How Congress Can Lower Drug Prices, Boost Competition

Bipartisan, Market-Based Solution Would Streamline Drug Approval Process and 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. Congress can help promote competition and lower drug prices for American consumers by passing the bipartisan **Expedited Access to Biosimilars Act.**

EXPEDITED ACCESS TO BIOSIMILARS ACT (S. 1414 | H.R. 9661)

The Expedited Access to Biosimilars Act (S. 1414 | H.R. 9661) would streamline the approval pathway for more affordable alternatives to high-priced brand name biologic drugs to foster greater competition and help lower drug prices for American patients.

Although biosimilars already undergo a rigorous U.S. Food and Drug Administration (FDA) review process, current requirements often mandate duplicative clinical studies – even when existing evidence confirms their safety and effectiveness – adding unnecessary time and expense, delaying patient access to more affordable treatment options.

By eliminating redundant testing requirements and adopting a more efficient FDA review standard, the legislation would remove barriers to market entry, accelerate biosimilar competition and expand patient access to lower-cost biologics while maintaining FDA's high standards for safety and efficacy.

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

> "For too long, the FDA has forced companies to jump through bureaucratic hoops and produce redundant clinical studies that offer no new meaningful scientific information for the approval process. My bill puts an end to wasteful and repetitive clinical requirements that create unjustified barriers, further delaying competition in the market."
>
> **– U.S. Senator Rand Paul (R-KY)**

> "Our bipartisan bill cuts unnecessary red tape, provides greater regulatory certainty, and helps bring lower-cost treatment options to patients faster without compromising the FDA's rigorous safety standards. This is a commonsense reform that will increase competition, expand patient choice, and help reduce prescription drug costs for families."
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> **– U.S. Representative Nick Langworthy (R-NY-23)**

> "It is past time the Food and Drug Administration improve the approval process for biosimilars, which are lower-cost, lifesaving, and effective treatments. I am glad to introduce this legislation to streamline the FDA's process, lower drug prices, and make medicine more accessible for patients across the country."
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> **– U.S. Representative Kim Schrier (D-WA-08)**