Biosimilars FORUM

Statement for the Record by the Biosimilars Forum
House Judiciary Subcommittee on IP, Hearing on Patents

June 3, 2026

The Biosimilars Forum thanks the House Judiciary Subcommittee for convening this important hearing on the role of 'Skinny Labels' in shaping prescription drug prices and patient access. At its core, this is not an abstract policy debate. This hearing will focus on whether American patients can access the medicines they need at prices they can afford.

Decades of experience have demonstrated that robust, timely competition from biosimilars lowers drug costs while fostering innovation. Biosimilars deliver significant savings and expanded treatment options for patients, contributing to billions of dollars in reduced healthcare spending and increased access to life-saving medicines.

A Skinny Label is a pivotal mechanism designed to support timely market entry of a biosimilar drug 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, to seek timely FDA 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 on patents.

True to its promise, the HWA and BPCIA successfully increased competition, improved access to medicines, and generated billions of dollars in annual savings for patients and the American healthcare system. **From 2015 to 2020 alone, just 15 Skinny Labels led to an extraordinary $14.6 billion in Medicare savings. More than 67% of biosimilars had a Skinny Label at the time of FDA approval.**

By allowing timely entry of 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 or biosimilars more than 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.

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 and biosimilar 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 or biosimilar alternatives from entering the market with Skinny Labels. As such, this precedent creates a lose-lose dynamic.

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The Skinny Labels, Big Savings Act would help manufacturers bring more lower-cost, FDA-approved biosimilars to market more quickly for Americans that need them. This bill will lower drug prices by accelerating the roll-out of biosimilars and creating legal protections from endless lawsuits for drug manufacturers that obtain Skinny Label FDA approvals.

Targeted, bipartisan reforms can protect and promote innovation while ensuring that the patent system fulfills its intended purpose of advancing competition, lowering costs, and expanding patient access, instead of prolonging monopolies at the expense of patients.

The Biosimilars Forum strongly supports the Skinny Labels, Big Savings Act. This bipartisan legislation will promote free-market competition of biosimilars and improve patient access to lower-cost, FDA-approved medications. This bill will help patients, taxpayers, and the healthcare system as a whole save money on prescription drugs because it will help biosimilar manufacturers bring more biosimilars to market more quickly.

The Biosimilars Forum is comprised of the companies with the most significant U.S. biosimilar development portfolios. We stand ready to work with lawmakers to help lower drug costs for all Americans.