Check the Facts on "Pay-for-Delay" Legislation

FACT CHECK: In 2013, the Supreme Court prohibited "pay-for-delay" deals and the Federal Trade Commission reviews all deals to ensure compliance.

- In 2013, the Supreme Court decided in FTC vs. Actavis that large, unexplained reverse payments between brand-name drug companies and generic manufacturers "bring with it the risk of significant anticompetitive effects."[1]
- As a result, the number of so-called "pay-for-delay" deals with large, unexplained reverse payments declined significantly in the years following the *Actavis* decision.
- In its latest report, the FTC identified **only 5 settlement agreements** as potentially involving "pay-for-delay."[2] And the FTC **currently** has the authority to challenge these agreements as anti-competitive.

FACT CHECK: The Federal Trade Commission reviews more than 140 agreements every year, and it has found that the vast majority do not delay generic competition.

- In 2003, Congress required any patent settlement agreement between brand-name pharmaceutical companies and generic manufacturers to be filed with the FTC within 10 days of such an agreement. In 2018, Congress expanded the requirement to include agreements for branded biologics and biosimilars.
- The FTC, as established in the Federal Trade Commission Act of 1914 and as provided for in its annual appropriation, is empowered to "prevent unfair methods of competition" and to "conduct investigations."
- With the ability to review the text of all settlement agreements and the authority to pursue legal action, FTC is already well-positioned to stop any "pay-for-delay" agreements.
- And the FTC's own data shows the success of the Commission's work. Following the *Actavis* decision, there's been a dramatic decline in the number of potential "pay-for-delay" deals.

FACT CHECK: "Pay-for-delay" legislation turns back the clock and would make many patent settlements unlawful all the way back to 2013. This would deprive patients of generic drugs they count on now and delay access for future generics and biosimilars.

- The Supreme Court, with Justice Stephen Breyer delivering the 5-3 majority opinion, "decline[d] to hold that

1 U.S. Supreme Court, FTC v. Actavis Opinion, June 17, 2013, available at https://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf.

2 Federal Trade Commission, "Overview of Agreements Filed in FY2015," November 1, 2017, available at https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/overview_of_fy_2015_mma_agreements_0.pdf

reverse payment settlement agreements are presumptively unlawful."[3]

- "Pay-for-delay" legislation, however, **overturns** the Supreme Court's decision in *Actavis* and makes virtually all settlement agreements – not just the ones with alleged reverse payments – unlawful.
- Moreover, consistent with the *Actavis* decision, aprivate parties reached agreements over the last five years. Retroactively imposing a higher legal standard amounts to unfairly changing the rules after the fact.
- "Pay-for-delay" proposals should be amended to only impact agreements going forward and to be consistent with the Supreme Court's *Actavis* decision.

FACT CHECK: The vast majority of agreements (92 percent) *accelerate* patient access to more affordable medicine.

- Since the Supreme Court's decision in *Actavis*, the FTC has noted the significant decline in the number of patent settlement agreements potentially involving "pay-for-delay."
- The most recent FTC data shows "the vast majority (at least approx. 86% and up to approx. 92%) of patent disputes filed were resolved without compensation to the generic manufacturer and/or without restrictions on generic competition."[4]
- These patent settlement agreements reduce the barriers to competition that would otherwise exist if not for the agreement and provide a date certain for generic and biosimilar entry.
- Patients benefit with earlier access to more affordable medicine as a result.

FACT CHECK: "Pay-for-delay" legislation will delay patient access to more affordable medicine and force patients to continue to pay the high price of brand-name drugs.

- "Pay-for-delay" proposals presume that almost all patent settlement agreements are unlawful or anti-competitive unless demonstrated otherwise.
- As the Supreme Court noted in the *Actavis* opinion, "We recognize the value of settlements and the patent litigation problem" and later, "These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases."[5]
- Changing the legal standard would have a chilling effect on the ability of two private parties to reach an agreement that clears the patent thickets and provides a date certain for competition.
- Generic and biosimilar manufacturers would be more likely to wait until all patents are expired, rather than incur the costs and risks associated with challenging patents.
- Without addressing abuse of the patent system, patient access to more affordable medicine will thus be delayed.

3 Ibid., FTC v. Actavis.
4 Ibid., FTC Annual Report.
5 Ibid., FTC v. Actavis.

FACT CHECK: "Pay-for-delay" legislation could delay biosimilar competition on Humira® – the top-selling drug in the U.S. – by 11 years, forcing patients to wait for more affordable alternatives until 2034.

- Abuse of the patent system is perhaps the greatest barrier to competition.
- Brand-name pharmaceutical companies build patent "estates" around blockbuster drugs. Look no further than Humira.
- Approved in 2002, 132 late-stage patents were filed to delay competition until 2034.
- Seven biosimilar manufacturers challenged the validity of Humira's patent estate and used settlement agreements to clear the way for competition starting in 2023.
- Under the proposed "pay-for-delay" legislation, those settlements would be considered unlawful and patient access to more affordable alternatives could be delayed until all patents expire in 2034.

FACT CHECK: AAM supports modifying "pay-for-delay" legislation to preserve the Supreme Court's *Actavis* decision and provide for substantial consumer cost-savings through timely generic entry.

- Policymakers could strengthen current law and the ability of the FTC to review patent settlement agreements by codifying the Supreme Court's *Actavis* decision into law.
- AAM does not support patent settlement agreements with large unexplained reverse payments, or "pay-for-delay" deals.
- Preserving the ability of two private parties to resolve pending litigation that ensures timely patient access to more affordable medicine is critical.
- Unfortunately, as currently drafted, "pay-for-delay" legislation upends current practice and would result in patients paying the high price of brand-name drugs for longer.