

Skinny Labels, Big Savings Act

Sens. Hickenlooper, Welch, Cotton, & Collins

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.

Solution

The Skinny Labels, Big Savings Act would create a safe harbor for generic manufacturers from liability in patent infringement cases if they seek or obtain FDA approval for skinny label indications. This bill text stipulates that this safe harbor is only applicable to the approved indications included in the skinny label application, as determined by the FDA. The bill states that the following actions are not considered violations of a method of use patent under the Federal Food, Drug, and Cosmetic Act (FFDCA):

- 1) Submitting or seeking approval of a skinny label for a generic or biosimilar pharmaceutical product;
- 2) Labeling, promoting, or commercially marketing a drug with skinny labeling approved by the FDA;
- 3) Describing, consistent with FFDCA, a drug approved via skinny label as a generic of or therapeutically equivalent to the branded drug.

This bill is supported by the Association for Accessible Medicines, the Generics Access Project, the Campaign for Sustainable Rx Pricing, and Patients For Affordable Drugs NOW.

Contacts: Hannah Berner, hannah_berner@hickenlooper.senate.gov & Hannah Geisman, hannah_geisman@hickenlooper.senate.gov

