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."
- 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 noted that the number of settlements that include the types of "reverse payments likely to be anticompetitive ***remain very low***." And the FTC ***currently*** has the full authority to challenge these agreements as anti-competitive.

FACT CHECK: The Federal Trade Commission reviews more than 200 agreements every year, and it has found that the vast majority are lawful and appropriate.

- 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 alleged "pay-for-delay" deals.

FACT CHECK: The vast majority of agreements (98 percent) do not involve any "compensation."

- 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 that only 3 settlements out of 226 involved alleged compensation other than litigation fees to the generic company.
- 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: Patent Settlement Legislation is Unconstitutional.

- The Supreme Court recently reemphasized the Seventh Amendment right to a jury trial in *SEC v. Jarkesy* when civil monetary penalties are being imposed in an administrative setting.
- Despite that constitutional right, patent settlement legislation proposes to impose liability based on a proceeding before an administrative law judge whose decisions are reviewed by the FTC.
- A trial judge's only role is to determine penalties; the agency's findings about liability are "conclusive."
- A jury is not present at either step of the process.
- If enacted, patent settlement legislation will likely be promptly challenged.

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."
- 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.

FACT CHECK: "Pay-for-delay" legislation would have delayed biosimilar competition on Humira® 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 later-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.
- These settlement agreements expedited patient access to lower-cost biosimilars by 11 years.

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