EXPAND PATIENT ACCESS TO LOWER-COST GENERIC MEDICINES
BY PREVENTING LAST-MINUTE BRAND LABELING CHANGES
Cosponsor H.R. 6973, Enhanced Access to Affordable Medicines Act of 2022

Background

- Labels on generic drugs are required to be the same as the referenced brand product in order for an abbreviated new drug application (ANDA) to be approved. In an effort to game the system and delay generic competition, brand pharmaceutical manufacturers often submit last minute labeling changes. The resulting **delays have cost patients and the healthcare system millions** of savings annually.
    - Between January and June 2019, FDA approved brand labeling changes within 90 days of approval of about 36 ANDAs.[1]

Advair Case Study

The first ANDA for generic Advair® faced a late-stage labeling change, which delayed approval of the ANDA. Each day that passed without approval of the ANDA **cost the healthcare system up to an estimated $8.5 million in savings.**

- When the labeling for the brand product is changed shortly prior to the approval of a generic application, approval of the generic is delayed until the generic applicant amends its ANDA with updated labeling and FDA reviews the labeling amendment. **Generic approvals can be delayed by as long as three months** as FDA assigns a three-month goal date to labeling amendments.

- In addition to delaying approval, such late-stage labeling changes by the brand can also delay when a generic company can commercially launch its product. To immediately launch a generic product upon receipt of approval, supply must be manufactured and packaged months in advance, which includes printing labeling components. If the labeling for the product changes prior to approval, a generic applicant must reprint the labeling and repack the product, or, in some cases, discard the previously manufactured product and make new product. **This product rework takes significant time and resources and further delays patient access to lower-cost generic drugs.**
    - For example, the launch of the first generic Advair was delayed by approximately 12 days after receipt of final approval to ensure its product bore the updated labeling, **ultimately costing the healthcare system up to an estimated $102 million in savings.**

- While the generic company is expected to amend its ANDA and rework or make new product that bears the updated labeling, the brand company can continue to distribute previously manufactured product that bears the previous version of the labeling because **the statute treats unapproved drugs differently from approved drugs.** Because the brand can continue to distribute already manufactured product with the previous version of the labeling, even where there are safety-related labeling changes, **there is no benefit to the public health for requiring a generic company to make the last-minute labeling changes prior to approval.**

Solution: H.R. 6973, Enhanced Access to Affordable Medicines Act of 2022

Sponsored by Rep. Buddy Carter (R-GA)

While Congress attempted to address this problem in 2010, by enacting section 505(j)(10) of the Food, Drug, and Cosmetic Act, there are gaps in implementation that allow brand labeling changes to continue to delay generic approval. H.R. 6973, Enhanced Access to Affordable Medicines Act of 2022, will close the gaps in the existing statutory provision and prevent last minute brand labeling changes from further delaying generic entry by:

- Making the section easier for FDA to use by increasing the number of labeling changes to which the provision applies.
- Conforming the timelines to the actual FDA approval process.
- Creating parity in the way brands and generics are treated after brand labeling changes are approved.

2019 GAO Study Findings Identify Last-Stage Label Changes as Barrier to Patient Access

"Opportunities exist to enhance FDA's efforts to increase the rates of approval for generic drugs in the first review cycle, including improving the consistency and clarity of reviewer comments and assessing the effects of the timing of brand-name companies' changes to labeling…The Commissioner of FDA should assess the extent to which the timing of brand-name drug companies' drug labeling changes affect the approval of generic drug applications in the first review cycle, and take steps, as appropriate, to limit the effect of brand-name drug labeling changes on pending generic drug applications[2]."

[1] Based on a review of data on Drugs@FDA.
[2] GAO Report, "FDA Should Take Additional Steps to Address Factors That May Affect Approval Rates in the First Review Cycle."