Ryan White Clinics for 340B Access

GET THE FACTS

Drug Shortages Are the Result of Manufacturer Actions

No Link Between Drug Shortages and 340B Program

The root causes of drug shortages are almost always driven by manufacturer conduct. While the 340B program is a small percentage of drug spend in the United States, 340B program critics allege – with little to no supporting evidence – that 340B is a cause. The FDA found three primary causes for drug shortages, none of which involve 340B: 1) inadequate incentives for manufacturers to produce more affordable drugs; 2) no market reward for manufacturers that implement systems focused on early detection of supply chain issues; and 3) regulatory and logistical challenges that impede the market's ability to recover from a disruption.[3] Further, to the American Society of Health System Pharmacists (ASHP) found no link between 340B and drug shortages.

Penny Pricing Is Not the Cause of Drug Shortages

The 340B statute imposes an inflationary penalty on manufacturers that raise the price of their drugs faster than the rate of inflation. The amount by which the drug's average price exceeds the inflation rate is deducted from the 340B ceiling price. Sometimes manufacturers raise prices so quickly that the inflationary penalty drives the 340B price to a zero or near-zero price. In that case, manufacturers are directed to charge no more than a penny for the 340B drug. Critics allege that penny pricing contributes to drug shortages as a result of "potential stockpiling" by covered entities, a position that the Health Resources and Services Administration has unequivocally refuted.[4] If ANY pharmacy orders excess stock, it is only AFTER there's a shortage, and it's due an attempt to ensure an uninterrupted supply, and not by the purchase price. More importantly, manufacturers can avoid penny pricing by simply exercising greater restraint when raising their prices.

Drug Shortages Threaten HIV Care/Narrowing 340B Eligibility Is the Wrong Answer

RWC-340B is bracing for imminent drug shortages caused by recent decisions by manufacturers to discontinue certain drugs. For example, a lead manufacturer of HIV/AIDS drugs announced that several treatment options will be discontinued at the end of 2023: formulations of Epzicom (abacavir sulfate, lamivudine), Lexiva (fosamprenavir calcium), Selzentry (maraviroc), Tivicay (dolutegravir), Trizivir (abacavir sulfate, lamivudine, zidovudine), and Ziagen (abacavir sulfate). As a result, people living with HIV will be forced to change medications and they may not be able to tolerate their new therapies. Critics have proposed creating 340B exemptions for drugs in short supply as a way to address the problem. But such proposals would have little impact and would lead to more serious consequences by undermining the ability of safety net providers to meet the needs of their patients. For Ryan White clinics, the proposal could impede the clinics' fight against the HIV epidemic. While RWC-340B continues to advocate for Congressional solutions to the drug shortage problem, any such solution must target the real source of the crisis – manufacturers.

www.rwc340b.org Contact: info@rwc340b.org

[3] Drug Shortages: Root Causes and Potential Solutions, FDA (Mar. 11, 2020) Report | Drug Shortages: Root Causes and Potential Solutions | FDA.

[4] *Id.*