NATIONAL ASSOCIATION OF Community Health Centers

June 15, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Becerra:

On behalf of the National Association of Community Health Centers (NACHC) and in the interests of the nation's 1,400 health centers, we are grateful for your longstanding support of Community Health Centers. Moreover, we appreciate the Department of Health and Human Services' (HHS) strong commitment to protecting the 340B drug discount program against pharmaceutical manufacturers' relentless attacks. In that spirit, we wanted to update you on the constant challenges that health centers are experiencing due to the continued assault on the program.

Health centers continue to experience devastating financial losses as we wait for final decisions in the Alternative Dispute Resolution (ADR) process and ongoing federal court litigation. NACHC is very concerned that the current threats to the 340B Program will jeopardize health centers' ability to continue to fight on the front lines of the COVID-19 pandemic, assist their states with Medicaid redeterminations, and serve the most vulnerable and underserved patients across the nation. Additionally, as health centers are federal grantees, the financial losses caused by the manufacturers' unlawful actions diminish health centers' ability to carry out their federally-funded mission, resulting in greater reliance on federal funding.

For nearly two years, manufacturers have refused to sell 340B priced drugs to covered entity health centers where those drugs will be dispensed to eligible health center patients through contract pharmacies. As detailed below, we strongly encourage HHS to assess and exercise its full authority to hold pharmaceutical manufacturers accountable for violating the 340B statute and, in doing so, to restore health centers' access to 340B discount pricing. In particular, we are concerned that (1) although the manufacturers' actions were referred to the HHS Office of Inspector General ("OIG") in September 2021 and March 2022, no material facts are in dispute, and HHS's interpretation of the statute is well established, the OIG has yet to take appropriate enforcement action; and (2) HHS has neither threatened nor taken any action in light of the manufacturers' clear—and HHS-acknowledged—violations of their statutory and contractual obligations.

Health centers play a vital role in their communities, serving as a medical home to the country's most vulnerable populations. In 2020, health centers served 17.5 million people living in poverty, 2.9 million people 65 and older, 18.5 million people of minority background, and 1.3 million people experiencing homelessness. More than 90% of health center patients were at or below 200% of the Federal Poverty Level (FPL). Health centers are truly embedded in their communities and provide high-quality, affordable primary care, and housing support, food, transportation, and social services to the people they serve. We are so grateful for the confidence the Biden administration

has placed in health centers to vaccinate, test, and educate the hardest-to-reach communities during the pandemic. Health centers have administered over 19 million COVID-19 tests and over 21 million COVID-19 vaccinations. We believe health centers have risen to that challenge and delivered results for the country.

Yet, while that important work has been happening, pharmaceutical manufacturers have callously and unlawfully chosen to restrict health centers' access to 340B priced medications. It is puzzling that some of the manufacturers developing COVID-19 vaccines and treatments are the same manufacturers attacking the safety-net providers needed to move our nation out of the pandemic. 340B savings enable health centers to keep their doors open and create flexible funding to meet the unique needs of their communities. We have yet to see evidence of how the current contract pharmacy restrictions benefit patients. It is health centers' 29 million patients who suffer detrimental consequences at the hands of corporate greed.

In a recent survey, health centers' leaders believe that millions of patients will be harmed if drug manufacturers continue to ramp up efforts to dismantle the 340B program. Nearly 86% of health centers utilize contract pharmacies to fulfill their patients' pharmaceutical needs. This figure includes health centers that operate in-house pharmacies. Contract pharmacies serve as an extension of health centers, increasing patient access and ensuring patients can receive discounted medications without creating additional barriers. Health center patients with diabetes, heart disease, and behavioral health needs rely more on 340B program medications than any other patient population. Nearly half of the manufacturer restrictions impact medications that help patients manage and treat diabetes.

In alignment with HHS' strategic Objective 2.2, NACHC requests that the Department act, including by taking the proposed actions detailed below, to protect patients' access to affordable medications and services that prevent and treat chronic diseases like heart disease, diabetes, and respiratory conditions.

Health centers are diligently challenging the drug manufacturers' actions, including by the filing of a petition in HHS's 340B ADR process, amicus participation in manufacturer suits against HHS brought in federal court, and advocacy efforts at the national level. Still, health centers see no end in sight. Manufacturers are doing everything in their power to slow down the ADR process, which is the only forum in which covered entities may legally bring a claim against a manufacturer for violating the 340B statute and be afforded relief. As we watch manufacturers use every tactic to delay the ADR process and otherwise avoid their 340B obligations, NACHC strongly urges HHS to promptly pursue all available enforcement authority against manufacturers that fail to comply with the 340B statute.

Below are specific recommendations we strongly urge the agency to take into consideration:

- Encourage the Office of Inspector General (OIG) to swiftly impose Civil Monetary Penalties (CMP) on pharmaceutical manufacturers. On September 22, 2021, and March 29, 2022, the Health Resources and Services Administration (HRSA) referred seven manufacturers to the OIG to impose CMPs. NACHC appreciates HRSA taking this vital step, but it has not deterred other manufacturers from restricting the sale of 340B-priced drugs to contract pharmacies. The

OIG needs to move forward with issuing CMPs and taking other necessary actions to enforce the 340B statute. We ask that HHS inquire as to why OIG has not swiftly completed its investigation, determined whether the statute is being violated, and acted as necessary to enforce drug manufacturers' 340B statute and PPA obligations.

- Evaluate pharmaceutical manufacturers' failure to comply with the pharmaceutical pricing agreement (PPA) with the Secretary of HHS. Each drug manufacturer's PPA, as required by the 340B statute, requires it to offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price. Additionally, the agreement prohibits a manufacturer from conditioning the offer of 340B discounts upon a covered entity's assurance of compliance with section 340B Program requirements. HHS has made clear in various federal court litigations that it has determined manufacturers to be in breach of their PPAs. NACHC encourages HHS to hold manufacturers accountable for the breach of their PPAs.

Again, on behalf of our 29 million patients, we appreciate your steadfast commitment to health centers and their patients. We respectfully request that HHS continue to work with NACHC and other 340B covered entities to ensure that manufacturers comply with the 340B program and protect access to affordable and quality care for the most vulnerable communities as Congress intended.

Should you or your staff have any questions, please feel free to contact Joe Dunn, NACHC's Senior Vice President for Public Policy & Research, at jdunn@nachc.org. Thank you in advance for your consideration.

Sincerely,

Rachel Gonzales-Hanson
Interim President and Chief Executive Officer

NATIONAL ASSOCIATION OF Community Health Centers

March 21, 2022

Daniel O'Day
Chairman and Chief Executive Officer
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Dear Mr. O'Day:

On behalf of the National Association of Community Health Centers (NACHC) and the nation's 1,400 Community Health Centers, I write today to express our strong opposition to Gilead's recent decision to restrict shipments to 340B contract pharmacies. This decision will place health center patients' ability to receive Gilead drugs at risk and harm the most vulnerable in our society. Your actions are unconscionable, and I would encourage you to reverse course immediately.

Federally Qualified Health Centers serve as the largest primary care network in the nation, serving nearly 29 million patients in underserved and rural communities. Roughly half of health center patients are on Medicaid, over one-fifth are uninsured, and over 90 percent are low-income. Moreover, almost 60 percent are racial and ethnic minorities. Health centers rely on the 340B program to stretch scarce federal resources, just as Congress intended when it established the program 30 years ago. Health centers are statutorily required to reinvest all their 340B savings into patient care to increase access to high-quality, affordable care for medically-underserved populations.

Gilead's recent actions came as a shock to the health center stakeholders across the nation but reflect a continued commitment to profits over patients by the company. This decision is reminiscent of the pricing and marketing strategies that led to the launch of Sovaldi at $1,000 per pill, or $84,000 for a single course of treatment to maximize revenue. This launch price was followed by the introduction of Harvoni at $94,500. As the Senate Finance Committee found in its 2015 bipartisan investigation, fostering broad, affordable access was not a key consideration in setting the wholesale prices. At the conclusion of that investigation, the Committee found that "U.S. sales of Sovaldi and Harvoni, including through public programs and private payers, totaled $20.6 billion after rebates in the 21 months following Sovaldi's introduction[1]."

Your company has made billions from the four hepatitis drugs listed in your recent announcement. Yet you are now taking steps to cut off access to low-income patients who rely on care from health centers and other 340B grantees. This is appalling but just the latest example of corporate greed from a pharmaceutical company.

[1] https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug

Again, I would urge you to reverse this wrongheaded decision prior to the May 2, 2022, effective date before real and lasting damage is done to safety net providers and their patients.

Sincerely,

Rachel Gonzales-Hanson
Interim President and Chief Executive Officer

NATIONAL ASSOCIATION OF Community Health Centers

June 14, 2022

Robert Davis
Chief Executive Officer and President
Merck & Co., Inc.
126 East Lincoln Avenue
Rahway, NJ 07065

Dear Mr. Davis,

On behalf of the National Association of Community Health Centers (NACHC), I write today to express our shock and profound disappointment in Merck's recent decision to target the nation's 1,400 health centers and restrict shipments to their contract pharmacies. This decision threatens health centers' ability to provide affordable, comprehensive primary care and medications to the most vulnerable patients and underserved communities. Merck's 340B Program integrity initiative is based on a fundamental misinterpretation of the 340B statute, which **requires** manufacturers to sell 340B drugs to covered entities without any restrictions, including whether those drugs are dispensed directly or through contracted pharmacies. Health centers are required to deliver pharmaceutical services directly "or through contracts or cooperative arrangements."[1] If Merck truly supports the mission of health centers and the 340B program, we strongly urge you to reconsider your definition of "collaboration" by eliminating all conditions imposed on health centers to receive 340B price drugs at contract pharmacies.

Federally Qualified Health Centers serve as the largest primary care network in the nation, serving nearly 29 million patients in underserved and rural communities. Roughly half of health center patients are on Medicaid, over one-fifth are uninsured, and over 90 percent are low-income. As federal grantees, Community Health Centers have a statutory and regulatory requirement to reinvest all 340B savings back into patient care. For nearly 30 years, health centers have utilized 340B savings to provide access to affordable medications for chronic conditions like diabetes and heart disease. The health center mission stretches beyond just affordable and discounted medications for patients to include providing patients the services and tools to manage and live with those conditions. For patients battling diabetes, health centers use 340B savings to support nutrition classes, over-the-counter medications, transportation assistance, and other services that make life a little bit easier for our patients.

Merck's choice to single out health centers from other grantees – even though health centers are statutorily authorized to deliver required pharmaceutical services through contracted entities - begs the question if this integrity initiative's goal is to increase patient access or increase your company's revenue. The distinction cannot be explained by logic, only greed. As one of the first manufacturers to request claims level data from covered entities, Merck's true intent rings loud and clear. Health centers are collateral damage in a fight between who deserves 340B savings more: manufacturers or pharmacy benefit managers. Health centers have implemented a number

[1] 42 U.S.C. § 254b(a)(1) and (b)(1)(A)(i)(V).

of safeguards to prevent diversion and statutory duplicate discounts in Medicaid and transparently report 340B savings utilization to federal regulators. Currently, there are no requirements for health centers to assist Merck in reducing the amount of rebates paid the pharmacy benefit managers.

Regardless of Merck's unconscionable integrity initiative, health centers will continue to stay true in our values and provide care to all patients, irrespective of their ability to pay. We only ask that Merck honor your contractual and statutory obligations to comply with the 340B statute.

Sincerely,

Rachel Gonzales-Hanson
Interim President and Chief Executive Officer