How Congress Can Lower Drug Prices, Boost Competition

Trio of Bipartisan Solutions – the Biosimilar Red Tape Elimination Act, Medication Affordability and Patent Integrity Act and Ensuring Timely Access to Generics Act – Would Crack Down on Big Pharma's Anti-Competitive Tactics, Bring More Affordable Alternatives to Market

the campaign for SUSTAINABLE Rx PRICING

Big Pharma's egregious pricing practices and anti-competitive tactics are driving health care inflation and blocking more affordable alternatives, like generics and biosimilars, from reaching American patients and lowering prices in the marketplace.

Big Pharma opposes market-based solutions that would lower prescription drug prices by falsely claiming egregious prices and extended monopolies are justified by investments in innovation, despite routinely spending more on marketing than research and development (R&D) and numerous studies debunking any connection between prices set by brand name manufacturers and clinical value for patients or investments in R&D.

There are three bipartisan solutions Congress can advance in an upcoming meeting in the U.S. Senate Health, Education, Labor and Pensions Committee. These solutions are:

- **The Biosimilar Red Tape Elimination Act (S. 1954)**
- **The Medication Affordability and Patent Integrity Act (S. 2658)**
- **The Ensuring Timely Access to Generics Act (S. 3014)**

BIOSIMILAR RED TAPE ELIMINATION ACT (S. 1954)

The Biosimilar Red Tape Elimination Act (S. 1954) would eliminate outdated U.S. Food and Drug Administration (FDA) requirements and modernize the drug approval process to expedite biosimilar substitution and increase competition from more affordable alternatives to high-priced brand name products.

By eliminating unnecessary red tape in FDA requirements, this bipartisan, market-based solution will help bring more biosimilars to market more quickly, fostering greater competition from more affordable alternatives to high-priced brand name drugs to help lower prices for patients, taxpayers and the U.S. health system.

Here's what lawmakers from both parties have said about the bill:

> "Americans are missing out on lower drug prices thanks to bureaucratic red tape that protects big pharma monopolies. Many consumers would choose a cheaper generic-brand version of their medications, but technicalities from Congress have kept these out of reach. Our legislation will cut the red tape to bring drug prices down, break up the big pharma monopolies, and let Americans make their own medication choices."
>
> **– U.S. Senator Mike Lee (R-UT)**

> "Limited competition drives up drug prices, making it harder for people to afford the medications they need to survive. Expanding access to biosimilar drugs can improve patients' lives and reduce costs. But too often, access can be limited due to regulatory red tape that scientists agree is not necessary. This bipartisan bill will help simplify that process while maintaining rigorous safety and effectiveness standards. By increasing competition, this legislation will allow more patients and families to access the treatments they need."
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> **– Senator Ben Ray Luján (D-NM)**

MEDICATION AFFORDABILITY AND PATENT INTEGRITY ACT (S. 2658)

The Medication Affordability and Patent Integrity Act (S. 2658) would strengthen coordination between the U.S. Patent and Trademark Office (USPTO) and FDA by requiring more consistent information across agencies, helping improve patent quality, reduce Big Pharma abuse of the patent system and prevent costly delays in the availability of more affordable generics.

Currently, brand name drug manufacturers are able to game the patent system and drug approval process by presenting one narrative to FDA and another to the USPTO. While both agencies receive the same core information during the approval process – such as a drug's composition and chemistry – brand name manufacturers abuse gaps in agency coordination

by withholding key information from the USPTO. This deceptive strategy enables Big Pharma to secure secondary patents long after a drug's original approval, artificially extending its market exclusivity.

The result is the creation of overlapping or contradictory patents that can unfairly prolong a product's market dominance, blocking biosimilar and generic drugs from market entry, years after the drug's original patent expired.

Myth vs. Fact: The Medication Affordability and Patent Integrity Act

The pharmaceutical industry is making false claims about what the impact of this bill would be because they want to keep drug prices high and block competition.
Get a dose of reality on their false rhetoric here:

Big Pharma Claim:
The bill will expose industry trade secrets.

DOSE OF REALITY:

The legislation includes explicit trade secret protections that were negotiated with industry itself. The USPTO and FDA already have protocols in place to protect sensitive information.

Big Pharma Claim:
The bill forces drug companies to send an overwhelming amount of sensitive clinical trial data to the USPTO.

DOSE OF REALITY:

That's false. The legislation was revised to exclude sensitive clinical trial data entirely and only includes information sharing provisions directly related to patentability.

Big Pharma Claim:
The bill gives the FDA too much power over patents.

DOSE OF REALITY:

The FDA's role stays the same. This legislation only requires manufacturers to certify that they are submitting the same information to both the FDA and USPTO. The FDA isn't adjudicating patents. It's just accepting an attestation in the normal drug approval process.

Here's what lawmakers from both parties have said about the bill:

> "For too long, Big Pharma has been abusing the patent process to block generic competition and keep prices for patients artificially high. Granite Staters deserve better than a system that allows Big Pharma to exploit our patent system at the expense of families struggling to afford their medications. This bipartisan bill would help close a key loophole and bring down prescription drug costs for families across New Hampshire and the country."
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> **– U.S. Senator Maggie Hassan (D-NH)**

> "Big Pharma companies have been driving up their profits by gatekeeping select drug information and exploiting our bloated bureaucracy. But their habit of gaming the U.S. patent system means delaying Americans' access to affordable medications. This bipartisan legislation would require manufacturers to disclose critical drug information across agencies, so Congress can finally begin to upend Big Pharma's anticompetitive practices."
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> **– U.S. Senator Josh Hawley (R-MO)**

ENSURING TIMELY ACCESS TO GENERICS ACT OF 2025 (S. 3014)

The Ensuring Timely Access to Generics Act (S. 3014) would improve oversight of the citizen petition process at the FDA, ensuring drugmakers can't game the system to stall generic competition and patients can benefit from lower-cost alternatives sooner.

The FDA's citizen petition process – designed to allow public input on drug safety and efficacy – has been exploited by the pharmaceutical industry to delay the approval of generic and biosimilar medicines and undermine competition.

By filing petitions that are designed more to create regulatory drag than to address genuine safety or quality issues, these companies can delay generic approvals, effectively extending their monopoly pricing power and keeping costs high for patients and the health system.

Here's what lawmakers from both parties have said about the bill:

> "Addressing the soaring price of prescription drugs is a tangible way that Congress can help lower health care costs and give families some breathing room in their budgets. By increasing competition, our bipartisan legislation would help bring more generic drugs to the market and reduce costs for the Granite State families who rely on them."
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> **– U.S. Senator Jeanne Shaheen (D-NH)**

> "We know that increasing generic drug competition is key to lowering prescription drug prices for individuals and reducing drug spending overall. On average, generic drugs cost 80 to 85 percent less than their brand-name equivalents. This bipartisan bill would help address barriers that currently delay market entry for generic drugs, improving competition and saving patients money."
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> **– U.S. Senator Susan Collins (R-ME)**

THE BOTTOM LINE

Congress can lower drug prices, boost competition and protect patients and taxpayers by passing the Biosimilar Red Tape Elimination Act, Medication Affordability and Patent Integrity Act and Ensuring Timely Access to Generics Act.