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Response to Questions for the Record
Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Health Markets

**Question from Ranking Member Collins**

*Question: Post Actavis there has been a precipitous decline in the number of settlements that the Federal Trade Commission has raised anti-competitive concerns with. Based on this, what would be the comparative advantages of letting the judicial system continue to deal with the residual element of the problem, as opposed to legislating restrictions on freedom of contract and the ability of litigants to manage litigation between them?*

This is an important question. In thinking about the trade-off between passing legislation or relying on the status quo, two key principles stand out. First, pay-for-delay deals are very profitable, so there is a natural and strong incentive for the settling parties to find loopholes or exploit complications to reach such deals. Second, there is little evidence that bright-line rules would limit the litigants' flexibility to settle.

Although the Supreme Court's decision in *FTC v. Actavis* has had an impact in deterring anticompetitive pay-for-delay patent settlements, failing to legislate raises significant risks of consumer harm and unnecessarily requires the FTC to expend resources. In contrast, passing narrowly tailored legislation, such as the Preserve Access to Affordable Generic and Biosimilars Act eliminates this risk without imposing more than a negligible burden on the litigating parties.

Congress previously faced this choice in 2004. Congress considered addressing the issue of reverse-payment patent settlements through legislation in the Medicare Modernization Act, or MMA. At the time, industry argued that the practice had stopped, which it had, and that the antitrust laws were sufficient, so all Congress needed to do was require parties to file the agreements with the Federal Trade Commission. Congress followed this approach.

That approach failed. A few weeks after the MMA was enacted, the 11th Circuit issued its decision in *Valley Drug Company v. Geneva Pharmaceutical, Inc.* beginning the trend toward the scope of the patent test (adopted and expanded by *FTC v. Schering*, *In re Tamoxifen*, and *In re Ciprofloxacin*, and the Eleventh Circuit's decision in *FTC v. Actavis)*, which made pay-for-delay agreements per se legal as long as generic entry occurred by the expiration of the patent, the patent litigation was a sham, or the patent was obtained by fraud. The lenient legal rule altered industry behavior dramatically as the number of potential pay-for-delay deals increased from zero in 2004 to 40 in 2012 (see Figure 1 below).

Although the Supreme Court's decision in *FTC v. Actavis* has dramatically reduced the number of agreements so far, there are three risks in not legislating. First, it is unclear how the case law would apply to biologics. Because, as of yet, no follow-on biologics are interchangeable with their branded counterparts, proof of market power may be more difficult to discern even though pay-for-delay agreements in the biologic sphere, because of the cost of the drugs, could dramatically increase prescription drug costs.

Second, at least one court has already significantly undermined the *Actavis* decision. The Third Circuit in *In re Wellbutrin Xl Antitrust Litig. Indirect Purchaser Class* suggests that if the patent holder is risk averse or thinks the generic has overestimated its chances, then there is no inference to be drawn from the payment. 863 F.3d 132, 168 (3rd Cir. 2017).

Third, companies have shown creativity in hiding payments through the use of a side deal. For example, a generic company agrees to delay its entry. Instead of simply paying the generic company, the branded company licenses the rights to a product in development. Because the value of such assets is difficult to determine, it is easy for the branded company to over pay and hard for a court or the Federal Trade Commission to determine the value of the overpayment. *See* C. Scott Hemphill, "An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Competition," 109 Colum. L. Rev. 629, 663-670 (2009).

At the same time, limiting the use of payments in pharmaceutical patent settlements will not limit the parties' flexibility to settle litigation. The number of patent settlements without payments reached record highs in each of the first two fiscal years after the *Actavis* decision. See Federal Trade Commission Staff, "Overview of Agreements Filed in Fiscal Year 2015: A Report By the Bureau of Competition," at 4 ("FTC 2015 Report) https://www.ftc.gov/news-events/press-releases/2017/11/ftc-staff-issues-fy-2015-report-branded-drug-firms-patent

The Preserve Access to Affordable Generics and Biosimilars Act addresses all three risks. It explicitly applies to settlements involving biological products. It eliminates the danger of courts intentionally or unintentionally adopting interpretations that weaken the law. Finally, by requiring defendants to establish their justification by clear and convincing evidence, the bill strongly discourages attempts to find a loophole or hide a payment.

At the same time, the bill provides significant flexibility to parties settling litigation. It clearly identifies the types of competition, including a de minimis payment for saved litigation expenses, that do not trigger the bill's presumption. The bill also allows companies to rebut the presumption if they have a clear justification. Past history underscores the flexibility the bill would provide. In fiscal years 2014 and 2015, only 19 of the 330 pharmaceutical patent settlements could have triggered the presumption. FTC 2015 Report at 4.[1]

[1] This reflects the total of potential pay for delay settlements that exceeded attorneys' fees, which would be exempted under the proposed legislation.

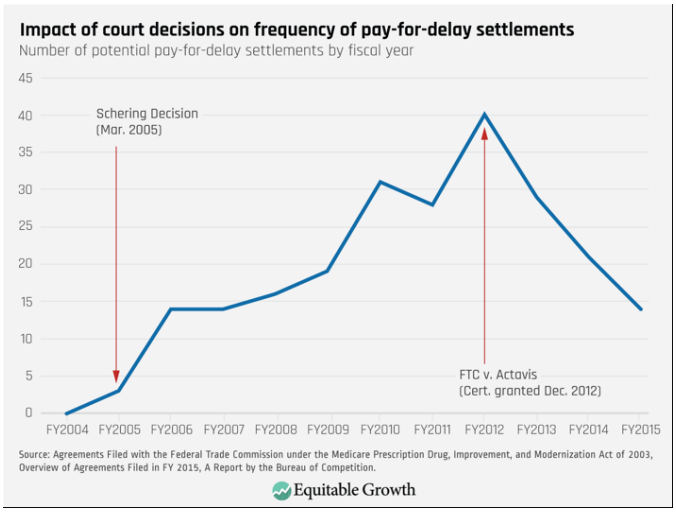


*Figure 1*

## Question from Chairman Cicilline

*Christine Varney, the former Assistant Attorney General of the Antitrust Division, previously testified in 2009 that "the McCarran-Ferguson Act antitrust exemption is very expansive with regard to anything that can be said to fall within the business of insurance, including premium pricing and market allocations. As a result, the most egregiously anticompetitive claims, such as naked agreements fixing price or reducing coverage, are virtually always found immune."*

*Do you agree that when health insurance companies engage in bid rigging, price fixing, or market allocation their conduct should not be exempt from the antitrust statutes?*

Yes. There is no reason to immunize insurers from nakedly anticompetitive activity such as bid-rigging price fixing, or market allocation. Such conduct will increase prices and reduce quality. Whatever justification may have existed for the McCarran-Ferguson Act, the act is an artifact and no longer necessary. As then Assistant Attorney for Antitrust Varney explained, antitrust law is sufficiently flexible to allow procompetitive conduct. See Statement of Christine Varney, Assistant Attorney General Antitrust Division, U.S. Department of Justice Before the Committee on the Judiciary, United States Senate, "Prohibiting Price Fixing and Other Anticompetitive Conduct in the Health Insurance Industry (October 14 2009) at 4 https://www.justice.gov/archive/atr/public/testimony/250917.pdf.

Further, the McCarran-Ferguson Act may unintentionally protect anticompetitive conduct that increases the cost of insurance. Multiple studies support limiting or eliminating this exemption, including a 1977 Justice Department study, a 1979 National Commission for the Review of Antitrust and Procedures, a 1989 American Bar Association Commission to Improve Liability Insurance System report, and the 2007 Antitrust Modernization Commission report.[2]

[2] *Id.* At 2.

## Questions from Representative Buck

*Background: When Congress passed the Biologics Price Competition and Innovation Act (BPCIA), it was intended to increase competition in the biologic market by creating a pathway for approval for interchangeable biologics and biosimilars. Unfortunately, while FDA has now approved 17 biosimilars, only 7 of them are on the market. The others remain tied up in patent disputes between the brand and biosimilar manufacturers. These patent disputes occur even when the brand's exclusivity period has long since expired.*

*Question: FDA has now approved 17 biosimilars, but most of them aren't on the market due to patent disputes. Why?*

This is an important question as there are concerns that some companies may be abusing the patent system by creating patent thickets. To be clear, patents and intellectual property rights play an important role in drug development. When products infringe patents, then patent holders have every right to assert their patents and protect their inventions.

But patent thickets are an abuse of the system that inappropriately delays biosimilar competition. Professor Carl Shapiro defines patent thickets as "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology." The shear number of patents, regardless of each patent's strength, can deter competition, or the time of litigating on all of the patents in the thicket can delay competition. Former Food and Drug Commissioner Scott Gottlieb pointed to thickets and the litigation they spawn as the cause of "anemic" biosimilar competition: "It's anemic because litigation has delayed market access for biosimilar products that are, or shortly will be, available in markets outside the U.S. several years before they'll be available to patients here."[3] Congress should examine whether abuse of the patent system by some companies is stifling biosimilar competition.

[3] Scott Gottlieb, Remarks as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilar Action Plan," (July 18, 2018, available at, https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas

**Questions to the Panel on PBMs**

*Three Performance Benefit Mangers (PBMs) control 80% of the PBM market. In theory, this should give them leverage to negotiate lower drug prices. But my understanding is that PBM's profits are at least partially tied to the manufacturer's list price.*

- *Doesn't that actually create an incentive for PBMs to see prices increase?*

*One of the three PBMs, OptumRx, recently told drug companies they couldn't lower prices unless they gave almost two years notice and paid the PBM the same amount of money, despite the lower price. (https://www.beckershospitalreview.com/pharmacy/optumrx-sets-demands-for-drugmaker-price-reductions.html)*

- *Why would a drug manufacturer ever lower its price if a PBM is just going to take more of its profit?*

Both of these questions emphasize the importance of the Prescription Pricing for the People Act of 2019. The answer to both questions depends on whether PBMs have market power. If a PBM has market power, then it could exploit that power by negotiation higher list prices to increase its commission. And there would be little reason for a branded drug manufacturer to lower its list price and pay the PBM the same amount.

In contrast, if the PBM faces competition, then if it seeks higher prices to increase its revenue it will lose business to other PBMs that provide a better value to insurers. And in a competitive market, a drug manufacturer could lower its list price and still pay the PBM the same amount if the PBM is able to increase the volume of sales on the drug.

The Prescription Pricing for the People Act of 2019 requires the Federal Trade Commission to study the PBM market and assess how competitive it is. Its report should help understand whether there is a competition problem in the PBM industry and, if so, how significant that problem is.