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. 1096, the 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 settle.
- 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. 1096 declares settlements to be presumptively anticompetitive, ignoring settlements' role in promoting competition. It also imposes a virtually irrebuttable presumption that will severely chill settlements.
- S. 1096 specifically contemplates that companies would have to defend themselves before the Federal Trade Commission rather than a jury as required under the Seventh Amendment in *SEC v. Jarkesy*, 144 S. Ct. 2117 (2024).
- S. 1096 would also permit FTC to unilaterally bring cases against pharmaceutical manufacturers for civil monetary penalties without consultation with DOJ despite President's recent Executive Order on independent agency authority and the separation of powers concerns that these issues raise.

Enact H.R. 3269, the Eliminating Thickets to Increase Competition (ETHIC) Act

- H.R. 3269 would address the problem of patent thicketing: when brand-name drug companies obtain so many patents relating to their blockbuster small molecule and biological products that the density of patents, not scientific innovation, blocks 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 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.

- H.R. 3269 limits brand companies to a single asserted patent per "terminally disclaimed" family. This means that brands can only assert a single patent in a family of duplicative patents that were subject to obviousness-type double patenting rejections. By limiting the assertion of duplicative patents, H.R. 3269 streamlines patent litigation and ensures the court and parties are not repetitively litigating the same issues.
- The legislation does not limit a brand company's patents on its own core innovation—brands are free to assert patents that were not subject to obviousness-type double patenting rejections and terminal disclaimers in an uncapped context.

Enact S. 43, the Skinny Labels, Big Savings Act

- 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 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 or biosimilar company properly uses a skinny label but would not provide protection if the manufacturer 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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