RUTGERS Law School

Rutgers, The State University of New Jersey
217 N. Fifth Street
Camden, NJ 08102-1203

Michael A. Carrier
Distinguished Professor

mcarrier@law.rutgers.edu
(856) 225-6380

Michael A. Carrier
Response to Representative Pallone's Questions for the Record

House Committee on Energy and Commerce, Subcommittee on Health
Hearing on "Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs"

August 10, 2021

I. Frequency of agreements and necessity of H.R. 153

A. Since Supreme Court's *FTC v. Actavis* decision in 2013, there have been fewer pay-for-delay settlements
   1. Number of settlements with compensation higher than litigation fees has declined from 33 in FY2012 to 3 in FY2017 (most recent data available)
   2. But they still happen, as shown in most recent FTC report by not only 3 pay-for-delay settlements but also 8 settlements that contain "possible compensation" because of the increasing complexity of arrangements
      a) Example: brand firm's commitment not to use third party to distribute authorized generic can resemble an anticompetitive "no-authorized-generic" agreement if brand doesn't market generics in U.S.
      b) Example: declining royalty structure, in which generic's obligation to pay royalties is reduced or eliminated if brand launches authorized generic, can achieve same effect as no-authorized-generic agreement

B. H.R. 153 has two primary benefits:

C. Benefit 1: Makes clear that pay-for-delay settlements are anticompetitive and helps FTC prove cases in court
   1. Payments have migrated from cash to compensation hidden in increasingly obscure corners
   2. Treating pay-for-delay settlements as anticompetitive will deter blatantly illegal conduct that courts do not always recognize and that bogs down the FTC for years in resource-intensive litigation
      a) *E.g.*: The FTC's *Actavis* litigation, which did not even involve a trial, took *10 years* to settle.[1]

D. Benefit 2: Legislation addresses judicial errors relating to payment, the "scope of the patent," and risk aversion. For example:
   1. *AbbVie* district court: Brand provided generic with drug at price "well below what is customary" but court (despite recognizing deal's "large value") concluded that it "was not a reverse payment."[2]
   2. *AbbVie* district court and Administrative Law Judge in *Impax*: Assumed entry before patent expiration procompetitive (despite Supreme Court's overturning of scope-of-patent test).[3]
   3. *Wellbutrin*: Relied on risk aversion defense (rejected by Supreme Court) to dismiss argument that payment size reflects patent weakness.[4]

II. Pay-for-delay legislation would not slow generics/biosimilars

A. The settling parties' claims that pay-for-delay legislation would slow generics/biosimilars and that pay-for-delay settlements lead to earlier entry are both 100% wrong.
   1. For starters, it's worth noting that unlike other anticompetitive pharmaceutical conduct, settling generics are in the same position as brand firms in benefitting from pay-for-delay settlements.[5]

B. Non-pay-for-delay settlements can *speed* entry; pay-for-delay settlements delay entry
   1. Non-pay-for-delay settlements exclude generics based only on the strength of the patent
   2. Pay-for-delay settlements exclude generics *beyond* what the patent strength would provide based on payment

C. After the *Actavis* decision, the number of total settlements significantly increased from 140 (FY2012) to 226 (FY2017)
   1. In other words, the parties are still able to settle, but they do so legally, without payment

---

[1] FTC, *Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company "Reverse Payments,"* Feb. 28, 2019.

[2] *FTC v. AbbVie*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015), *rev'd*, 976 F.3d 327 (3d Cir. 2020).

[3] *In the Matter of Impax Labs.*, Dkt. No. 9373, at 144, 146 (FTC ALJ Chappell May 18, 2018).

[4] *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017). For a discussion of additional errors in settlement cases, see Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 SANTA CLARA L. REV. 613 (2020).

[5] See Michael A. Carrier, *Pay-for-Delay: Who Does the Generic Industry Lobby Represent?*, CPI ANTITRUST CHRONICLE, at 2 (May 2020) (concluding that generics industry lobby, "in defending . . . blatantly anticompetitive" settlements, "does not represent the public interest").

III. Ending pay-for-delay settlements would help consumers

A. Ending pay-for-delay settlements would *speed* generics' entry to the market while encouraging *legal* settlements
B. Patients harmed from collusion, not innovation
   1. The FTC has calculated that pay-for-delay settlements cost consumers $3.5 billion a year.[6]
   2. Generics agree to delay entry in return for dropping their patent challenge
      a) But most (89%) of the patents at issue in settlements are secondary patents on which the brand firm is less likely to win (32%), as compared to active-ingredient (92%) patents.[7]
      b) Examples of settlements on secondary patents: Actos, AndroGel, Cephalon, Effexor, K-Dur, Lidoderm, Loestrin, Niaspan, Opana, Solodyn, Wellbutrin
   3. Consumers unable to afford high prices cut pills in half, choose between paying for drugs and food/rent, and do not take needed medicines
C. Legislation would help the FTC prove cases in court and address judicial errors relating to payment, the "scope of the patent," and risk aversion
D. When the settling parties (not only brands but also generics) claim that the sky would fall from H.R. 153, consider their incentives: the brand extends its monopoly and the generic is paid not to enter!
E. Narrowly-targeted H.R. 153 would not harm innovation while speeding generic entry and making consumers' lives better.

[6] FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (2010).

[7] C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013).

RUTGERS

Michael A. Carrier
Response to Representative Kelly's Questions for the Record

House Committee on Energy and Commerce, Subcommittee on Health
Hearing on "Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs"

August 10, 2021

I. Affordable drugs

A. Other countries have different reimbursement regimes by which manufacturers need to show drug safer, more effective, or more affordable to be covered on drug formularies
   1. Just to pick one example, Germany relies on "a scientifically focused but politically accountable entity that conducts health technology assessments for each new drug."[1]
   2. In contrast, in U.S., pharmacy benefit mangers (PBMs) play critical role, and one of the central criteria they use in putting drugs on formularies is the size of the rebates they receive from manufacturers.[2]

II. Additional funds not for R&D

A. Extra profits brand drug firms take from customers often not invested in R&D
B. Instead, they're used for stock buybacks and dividends, and to provide significant compensation to top executives
   1. The House Committee on Oversight and Reform found that, from 2016 to 2020, "the 14 leading drug companies spent $577 billion on stock buybacks and dividends--$56 billion more than they spent on R&D."[3]
      a) Amgen, for example, "spent nearly six times as much on buybacks, dividends, and executive compensation as it did on R&D in 2018."[4]
      b) Of the 14 companies the Committee studied, "the eight U.S.-based drug companies spent a greater proportion of their expenditures on buybacks and dividends as compared to their foreign peers."[5]
   2. From 2016 to 2020, "compensation for the 14 companies' top executives totaled $3.2 billion."[6]
      a) The Committee found that "price increases on certain brand-name drugs led directly to higher bonuses for executives."[7]
C. In fact, innovation typically comes from small firms
   1. Research examining the highest-selling prescription medicines of Pfizer and Johnson & Johnson found that the companies "did not actually invent most of the drugs they sell."[8]
      a) Based on 2017 annual reports, "[t]he discovery and early development work were conducted in house for just 10 of Pfizer's 44 products (23%)" and for "[o]nly two of J&J's 18 leading products (11%)."
      b) In contrast, "[t]he majority (81%) of other products were discovered and initially developed by third parties."[9]
D. One study found that firms that enter into pay-for-delay settlements "face dampened incentives to innovate"; in contrast, the application of antitrust law "may increase [the firms'] innovation incentives."[10]

---

[1] James C. Robinson, Patricia Ex, & Dimitra Panteli, *Drug Price Moderation in Germany: Lessons for U.S. Reform Efforts*, COMMONWEALTH FUND, Jan. 23, 2020, https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/drug-price-moderation-germany-lessons-us-reform-efforts.

[2] *E.g.*, Brent Eberle, *How to achieve a drug formulary that reduces costs and maintains access to care*, BENEFITSPRO, Mar. 22, 2021, https://www.benefitspro.com/2021/03/22/how-to-achieve-a-drug-formulary-that-reduces-costs-and-maintains-access-to-care/?slreturn=20210710190052.

[3] House Committee on Oversight and Reform, Drug Pricing Investigation: Industry Spending on Buybacks, Dividends, and Executive Compensation, at 1 (July 2021), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf.

[4] *Id.* at 2.

[5] *Id.* at 5-6.

[6] *Id.*

[7] *Id.* at 8.

[8] Emily H. Jung, Alfred Engelberg, & Aaron S. Kesselheim, *Do large pharma companies provide drug development innovation? Our analysis says no*, STAT, Dec. 10, 2019, https://www.statnews.com/2019/12/10/large-pharma-companies-provide-little-new-drug-development-innovation/.

[9] *Id.*

[10] Xuelin Li, Andrew W. Lo, & Richard T. Thakor, Paying off the Competition: Market Power and Innovation Incentives, NBER Working Paper No. 28964, at 37, June 2021, https://www.nber.org/system/files/working_papers/w28964/w28964.pdf