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STATEMENT FOR THE RECORD

HEARING: House Judiciary Committee, Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet

"Medicines and IP: Balancing Innovation and Access."

June 4, 2026

Chairman, Ranking Member, and Distinguished Members of the Subcommittee:

We are excited to see this committee's interest in the connection between high drug prices and patent policy. Thank you for the opportunity to submit this written testimony. In particular, we'd like to highlight the importance of two essential pieces of bipartisan legislation: **The ETHIC Act (H.R.3269)** and the **Skinny Labels, Big Savings Act (H.R.6485)**. These bills and other policy solutions are important to protect American consumers from high drug prices by restoring fair competition in the pharmaceutical market.

Millions of Americans rely on prescription medication to sustain a pain-free and active lifestyle, and others need medication to survive. Unfortunately for many, the high prices of drugs make therapies out of reach. The very root of high drug prices lies in the very beginning of a drug's development: patent gaming by brand name drug companies that artificially inflate drug prices by keeping generics and biosimilars off the market.

Widespread rationing of medication is not merely an economic issue; patients who can't take their medicines at full doses and on a regular schedule experience worsened clinical outcomes and avoidable hospitalizations. These consequences result in long-term costs across all entities paying for health care: patients, employers and the government..

The Problem: Abusive patenting processes thwart drug price competition

The foundational purpose of the U.S. patent system is to encourage inventors to share their discoveries publicly in exchange for a temporary, 20-year monopoly. The patent system is designed so that when a patent expires, anyone can build upon that innovation, introducing competition that drives down prices.

Unfortunately, over the last few decades, rather than allowing their monopolies to expire, pharmaceutical companies seek to amass dozens of secondary patents, often filed years after FDA approval of the foundational medical innovation. It is a standard practice to build "patent thickets."[1] Instead of filing a single patent to protect a breakthrough compound, pharmaceutical companies routinely file dozens of overlapping, secondary patents on a single medication. By 2021, the top ten best-selling prescription drugs in the United States were shielded by an average of 74 patents each.[2]

It's time to put an end to patent games that extend price monopolies rather than protect true innovation.

Solutions: The power of market competition

The most effective mechanism available to curb these rising costs is robust, fair market competition driven by generic and biosimilar manufacturers. The economic impact of competition is well-documented and profound[3]:

- Market data demonstrates that introducing **just one generic competitor** lowers brand-name prescription drug prices by up to **39%**.
- When **four competitors** enter the market, prices plummet by **79%**.

Because open competition so dramatically deflates profit margins, major pharmaceutical corporations are strongly incentivized to extend their market exclusivity by any means available. Rather than relying purely on genuine innovation, companies frequently exploit loopholes in the patent framework to block lower-cost competitors from reaching patients.

Two essential reforms to lower prescription drug prices

To dismantle these anti-competitive tactics, we urge the Subcommittee to advance the following legislative solutions:

1. The ETHIC Act (Ensuring Transparency and Healthcare Innovation for Consumers) (H.R. 3269)

The ETHIC Act targets costly "patent thickets" that block lower-priced alternatives from coming to market. Currently, generic and biosimilar manufacturers face a wall of dozens of secondary patents, making litigation prohibitively expensive and time-consuming.

- **Streamlined Litigation:** The ETHIC Act would allow **one patent per patent group** to be challenged in court.
- **Focus on True Innovation:** The patent holder can still defend their strongest patent per group, preserving reward for true innovation. However, generic competitors will no longer be forced to needlessly litigate dozens of weak, follow-on patents.

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[1]U.S. PIRG, "Hacking through thickets of drug patents to get to affordable medicine," March 31, 2021. https://pirg.org/articles/hacking-through-thickets-of-drug-patents-to-get-to-affordable-medicine/
[2]I-MAK, "Overpatented, Overpriced," September 2022. https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf
[3] FDA, "Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices," December 2019. https://www.fda.gov/media/133509/download

2. The Skinny Labels, Big Savings Act (H.R. 6485)

When a drug's primary patent expires, brand-name companies often maintain secondary "method of use" patents (how a drug is used to treat specific, secondary ailments). The Hatch-Waxman Act allowed for **"skinny labels"** so a generic drug can be approved and sold *only* for the uses no longer covered by a patent. This pathway saves money for patients.

From 2015 to 2019, **43% of all approved generic drugs** in the U.S. used skinny labels to enter the market.

However, recent court decisions (such as *GSK v. Teva*) have allowed brand-name companies to distort this process. Brands are now successfully suing generic companies, claiming that marketing a legal "skinny label" drug inherently "induces" doctors to prescribe it for the carved-out, patented use.

- **The Solution:** H.R. 6485 provides a **statutory safe harbor** from patent infringement claims for generic or biosimilar manufacturers utilizing skinny labels.
- **The Impact:** It clarifies the original intent of the law to allow competition on a skinny label.

To bring this issue home, we'd like to share one of our member's stories:

Jean's experience:
High prices worsen patient care; competitive pricing could improve it

Jean, from Massachusetts, suffers from plaque psoriasis. She has navigated through multiple medications and several pharmacies over the years, trying to find an effective medication at a price she's able to pay.

Eventually, she settled on a prescription for Clobetasol, supplemented by a handful of Vtama samples which her dermatologist provides at her regular 6 month appointments. While Clobetasol is less effective and has more side effects for her than alternatives like Vtama or Dovonex, the price of the others are too high: a 30 day supply of Vtama would be nearly $1000 under her Medicare part D coverage, and no generic version exists. Fortunately, the Vtama samples are enough to carry her through flare ups until the next appointment.

While she's grateful for her dermatologist's efforts and the samples, Jean's experiences sorting through the wildly different costs and availability options has been extremely time-consuming and maddening.

She believes that unjustifiably high prices hinder effective and timely care as patients bounce between prescriptions to find one that is reasonably priced. Jean believes a doctor's time would be better spent providing care than helping patients identify workarounds to expenses, such as trying to find free drug samples. With a generic alternative for Vtama, Jean might not have needed to jump through all these hoops.

Conclusion

Thank you for coming together to consider this important issue. Patients deserve your strong leadership to protect them from patent policies that hinder competitive pricing. Innovation should be rewarded, but no one ever expected the kind of abuse we are seeing by pharmaceutical companies today.

Please work toward solutions such as the **ETHIC Act** and **Skinny Labels, Big Savings Act.** Thank you for your anticipated commitment to balancing true innovation with affordable healthcare access.

Respectfully submitted,

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