

Guest Perspective

Skinny Labels Save Dollars And Lives

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by Henry A. Waxman

There is one basic truth that every patient and health expert knows: prescription drugs can save lives and treat disease *only* if they are affordable. Some life-saving treatments can cost [upwards of \\$1 million per year](#), a bright red indication that much more needs to be done to lower prescription drug prices in the U.S. And even setting outliers aside, many common drugs cost Americans -- [the majority of whom can't afford a \\$1,000 emergency -- hundreds of dollars a year](#). With out-of-control prices like these, it's no wonder a quarter of adults report having [difficulty affording their prescription medications](#), and 3-in-10 say they haven't taken their medicine as prescribed due to costs. Tragically, we also know all too well that high drug costs disproportionately harm the health and financial wellbeing of people of color and those who are uninsured. If patients had ready and timely access to cheaper versions of their medications -- namely FDA-approved generic and biosimilar products -- concerns about affordability would decrease and patients would be better able to attain the life-saving treatments they need.

Brand companies can charge so much for prescription drugs because they hold patents on their drugs that give them exclusive sales rights by blocking generic and biosimilar competition for 10-15 years. This patent monopoly was intentional, designed by law to create an incentive for brand companies to invest their resources in developing novel and needed therapies. But misuse of the patent laws to block competition from generic and biosimilar products *even after the company has enjoyed many years of exclusivities* has run rampant. Congress should act to address this and has many options to do so. Among those options, Congress should immediately pass the Skinny Labels, Big Savings Act ([S. 43](#)). Introduced to preserve "skinny labeling," this bill restates what has been in the law since 1984 and has worked tremendously well.

When Senator Hatch and I drafted the Hatch-Waxman Amendments, a 1984 law which opened the door to generic competition and extended certain brand-named drug patents, we understood that brand-name companies would use every tactic they could to extend their patent protections. After all, a few additional years of patent exclusivity can mean billions of dollars in revenue for a single drug. We knew we could not predict all the tactics that would be used, but one tactic we did anticipate was that brand companies--as the original patents were about to expire--would attempt to block generic competition by obtaining patents on a new method of using their drugs. For example, if the brand company has a patent on a drug that is approved to treat diabetes, and that patent expires in 2025, the brand company might obtain a patent for use of the same drug before the original patent expires, but this time to treat high blood pressure. The new patent could be used to block generic entry to the market, extending the monopoly on the drug for an additional decade.

To combat this precise tactic, the Hatch-Waxman Amendments include a provision allowing the generic manufacturer to omit from its labeling the *new* patented use (high blood pressure) and only label its product for the uses *where patents have expired* (diabetes), allowing them to sell the generic to treat diabetes but not for high blood pressure. The narrower generic label is known as a "skinny label." The skinny label provision, which is a central part of the Hatch-Waxman Amendments, has worked extraordinarily well for 40 years.

Unfortunately, in recent years, brand companies have been arguing in the courts, with some success, that generic companies are liable for hundreds of millions in damages for patent infringement *despite* a carved-out label -- the exact opposite of the scenario allowed by Hatch-Waxman. The brand position in these cases is fundamentally at odds with what we intended. The facts in one case were so concerning that the [Solicitor General encouraged](#) the Supreme Court to review that case, noting that "[t]he decision . . . subverts the balance struck by Congress, creates

significant uncertainty for FDA and generic manufacturers, and invites gamesmanship by brand-name manufacturers.”

This problem needs to be fixed now. If brand companies are successful in their legal challenges to the skinny label provision, the healthcare system will end up paying billions more for brand medications when there should be generic competition to drive down the cost of the drugs via the skinny label pathway. We should not wait for the courts to resolve this issue, and the resolution should not depend on arcane questions of patent law. Instead, Congress should step in and restate what is already in the law--namely, that generic products do not infringe a patent when they omit a patented use from their label. The Skinny Labels, Big Savings Act has strong bipartisan support because it is common sense. Because so much is at stake, Congress should prioritize passing this critical legislation. Patients' access to lifesaving and affordable medicine depends on it.

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