

# U.S. Sen. Baldwin: Helps introduce bipartisan bill to close orphan drug loophole

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WASHINGTON, D.C. – U.S. Senators Tammy Baldwin (D-WI), Bill Cassidy, M.D. (R-LA) and Jeanne Shaheen (D-NH) introduced bipartisan legislation to close a loophole in the *Orphan Drug Act* that has allowed drug companies to keep competition off the market and rake in profits.

Currently, drug companies can get seven years of market exclusivity for a widely used new drug if they are able to prove to the Food and Drug Administration (FDA) that a new drug would not be economically viable without that exclusivity. If granted, that exclusivity persists for seven years even if the drug becomes economically viable on its own, and be applied to new versions of the drug. By maintaining exclusivity, drug companies can make billions in profit without market competition, including for important medications that help treat opioid use disorder.

The Senators' bill closes the loophole. It allows the FDA to remove market exclusivity if the drug company cannot continue to prove that the drug would be economically unviable when facing competition. This will help increase competition and bring important new treatments to market.

“Washington needs to step up and be a stronger partner to communities fighting the substance abuse epidemic, and we need to make sure that all safe and affordable treatment options are available to patients. We can do this by taking on unfair practices and leveling the playing field so we can use every tool at our disposal to combat this public health crisis,” **said Senator Baldwin.** “This

legislation will close a loophole to help expand access to innovative medications. I'm proud to join this bipartisan effort to fight this epidemic and save lives."

"Monopolies within the health care system drive drug prices up, making drugs unaffordable. Closing the orphan drug loophole will lower drug prices by encouraging market competition. Drug companies must have the means to innovate, but they should not be allowed to exploit the market," **said Dr. Cassidy.**

"Congress needs to do everything in its power to curb skyrocketing prescription prices, and that includes cracking down on drug manufacturers who abuse the system to prevent more affordable competitors from coming to market," **said Senator Shaheen.** "As our communities fight to turn the tide of the substance use disorder epidemic, we need to be doing everything we can to ensure patients and treatment providers have access to affordable, effective medication to respond to this crisis. I'll continue to work across the aisle to reduce prescription drug costs and increase market competition among manufacturers so Granite Staters and Americans across the country don't have to pick between affording their medication and paying the bills."

The full bill text is available [here](#). An online version of this release is available [here](#).

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