Increase Patient Access to More Affordable Medicines – Ensure Timely Generic & Biosimilar Competition

Generic and biosimilar medicines are proven solutions to reduce patient and taxpayer prescription drug spending. Even though they make up 9 of every 10 prescriptions in the U.S., they are only 13 percent of drug spending. New generics and biosimilars bring lower prices – often beginning at 40 percent less than the brand and going as far as 90 percent less than the brand within months of market entry.

Unfortunately, generic and biosimilar competition is often delayed by brand patent thickets designed to extend monopoly status and entangle generic/biosimilar competitors in years of patent litigation.

Congress can ensure timely generic and biosimilar market entry by:

1. Maintaining the ability of generic & biosimilar manufacturers to reach lawful patent settlements,
2. Reducing abusive "patent thickets", and
3. Protecting the "skinny label" process that has facilitated billions in savings from generics and biosimilars.

Oppose S.142, Preserve Access to Affordable Generics and Biosimilars Act

- Getting a generic or biosimilar on the market before all of the brand's patents expire generally requires litigation.
- The generic or biosimilar has to either win that litigation completely or reach a settlement.
- As a result, settlements are often the only way to bring a generic or biosimilar to market other than waiting for the patent to expire, and many settlements allow generic/biosimilar entry years before the expiration of the last patent.
- But S.142 declares settlements to be presumptively anticompetitive, ignoring settlements' role in promoting competition.
    - Companies would have no access to a judge or jury—they would have to defend themselves *before the Federal Trade Commission*, the same set of political appointees pushing to make settlements illegal and whose lawyers would be prosecuting each case.
    - The only role for federal trial judges would be in deciding the penalty for violations—the FTC's finding of a violation is "conclusive."
    - The Supreme Court has explained that the Seventh Amendment right to a jury trial prevents having administrative agency judges determine whether citizens have violated the law. S. 142 ignores that constitutional rule.
- Rather than speeding competition, S. 142 would reward brand drug patent thickets by removing a critical tool used to bring generics and biosimilars to market.
    - For instance, biosimilar versions of Humira were able to use settlements to come to market *11 years prior to patent expiry*. S. 142 would require biosimilars to prevail in court against a large number of patents, a daunting if not impossible undertaking.

Enact S.150, the Affordable Prescriptions for Patients Act and H.R. 6986, to Address Patent Thickets

- S.150 would address the problem of patent thicketing: when brand-name drug companies obtain so many patents relating to their blockbuster biological products that the density of patents, not scientific innovation, blocks biosimilar competition.
    - Even when the patents may be largely invalid or unavoidable, the sheer number of patents makes the litigation too expensive for a biosimilar company even to get started.
    - Biosimilar companies must also "run the gamut" in biosimilars litigation – they generally must win on all patents and claims or their launches may be delayed.
- S.150 creates a cap (20) on the number of patents that a brand company can assert in litigation against a biosimilar company.
- The legislation does not limit a brand company's patents on its own core innovation, exempting patents that are filed before a cutoff date (four years after that product approval by the FDA).

Protect Generic "Skinny Labels"

- A "skinny label" was one of the key innovations of the Hatch-Waxman Act: once a drug is no longer covered by a compound patent, narrow patents on *specific ways of using the drug* should not block patients from getting access to that unpatented drug for unpatented uses.
- Skinny labels mean earlier access to generic drugs and much greater savings.
- But recent court decisions have allowed brands to distort that process—after FDA approves a skinny label and the generic comes to market, to claim that the generic is "really" encouraging doctors to prescribe for the carved-out use, and so infringing the carved-out patent.
    - Because brands use this strategy after the generic launches, they can claim huge amounts of money damages and demand a jury trial.
- The PTO, HHS, and FDA all agree that the Federal Circuit has gotten it wrong.
- This legislation would provide a safe harbor when a generic company properly uses a skinny label but would not provide protection if a generic steps over the line.

To learn more about these and other ways to ensure early generic and biosimilar competition, go to accessiblemeds.org.

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