THE SKINNY ON SKINNY LABELING

A Critical Pathway For Patient Access To Generic & Biosimilar Medicines

What is "skinny labeling"?

A skinny label is a pivotal mechanism designed to support timely market entry of a generic drug or biosimilar only for an indication that is no longer protected by patents or regulatory exclusivities. The Hatch-Waxman Act of 1984 (HWA) and the Biologics Price Competition and Innovation Act of 2010 (BPCIA) created abbreviated pathways for generics and biosimilars, respectively. Generics can seek timely approval by "carving out" patented indications from their labels. This approach enables generic and biosimilar manufacturers to enhance competition and broaden patient access to essential medications across different health conditions – all without challenging or infringing patents*.

By allowing timely entry of generic and biosimilar competition, skinny labels often lead to reduced prices across the healthcare landscape. In situations where a branded medication is approved for multiple indications yet does not have exclusivity across all of them, skinny labels facilitate access to generics about 50% of the time.

Without explicit protection for carve outs, the existence of a single, indication-specific patent could completely block generic and biosimilar versions from entering the market even for the other unprotected indications.

**A patent typically claims a specific active ingredient, chemical compound, indication, formulation, or method of administration.*

Skinny label generics **decrease the cost** of a given drug across branded and generics **by 98%** on average

From 2015–2020, **15 skinny labels** alone **generated $14.6 billion** in Medicare savings

Average prices when skinny labels become available are **34% lower** compared to the year before across branded and generics

Use of generics when a skinny label is in affect **rose by 13.5%** from 2015–2020

43% of 56 new brand-name drugs with generic alternatives **contained skinny labels** from 2015–2019

67% of biosimilars had a skinny label at the time of Food and Drug Administration (FDA) approval

Skinny label medicine is at risk.

Despite the remarkable patient access and health system savings benefits of skinny labeling, legal disputes have escalated between generic and brand manufacturers – adding additional layers of complexity to the already burdensome processes for generic drug approvals and patent enforcement. In recent years, brand-name drug manufacturers have sued generic manufacturers for patent infringement despite the generic's adherence to FDA guidelines for a skinny label.

These cases, which undermine HWA, raise concerns about the implications of enforcing patents beyond their clear boundaries and set a dangerous precedent for preventing more affordable generic alternatives from entering the market with skinny labels. As such, **this precedent creates a lose-lose dynamic**.

Sources:

- *https://www.ajmc.com/view/competition-from-skinny-label-generics-saved-medicare-nearly-15b-over-5-years*
- *https://fedcircuitblog.com/other-cases/amarin-pharma-inc-v-hikma-pharmaceuticals-usa-inc*

Call to Action

To protect patient access to affordable generic medicines, Congress must uphold this long-established pathway for skinny labeling that has benefitted millions of patients over the past 40 years thanks to HWA. Additionally, Congress should safeguard future biosimilars with more explicit skinny labeling protections. Patents are important to foster innovation, but it is Congress's responsibility to ensure they continue to be enforced as intended – not manipulated to monopolize the market.

Skinny Labels, Big Savings Act

Reps. Cline, Lofgren, Kiggans, Pfluger & Suozzi

Problem

To help speed up generic competition, federal law (specifically the Hatch-Waxman Act) permits the Food and Drug Administration (FDA) to approve generic and biosimilar drugs via a "skinny label" that carves out indications protected by existing patents or regulatory exclusivities. The law is intended to provide a pathway for manufacturers to more quickly launch a generic version of a product with unpatented uses without the risk of cost-prohibitive litigation. **Multiple cases involving brand name manufacturers filing suit against generic manufacturers for skinny label indications have worked their way through the courts and Hatch-Waxman is not having the intended impact.**

Skinny labeling for biosimilars is especially important to keep generic competition for biologic drugs speedy, lowering the overall cost for patients and saving the government billions of dollars. According to a recent study, skinny label approvals for 15 brand name drugs generated nearly $15 billion in Medicare savings between 2015–2020. As a result of two Federal Circuit decisions, skinny labeling fell from 56% in 2021 to 43% in 2022 to only 20% in 2023" after the Federal Circuit decisions.

Both Henry Waxman and the government agree that the skinny label pathway must be clarified.

"Section viii cannot function as Congress intended if a generic manufacturer's anodyne descriptions of its product create a serious risk of massive patent liability. Uncertainty about the section viii pathway will deter generic manufacturers from invoking that mechanism, thereby threatening the availability of lower-cost generic drugs, in contravention of the statutory design."

Solution

The Skinny Labels, Big Savings Act would create a safe harbor for generic and biosimilar manufacturers from liability in patent infringement cases if they seek or obtain FDA approval for skinny label indications.

*This bill is supported by AARP, the Academy of Managed Care Pharmacy, AHIP, Alliance of Community Health Plans, American Consumer Institute, American Society of Health-System Pharmacists, ASCP (American Society of Consultant Pharmacists), Association for Accessible Medicines, Blue Cross Blue Shield Association, Campaign for Sustainable Rx Pricing, Consumer Action, Generation Patient, the Generics Access Project, National Alliance of Healthcare Purchaser Coalitions, National Consumers League, Patients For Affordable Drugs NOW, PCMA, Public Citizen, R Street Institute, The ERISA Industry Committee, Transparency-Rx, US*MADE, U.S. PIRG*

Association for Accessible Medicines
601 New Jersey Avenue NW, Suite 805
Washington D.C., 20001

Tel: (202) 249-7100
Email: info@accessiblemeds.org

@accessiblemeds