

Grassley, Leahy: It's time to empower generic drug makers to bring down prices

By Patrick Leahy and Chuck Grassley
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<https://www.statnews.com/2018/03/16/creates-act-generics-drug-prices/>

In Vermont, Iowa, and every other state across the country, people are fed up with the high cost of prescription drugs. Prices continue to skyrocket as companies making brand-name drugs restrict competition by refusing to share samples of their drugs with companies aiming to make generic versions or refusing to negotiate a shared safety protocol. This is an abuse of government regulations that are intended to protect patients and ensure drug safety.

These practices punish patients and worsen illnesses. Families, businesses, government programs, and other payers in the health care system must bear the added, unnecessary costs that accrue when a generic is shut out.

Lawmakers across the political spectrum, including President Trump, agree that Congress needs to act to rein in spiraling prescription drug prices. We can start by cracking down on abuses by companies making brand-name drugs that engage in tactics to artificially delay the development of generic alternatives. These stifle competition and keep prices artificially high. It is no wonder that hardworking Americans feel like the system is rigged against them by corporations that are seizing any opportunity unfairly restrict competition and reap monopoly profits long after patents expire.

Some — not all — companies that make brand-name drugs limit release of their products to prevent access to samples as a way to delay the development of generic versions. These tactics block more-affordable FDA-approved generics that save patients — and taxpayers — money at the pharmacy counter. When a generic manufacturer is not able to buy drug samples, it is impossible to do the careful testing that's needed to ask the Food and Drug Administration to approve the medication. FDA Commissioner Scott Gottlieb has rightly called these tactics “unfair and exploitative” and “in direct conflict to our broader public health goals.”

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Cancer patient David Mitchell testified before Congress about one company's efforts to deny a generic company's access to samples of Revlimid, a lifesaving cancer treatment. Access to samples of the drug has been at issue since 2009. If it were not for this ongoing abuse of the FDA's safety programs, a generic alternative could be available to David and other patients as early as next year.

Because there is no generic alternative, the cost of Revlimid has remained artificially high and has actually risen fourteen times since this abuse began, from \$9,853 in 2010 to its current price

of \$18,546 for a 28-count bottle. This is just one example out of more than 150 complaints that the FDA has received from generic manufacturers.

To end these anti-competitive tactics, a bipartisan coalition of lawmakers — including Republican Sens. Mike Lee (Utah), Ted Cruz (Texas), Rand Paul (Ky.), and Democratic Sens. Amy Klobuchar (Minn.), Dianne Feinstein (Calif.), and Dick Durbin (Ill.), have joined us to introduce the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. This bill is supported by a broad and politically diverse coalition of 68 organizations representing hospitals, physicians, patients, employers, and unions. AARP, Families USA, FreedomWorks, and Heritage, to name just a few, have endorsed this common-sense legislation. The public also agrees: Recent polls show that 84 percent of Americans support the CREATES Act.

Our bipartisan bill targets anti-competitive behavior that keeps prices artificially high, such as when companies withhold drug samples from generic manufacturers or refuse to negotiate a shared safety protocol. Both steps undermine the FDA approval process and block potential generic competitors from creating less-expensive alternatives.

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Companies making brand-name drugs that stand in the way of the CREATES Act wrongly claim the legislation will lead to frivolous lawsuits. This is a red herring. Our bill is narrowly tailored and would only allow eligible product developers seeking to develop a medicine to sue, only after receiving FDA authorization. Trial lawyers will have no standing to sue under our plan.

Another baseless argument we have heard is that counterfeit product developers who do not intend to develop a drug will take advantage of the CREATES Act in order to seek damages from a brand-name company. Wrong again. Under the CREATES Act, court challenges are only allowed based on continued delays after the FDA has certified the safety and the brand has refused to release samples. The significant costs to submit protocols to the FDA also discourages this behavior. These arguments do not hold up against the clear and limited remedies available under the CREATES Act.

Conservatives who support the CREATES Act appreciate that it lowers drug costs by quickly bringing parties to the negotiation table under the threat of litigation instead of a drawn-out regulatory action. The act is not a drastic measure, but allows the generic development process to proceed as intended by Congress under the Hatch-Waxman Act. Companies making brand-name pharmaceuticals need only to negotiate in good faith and provide the samples for testing on market terms to avoid a lawsuit.

This bill offers Congress an opportunity to take meaningful action to lower the cost of prescription drugs. It would save \$3.8 billion in federal spending over the next 10 years and many billions more in costs to consumers.

The CREATES Act is a sensible, efficient, market-based way for generic drug manufacturers to address the delays in developing generics without jeopardizing patient safety or creating lengthy

battles in the courts. There is no question that pharmaceutical companies should be compensated for their important work developing lifesaving treatments. But they should not be allowed to use predatory practices to cling to their patents and delay the development of generics at the expense of their customers.

Congress has a straightforward and fully bipartisan chance to actually do something to wind down the upward spiral of drug prices. Enough talk. It's time for real action.

Democratic Sen. Patrick Leahy represents the state of Vermont. Republican Sen. Chuck Grassley represents the state of Iowa.