

How Congress Can Lower Drug Prices, Boost Competition

Bipartisan, Market-Based Solutions Would Streamline Drug Approval Process and Bring More Affordable Alternatives to Market



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 **Expedited Access to Biosimilars Act** and **Biosimilar Red Tape Elimination Act**. These bipartisan solutions will streamline the drug approval process, boost competition and lower drug prices.

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 & 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:

“ 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.”

– 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.”

– U.S. Representative Kim Schrier (D-WA-08)

BIOSIMILAR RED TAPE ELIMINATION ACT (S. 1954 | H.R. 5526)

The Biosimilar Red Tape Elimination Act (S. 1954 | H.R. 5526) 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:

“ For far too long, unnecessary barriers and outdated FDA requirements have prevented Americans from accessing a less expensive, generic version of their medication. Our legislation is a simple, commonsense step we can take to ensure Texans keep more of their hard-earned money by eliminating this burdensome red tape that disincentivizes competition and drives prescription drug prices up for all patients.”

– U.S. Representative August Pfluger (R-TX-11)

“ Outdated rules are keeping lower-cost drugs off the market, and our families are paying the price. This bill will allow innovative drugs to come to market faster and cheaper, and allow pharmacists to swap higher-cost prescriptions for safe and effective alternatives – lowering costs at the pharmacy counter and saving folks real money.”

– U.S. Representative Greg Landsman (D-OH-01)