Ryan White Clinics for 340B Access

July 7, 2023

Chair Cathy McMorris Rodgers
House Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

Ranking Member Mike Crapo
Senate Finance Committee
United States Senate
Washington, DC 20510

Chair McMorris Rodgers and Ranking Member Crapo:

On behalf Ryan White Clinics for 340B Access (RWC-340B), we write in response to your inquiry relating to your request for information (RFI) on the "ongoing surge in drug shortages" published on June 12, 2023. Specifically, RWC-340B is responding to your question – "What role, if any, has growth in the 340B program played in drug shortage trends?" While we share your interest in ensuring that people in this country have access to the medications they need, the evidence is clear that the 340B program does not contribute to drug shortages.

RWC-340B is a national association of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act and participate as "covered entities" in the federal 340B drug discount program. Like many other safety-net providers, Ryan White clinics rely on 340B savings to provide critical services that would otherwise be uncompensated, ranging from free or discounted medications to critical wrap-around support services for people living with HIV. The 340B program empowers Ryan White clinics to care for their patients holistically, enabling these clinics to be a key drivers in the Ending the HIV Epidemic (EHE) initiative, begun by the Trump Administration and advanced by the Biden Administration.[1]

340B Program Overview

The 340B Drug Pricing program was created by Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," in section 340B of the Public Health Service Act. The 340B statute requires manufacturers to enter into an agreement with the Secretary prohibiting them from charging above the 340B statutory ceiling price when selling covered outpatient drugs to covered entities. This agreement, known as the Pharmaceutical Pricing Agreement (PPA), must be signed by a manufacturer as a condition for participating in and having its drugs covered under Medicaid and Medicare Part B. The 340B program fortifies the U.S. public health infrastructure, without taxpayer expense, by allowing manufacturers to voluntarily access these massive federal payer markets in exchange for their participation in the 340B program.

Data Show that Drug Shortages Are Manufacturer Driven, Not Attributable to 340B

Drug shortages have plagued the nation's caregivers, pharmacies, and patients for decades.[2] The FDA defines a drug shortage as "a period when the demand or projected demand for the drug within the United States exceeds its supply."[3] Official tracing of the cause of drug shortages began in 2001, with 2011 constituting the peak of shortages of generic drugs.[4] Since that time, industry experts identified several root causes of drug shortages – none of them relating to the 340B status of safety-net providers.[5]

Importantly, in over thirty years of the 340B program's existence, critics have failed to provide a single study demonstrating a significant link between drug shortages and 340B purchases. Despite these facts, the question posed appears to shift the blame for drug pricing and manufacturing decisions that are far beyond the control of 340B safety net providers.

The inability to link 340B to drug shortages is obvious when one considers these two factors: (1) most of the value of the 340B program is in brand name products while drug shortages typically involve generic products; and (2) a mechanism for equitably controlling 340B purchases of drugs in short supply already exists.

The root causes of drug shortages, summarized below, are almost always manufacturer driven.[6]

- Lack of incentive for manufacturers to produce less profitable drugs
- Lack of incentive for manufacturers to maintain "mature quality systems" for drug production to improve and detect supply chain quality issues
- Market consolidation among manufacturers of a given category of drugs, thereby limiting their supply
- Disruption in complex constituent supply chains for manufacturers seeking to lower production costs by relying on unreliable outside entities to produce active pharmaceutical ingredients and finished dosage forms
- Regulatory hurdles – such as compliance with FDA requirements for safe and effective drugs – that slow the entry of new drugs into the market and/or reduce drug production because of quality concerns
- Natural disasters and public health emergencies, such as Hurricane Maria in Puerto Rico and the global COVID-19 pandemic
- Manufacturers' underproduction simply due to failure to anticipate spikes in demand.

HIV/AIDS Drug Shortages Are Manufacturer-Driven

Members of RWC-340B are bracing for a drug shortage problem that is already on the horizon and attributable solely to manufacturer misconduct. Manufacturers have announced that, of the few HIV/AIDS treatment options currently available in the U.S., several will be discontinued this year. Specifically, formulations of Epzicom (abacavir sulfate, lamivudine), Lexiva (fosamprenavir calcium), Selzentry (maraviroc), Tivicay (dolutegravir), Trizivir (abacavir sulfate, lamivudine, zidovudine), and Ziagen (abacavir sulfate) will be discontinued on January 1, 2024.[7] People living with HIV will therefore be limited in their treatment options, increasing health risks for certain patients who may not be able to tolerate the medications still on the market. This unfortunate truth hits harder for lower-income HIV patients who take drugs subject to arbitrarily hiked prices due to manufacturer deals to prolong market exclusivity.[8]

340B Program Has Effective Mechanism to Prevent Stockpiling of Penny-Priced Drugs and Other Low-Cost 340B Products

As a condition for participating in the 340B program, manufacturers must abide by the penny pricing rule which requires them to charge no more than a penny for a drug when the ceiling price formula yields a lower price as a result of manufacturers raising the price of their drugs faster than the rate of inflation. The penny price rule provides critical protection to U.S. citizens by deterring multinational drug companies from inflating their prices to increase profits within the U.S. drug market.

Critics of the 340B program allege, with little to no supporting evidence, that 340B covered entities stockpile 340B drugs that are subject to penny pricing which, in turn, causes drug shortages.[9] This claim is patently false. These manufacturer allegations were dispelled by the Department of Health and Human Services (HHS) in 2017 when the penny pricing rule was adopted for generic drugs. HHS' Health Resources and Services Administration (HRSA) went out of its way to refute 340B program critics' assertions that penny-priced 340B drugs would result in "potential stockpiling."[10]

- In its formal rulemaking, HRSA stated that the "penny pricing policy has been in place for many years and *HHS does not have evidence that the policy causes significant risks of stockpiling . . . .*"[11]
- HRSA noted that manufacturers "may address any resultant market distribution challenges by developing and executing a plan for limited distribution *to all purchasers* of the affected drug, including 340B covered entities when penny pricing occurs."

The option of establishing a 340B-neutral limited distribution plan for drugs in short supply was announced by HRSA in 2011. HRSA issued a 340B program notice stating that "when a 340B price drops to a penny price, a manufacturer may anticipate challenges with *equitable* market distribution of the drug, and should develop a plan for *non-discriminatory,* restricted distribution to all purchasers, *including 340B covered entities*."[12] The limited distribution plan mechanism ensures that 340B drugs are not purchased at a higher rate than non-340B drugs, thereby decoupling 340B utilization from the potential of drug shortages.

For further information, contact Peggy.Tighe@PowersLaw.com, Legislative Counsel to RWC-340B.

Sincerely,

Shannon Burger, MBA, CPA
Chief Executive Officer
Ryan White Clinics for 340B Access

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[1] *See, e.g.*, FACT SHEET: The Biden-Harris Administration's Efforts to End HIV/AIDS At Home and Abroad | The White House; RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction* (Sept. 2020), RWC Key Research.
[2] FDA, *Drug Shortages: Root Causes and Potential Solutions* (2019) , at 5-6, www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions.
[3] *Id.*
[4] American Society of Health-System Pharmacists, https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics?loginreturnUrl=SSOCheckOnly.
[5] *See* supra note 2, at 6.
[6] *Id.*
[7] Diana Ernst, *Discontinuation of Several HIV Medications Reported to FDA* (Jan 4, 2023), https://www.empr.com/home/news/discontinuation-of-several-hiv-medications-reported-to-fda/.
[8] *In re HIV Antitrust Litig*., 3:19-cv-02573-EMC (N.D. Cal. June 30, 2023) (antitrust lawsuit involving TEVA and Gilead arrangement under which Teva obtained approval from Gilead to exclusively market Gilead patent-protected formulations of HIV drugs in advance of patent term expiration).
[9] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1216 (Jan. 5, 2017).
[10] *Id.* at 1216.
[11] *Id.*
[12] 340B Drug Pricing Program Notice Release No. 2011-2.