industry is very unusual as well.

2064 Mr. {Scalise.} I am sure, and many are in their own
2065 rights. Many industries are. According to your reports on
2066 settlements, there have been over 50 settlements filed with
2067 the FTC in the last three years. Your testimony, I think,
2068 said a large number of them have side agreements, yet of
2069 those 50, the FTC has not filed legal challenges against any
2070 of them. And private plaintiffs have brought suits against
2071 only two of them. Why has the FTC not challenged any of
2072 those settlements?

2073 Mr. {Rosch.} It is quite simple, Congressman. We are
2074 trying to pick those settlements which we think are more
2075 pernicious and we think we can win. We want to win one of
2076 these cases because we feel that we are not only the
2077 guardians of consumers in this fight but also the guardians
2078 of you folks who enacted Hatch-Waxman.

2079 Mr. {Scalise.} I guess that means you don't feel you
2080 could have one the other ones that have been filed.

2081 Mr. {Rosch.} No, I don't mean to leave that impression.
2082 What I do mean to leave is the impression that the ones that
2083 we have challenged, we think, are the ones that are most
2084 obviously pernicious to consumers and most--

2085 Mr. {Scalise.} But obviously you make a calculated
2086 decision then if you don't--you only bring a suit if you feel
2087 that you can win.

2088 Mr. {Rosch.} No, that is not necessarily--

2089 Mr. {Scalise.} But that is what you just said.

2090 Mr. {Rosch.} If we had unlimited resources, we would
2091 probably be challenging all of them, but we don't.

2092 Mr. {Scalise.} Well, the same is the case with the
2093 generic company that brings a case to court as well. They
2094 don't have unlimited resources either, but obviously they
2095 feel they have merit. And that is why they bring the case,
2096 and then this bill would remove their ability to settle.
2097 Several settlements, including those involving Prozac and
2098 Tamoxifen have saved consumers and taxpayers billions of
2099 dollars. Looking back, do you believe such settlements were
2100 anticompetitive merely because they contained some type of
2101 settlement or reverse payment as you call it?

2102 Mr. {Rosch.} Do I think that Tamoxifen and--

2103 Mr. {Scalise.} Well, do you feel that those settlements
2104 were anticompetitive? They were legal. They would be
2105 illegal under this bill, yet they did save consumers billions
2106 of dollars. So how do you justify trying to take away that
2107 ability to save consumers billions of dollars, as has been
2108 the case in past settlements?

2109 Mr. {Rosch.} We certainly thought Tamoifen was a bad
2110 settlement. We thought that was an anticompetitive
2111 settlement, and we saw nothing, no data whatever, that would

2112 suggest to us that it could save consumers billions of
2113 dollars.

2114 Mr. {Scalise.} Mr. Whitehouse--I know I am running out
2115 of time--experts have testified that collateral agreements,
2116 side business deals like these licenses or co-promotion
2117 agreements on products unrelated to the patented product in
2118 dispute can help the litigants in the patent suit bridge the
2119 gap and reach a settlement on patent litigation. Have you
2120 experienced that? You have taken some of these cases before.

2121 Mr. {Whitehouse.} Yes, absolutely. That is crucial to
2122 the point that we have made in our testimony is that the
2123 ability to reach these settlements and bring these products
2124 to market sooner in cases that we must not forget we could
2125 have lost. I mean everybody sort of assumes if we didn't
2126 settle, we would have won. It is very important to remember
2127 that something else could have happened. We could have lost,
2128 and the consumers would not have any benefit until the
2129 expiration of the patent. And so the opportunity to come up
2130 with these alternative or additional terms that enable the
2131 parties to bridge their different perceptions of the case
2132 bring about a settlement that on average and typically will
2133 bring these products to market sooner to the benefit of
2134 consumers.

2135 Mr. {Scalise.} I see I am out of time. I yield back.

2136 Mr. {Rush.} Chair now recognizes Dr. Gingrey for 5
2137 minutes.

2138 Mr. {Gingrey.} Mr. Chairman, thank you very much, and
2139 direct my question to Commissioner Rosch. Commissioner
2140 Rosch, I think you have been very forthright in your response
2141 to the questions throughout the hearing. Having said that, I
2142 guess you are anticipating I am fixing to blast you.

2143 Mr. {Rosch.} Yeah.

2144 Mr. {Gingrey.} Not really but--

2145 Mr. {Rosch.} I call it piling on.

2146 Mr. {Gingrey.} Yeah.

2147 Mr. {Rosch.} That is fine.

2148 Mr. {Gingrey.} But in a number of ways, I do find your
2149 testimony to be counterintuitive. You say that the reverse
2150 payment settlements negatively impact consumers by delaying
2151 entry of generic drugs to the market. Based on the testimony
2152 of the other witnesses, many times these reverse payment
2153 settlements, they actually allow the patent holding company
2154 and the generic company to negotiate terms by which the
2155 generic can begin being marketed before the expiration of the
2156 patent. Presumably because of the unique nature of patent
2157 law in this area, the settlements actually help consumers, it
2158 would seem to me.

2159 But what then is anticompetitive or anti-consumer about

2160 this kind of settlement? And before you respond to that, a
2161 quick second. I think it was Mr. Radanovich that was asking
2162 you about the question about side deals, and you may have
2163 talked about other consideration in a settlement not
2164 including reverse payments.

2165 Mr. {Rosch.} Payment of dollars, correct.

2166 Mr. {Gingrey.} Yeah, but this bill, as I understand it,
2167 would prohibit any of that, not just dollar payments, reverse
2168 payments, but any other side deals. So if this bill passes,
2169 then what incentive would the brand name company have to
2170 settle? Certainly it would appear none whatsoever to
2171 negotiate with the generics. So two questions, and go ahead.

2172 Mr. {Rosch.} Okay, I think you are correct about the
2173 bill. As I read it, it would indeed go to side deals as well
2174 as to direct payments of money. As I said before, that
2175 doesn't really trouble me because our staff has taken a look
2176 at these agreements, including side deals, and they have
2177 concluded that, except in a very small number of instances,
2178 those side deals are anti-consumer and they are
2179 anticompetitive.

2180 And incidentally, Congressman, there is nothing at all
2181 unique about banning this kind of deal within the context of
2182 a settlement. The United States Supreme Court said that an
2183 anticompetitive aspect of a settlement agreement could be

2184 struck down as per se illegal many, many years ago in the
2185 Singer case. So this is not brand new.

2186 But let me get to sort of the first part of your
2187 question. Why, I ask myself, if indeed the effect of a
2188 reverse payment settlement would be to stifle entry, early
2189 entry, to delay early entry, why are these deals occurring?
2190 We are seeing them. Why is the brand willing to pay, as I
2191 say, millions of dollars in these settlements? And I would
2192 suggest to you that the reason is to delay entry because the
2193 brand is enjoying patent monopoly profits and prices. It is
2194 kind of as simple as that.

2195 Now, should we be litigating these cases on a case-by-
2196 case basis? I would suggest to you that we should not.
2197 There is already in the bill sort of a safety net if you will
2198 in our rulemaking authority. If we find that some of these
2199 deals shouldn't--that we shouldn't be challenging them on a
2200 case-by-case basis, we can carve those out as a safe harbor.

2201 Mr. {Gingrey.} Commissioner, reclaim my time, and I am
2202 down to 45 seconds because this is going to segue--

2203 Mr. {Rosch.} I didn't mean to--

2204 Mr. {Gingrey.} No, I appreciate your response. Segue
2205 into my question that I wanted to ask Ms. Bieri and Mr.
2206 Whitehouse. As representatives of PhRMA and the generic drug
2207 companies respectively, you know through practical

2208 implementation that both the FTC and the Department of
2209 Justice already had the ability to challenge any settlements
2210 that--and I think that is what the commissioner was about to
2211 say--that are anticompetitive and thus harm consumers.

2212 If the blanket ban on settlements, and H.R. 1706 is
2213 implemented, what incentive do your respective industries
2214 have to settle patent litigation out of court? And how would
2215 that affect consumers?

2216 Ms. {Bieri.} Thank you. I will begin by saying that I
2217 think because litigation is risky and expensive, I think
2218 there would still be incentives for companies to try to
2219 settle patent litigation even if H.R. 1706 were to pass.
2220 Unfortunately the options for them to do so are what would be
2221 very limited. And so you would be left in a situation where
2222 the brand and the generic company would be only able to
2223 negotiate over the date of entry for the generic.

2224 This is the heart of the patent dispute and obviously
2225 the parties are going to have very different views on that
2226 point. And so in many of these cases we think it would
2227 unable to reach an agreement, and the case would then have to
2228 proceed to litigation. And recent statistics show that in
2229 most of those cases, at least the majority, the brand company
2230 would ultimately be able to defend its patents. And so
2231 generic entry would be delayed.

2232 Mr. {Gingrey.} And, Mr. Whitehouse--Mr. Chairman, if
2233 you would bear with me, if Mr. Whitehouse can respond to that
2234 question as well.

2235 Mr. {Whitehouse.} Yes, Congressman. And the important
2236 point to focus upon here is that if you make it harder to
2237 settle, you are going to reduce the incentive to bring these
2238 cases in the first place. And the whole point of Hatch-
2239 Waxman was to precipitate litigation over doubtful patents
2240 and bring generic products to market sooner, if you diminish
2241 in any way the incentive in the generic companies to initiate
2242 those litigations, which is an inevitable consequence of
2243 making it harder to settle them, that is inherently anti-
2244 consumer and undesirable. And that is why we are opposed to
2245 this mechanism.

2246 Mr. {Rush.} The chair initially offered that we would
2247 go into a second round of questioning, but there is a vote on
2248 the floor, and in light of this fact, the chair wants to call
2249 this subcommittee hearing to an adjournment. But before he
2250 does that, he wants to make sure that the witnesses recognize
2251 the fact that we are indebted to you so deeply because of
2252 your--the investment of your time into this matter. You have
2253 really shed some tremendous light on this issue, and we will
2254 be referring to your statements more so in time for the
2255 duration of this legislative process on this particular

2256 matter.

2257 I just want to also alert you that we ask that you
2258 should be prepared to receive and respond to written
2259 questions submitted by members of the subcommittee, and I
2260 want for the record to remain open for 10 days to receive
2261 additional statements.

2262 And the final matter is that the ranking member of the
2263 subcommittee, Mr. Radanovich, has an opening statement that
2264 he wants to place into the record, and with hearing no
2265 objection, it is so ordered.

2266 [The prepared statement of Mr. Radanovich follows:]

2267 ***** COMMITTEE INSERT *****

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2268 Mr. {Rush.} This subcommittee is now adjourned. Thank
2269 you very much.
2270 [Whereupon, at 1:20 p.m., the subcommittee was
2271 adjourned.]