

PRESS STATEMENT: FOR IMMEDIATE RELEASE June 20, 2023

National Ryan White Clinic Organization Fires Back at Gilead-Funded "Study" Riddled with Inaccuracies, Faulty Assumptions, and Profit-Centered Analysis

Ryan White Clinics for 340B Access (RWC-340B), a national association of HIV/AIDS organizations receiving support under the Ryan White CARE Act, calls a Gilead-funded study unfounded, self-serving, and counter to the drug company's claims that it is "committed to meeting the needs of patients and helping improve the lives of the 37.7 million people living with HIV around the world and the many more at risk for HIV."

Funded by Gilead Sciences, Inc. (Gilead), the Berkeley Research Group (BRG) published a "study" titled "Federal Grantee Clinics and the 340B Drug Discount Program." The study accuses Ryan White Clinics of misusing the 340B drug discount program. RWC-340B dismisses the BRG report as drug industry propaganda that relies on unfounded assumptions and flawed estimates to reach conclusions that are antithetical to the needs of persons living with HIV/AIDS.

Gilead is the largest manufacturer of both HIV antiretroviral medications and pre-exposure prophylaxis (PrEP) drugs. BRG has a history of issuing opinion pieces, in the guise of studies, that are highly critical of the 340B program. Like the latest BRG report, these publications are authored by Aaron Vandervelde, an outspoken critic of the 340B program who is the managing director of BRG and founder of an industry-funded 340B clearinghouse platform called 340B ESP. Daniel O'Day, Gilead's Chairman of the Board of Directors and Chief Executive Officer, serves as Board Chair-elect of PhRMA, the national association of drug companies that is actively seeking to "reform" the 340B program in Congress, states, and the courts.

Shannon Burger, president of RWC-340B and CEO of Cempa Community Care, said, "We once thought of Gilead as our partner in the fight to end HIV/AIDS. This new report proves that Gilead is part of the problem, not the solution." She added, "Gilead's recent policies limiting access to 340B medications for persons living with HIV and AIDS and for patients needing hepatitis C drugs is appalling evidence that Gilead is more concerned about profits than patients."

The federal 340B Drug Pricing Program allows safety net providers, including HIV/AIDS clinics receiving support under the Ryan White CARE Act, to obtain prescription drugs at below-retail prices. With 340B savings, Ryan White Clinics are able to stretch their grant funds, to offer a

wider range of services, and to improve the quality of care for people living with HIV/AIDS. The well-recognized intent of the 340B program is to stretch scarce federal resources as far as possible to reach more eligible patients and to provide more comprehensive services.

In the last two years, Gilead cut pharmacy reimbursement for HIV medicines that it offers to uninsured individuals through its Advancing Access patient assistance program. Gilead also began withholding 340B discounts on Hepatitis C drugs dispensed by covered entities using third party pharmacies unless they submit detailed pharmacy claims data to the 340B ESP software platform. Gilead took these measures during a period in which it reported record growth in sales of its drugs.

"The BRG report is filled with pseudo-scientific 'analysis' intended to increase Gilead's profits," said Mark Malahosky, Vice President of Pharmacy Services at Trillium Health and RWC-340B Treasurer. The Gilead-funded publication asserts that "many of the same growth trends and financial dynamics that have been well studied in the context of hospitals also apply to grantees." Since 1992, Congress has required that drug companies give steep discounts on their drugs to safety net providers in exchange for accessing the important Medicaid and Medicare Part B drug markets. Malahosky noted, "Gilead and BRG are twisting the facts to develop a false narrative about the 340B program not worthy of the term 'analysis'. It uses questionable statistics and unfounded assumptions to draw the faulty conclusion that grantees are misusing the 340B program."

The report also alleges that Ryan White clinics need further transparency in their use of 340B savings to support patient care services and that the program may not be a "sustainable approach to funding these services going forward." Ryan White Clinics participating in the 340B program are already subject to extensive program income reporting requirements, are routinely audited by HRSA, and risk losing eligibility for program non-compliance. Further, RWC-340B's <u>research</u> shows that state and federal taxpayers would be forced to pick up the bill for care now provided by Ryan White Clinics if the 340B program is cut.

RWC-340B notes some of the more serious shortcomings of the BRG publication:

- The report criticizes the growth in the use of contract pharmacy arrangements and the
 margins realized from such arrangements. Yet it fails to acknowledge that contract
 pharmacies increase access to affordable medications and that grantees are obligated to
 use revenues that they receive to support the purposes of their grants.
- BRG's extrapolation of 340B utilization by Medicare Part D beneficiaries to other payer groups is speculative at best. BRG admits that it assumed that a grantee purchased a drug if the prescriber was "affiliated" with the grantee and the drug was purchased through a contract pharmacy or in-house pharmacy of the grantee.
- The study uses questionable data to conclude that margins on 340B drugs for grantees are about 3.7 times the discounted 340B price. According to two GAO reports 2020 <u>Drug Pricing GAO Report</u> and 2011 <u>Drug Pricing GAO Report</u> – 340B discounts only result in savings ranging from 20 to 50 percent. If the 340B price is merely 50 percent of the

- non-340B price, it is difficult to fathom how 340B grantees are generating the large margins that BRG alleges.
- The publication asserts that grantees gained "between \$8 billion and \$12 billion in 340B drug margin in a single year." Regardless of how that estimate was calculated, or if it is even accurate, the study fails to acknowledge that federal grantees are required to use these revenues to support the purposes of their federal grants. Gilead reported revenue of \$27.3 billion in 2022, 65% percent of which is attributable to HIV-related products.

For more information, please visit www.RWC340b.org or email info@rwc340b.org.

About Ryan White Clinics for 340B Access

Ryan White Clinics for 340B Access (RWC-340B) is a national organization of HIV/AIDS providers receiving support under the Ryan White CARE Act. Ryan White providers are eligible to participate in the federal 340B Drug Discount Program, which enables them to expand and support care.