

Pay-For-Delay



Health Policy Brief |

Policy solutions must address both generics and biosimilars and contemplate newer generations of “pay-for-delay” settlements that may not involve direct payments.

THE ISSUE

Branded drug manufacturers are able to block generic competition using patent settlements that keep lower-cost alternatives off the market. These “pay-for-delay” patent settlements use a variety of tactics to block generic drug competition and can be very difficult for the Federal Trade Commission (FTC) to prosecute. Even if fines and enforcement actions are taken by the FTC, the sales from extra weeks or months of monopoly power are highly profitable, which incentivizes brand manufacturers to pursue these settlement agreements.

\$300M

What drug manufacturer Teva paid to four potential competitors to delay generic competition for its narcolepsy drug Provigil

50%

The rate at which the number of settlements between brand-name and generic companies increased between 2010 and 2015

80%

Discounts generated from Humira’s biosimilar in Europe, which will not be available in the US until 2023 because of “pay for delay” settlements

THE EVIDENCE

In order to delay generic competition for its narcolepsy drug Provigil, Teva paid roughly \$300 million to four potential competitors. Although Teva paid \$1.2 billion in fines and an additional \$500 million to settle a class action lawsuit resulting from the deal, the settlement agreement enabled it to generate an additional \$4 billion in sales.¹

Newer generations of “pay-for-delay” settlements are increasingly complex to examine and regulate. The FTC noted that an increasing number of settlements are completed without direct payments.² However, the number of settlements between brand-name and generic companies increased by roughly 50 percent between 2010 and 2015 and the majority resulted in generic entry delay.^{3,4}

“Pay-for-delay” is prevalent in the lucrative biologics market, due in part to the complex patent thickets surrounding most blockbuster biologic products.⁵ Patent thickets consist of patents for the active ingredient in addition to secondary patents on manufacturing processes, methods of use, delivery devices, and other aspects of a product. Because of the uncertainty and litigation cost for biosimilar manufacturers to challenge each patent, some opt to settle with the originator manufacturers instead. For example, AbbVie has secured patent settlements from biosimilar manufacturers that stop market entry for approved Humira biosimilars in the US until 2023. Its agreements actually have biosimilar manufacturers paying royalties to AbbVie once their biosimilar products launch in the United States.⁶ Biosimilar versions of Humira are currently available in Europe with nearly 80% discounts being seen in early experience.

THE SOLUTIONS

A bipartisan bill, *Preserve Access to Affordable Generics and Biosimilars Act* (H.R. 2375), would limit anticompetitive agreements that prevent or delay the introduction of lower cost generic or biosimilar products.⁷ Notably, the act would require that manufacturers prove an agreement is not anticompetitive rather than asking the FTC to prove an agreement is anticompetitive. A version of the bill has been introduced in every Congress since 2005.⁸ CBO found the bill would reduce federal budget deficits by over \$613 million over 10 years.⁹

In the FY2020 budget, the Administration proposed to cut the payment rate in Medicare Part B for a product that has entered into a pay-for-delay agreement until a competitor is available.

Any policy solution for this issue must address both generics and biosimilars and attempt to contemplate newer generations of “pay-for-delay” settlements that may not involve direct payments. Additionally, the penalties must be sufficiently strong so that this behavior is discouraged in the future.

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- ¹ Robin Feldman & Evan Frondorf, *Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market* (Cambridge 2017).
- ² See Fed. Trade Comm'n, *Overview of Agreements Filed in FY 2015: A Report by the Bureau of Competition 1* (2017) (noting the continuing decline in the number of "potential" pay-for-delay settlements despite an increasing number of total settlements, and explaining the lowest ratio of potential pay-for-delay settlements relative to total final settlements since FY 2004).
- ³ Robin Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay* (forthcoming CHICAGO-KENT J. OF IP).
- ⁴ *Supra* note 3.
- ⁵ <http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>
- ⁶ <https://insidehealthpolicy.com/daily-news/abbvie-reaches-deal-pfizer-delay-seventh-humira-biosimilar>
- ⁷ <https://www.congress.gov/116/bills/hr2375/BILLS-116hr2375ih.pdf>
- ⁸ <https://www.congress.gov/search?q=%7B%22source%22%3A%22legislation%22%2C%22search%22%3A%22%5C%22Preserve%20Access%20to%20Affordable%20Generics%20Act%5C%22%22%7D&searchResultViewType=expanded>
- ⁹ <https://www.cbo.gov/system/files/2019-05/hr2375.pdf>