Congress of the United States
House of Representatives
Washington, DC 20515

September 10, 2020

Stephen J. Ubl
President and CEO
PhRMA
950 F St NW
Suite 300
Washington, DC 20004

Dear Mr. Ubl,

We write today to ask you to work with your member companies to immediately stop measures that violate, or threaten to violate, the law establishing the 340B program. Our Community Health Centers (CHCs) and the vulnerable patient populations they serve depend on the 340B program to provide their patients with access to affordable prescriptions and other services. While pharmaceutical companies continue to rake in massive profits during this pandemic, our communities are suffering.[1] With millions of Americans out of work, many have found themselves unable to pay for care and services they need, turning to CHCs to receive care. As a result, the COVID-19 pandemic has strained our CHCs and other healthcare providers to their breaking point.

Several of your member companies are threatening to shirk their statutory obligations under the 340B program or have begun doing so already. This not only violates the law but also puts CHCs at risk of financial failure. The result is to endanger patients, which is directly counter to the stated purpose of PhRMA to "enable patients to live longer, healthier, and more productive lives."[2] Left unchallenged, these actions by your members—the nation's largest pharmaceutical companies—threaten to end the 340B program as Congress intended it. This intentional undermining of patient care for low-income communities is occurring during one of our nation's greatest public health challenges.

Community Health Centers (CHCs) are the backbone of the health care delivery system for vulnerable patients. They help millions of low-income, uninsured, and under-insured patients access medical, behavioral, and oral health services. CHCs provide care to everyone, regardless of ability to pay, with a focus on providing culturally and linguistically appropriate services to low income and non-English speaking patients.[3] This patient-driven care allows CHCs to provide essential services, but the resources needed to accomplish these goals are often stretched impossibly thin. The 340B program requires drug manufacturers who participate in Medicaid and Medicare to provide certain outpatient drugs to safety net

[1] The Pandemic Hasn't Hampered the Healthcare Industry, Axios, Retrieved at: https://www.axios.com/health-care-industry-coronavirus-pandemic-second-quarter-78f19a89-e7d8-4c91-927b-e6b49f7ee60a.html
[2] About, Pharmaceutical Research and Manufacturers of America, Retrieved at: https://www.phrma.org/en/About
[3] What is a Health Center? Bureau of Primary Care, Health Resources and Services Administration, Retrieved at: https://bphc.hrsa.gov/about/what-is-a-health-center/index.html

providers at significantly reduced prices.[4] These savings are then passed on to patients in the form of reduced prices and other key services.[5]

Over the last two months, various big pharmaceutical companies have taken steps that could make this program nonviable for CHCs. In early July, drug manufacturer Eli Lilly announced that it would stop allowing certain drugs purchased at the 340B price to be delivered to "contract pharmacies."[6] Contract pharmacies are those not owned by the 340B provider.[7] Nationally, estimates suggest that roughly half of drugs that CHCs dispense are dispensed via contract pharmacies. Providing services through contract pharmacies is fully compliant with the statute governing CHCs and helps them provide a variety of services they may not be able to otherwise.[8] Since its initial announcement, Eli Lilly has since expanded this to all of their drugs included in the program without giving prior warning to CHCs.[9]

Eli Lilly led the charge, and many more of PhRMA's companies have followed, implementing new policies which could drain CHC resources and reduce their ability to serve uninsured and underinsured patients. A few days after Eli Lilly's July announcement, Merck, one of the largest drug companies in the world, informed all 340B providers that they would have to begin providing extensive data bi-weekly on all Merck products dispensed by contract pharmacies.[10] These new reporting actions will place an onerous and inappropriate burden on many CHCs, and further restrict patient access both to affordable pharmaceuticals and other services. Merck has explicitly stated that they will use these data to avoid paying voluntary rebates to Pharmaceutical Benefits Managers (PBMs) on drugs purchased under 340B. As these rebates are incentives that manufacturers offer to PBMs to increase sales volume, health centers are under no obligation to assist manufacturers in avoiding them.[11] More importantly, recent history makes clear that once PBMs stop receiving manufacturer rebates on 340B drugs, they respond by reducing reimbursement to health centers – effectively transferring the benefit of the 340B discount from the health center to their own pockets. Thus, Merck is asking safety-net providers to undertake an onerous reporting process in order to save the manufacturer money – at the expense of health centers' own financial stability and their patients' access to care.

Soon after, Sanofi announced that, as of October 1, 2020, the multinational company will refuse to allow any drugs purchased at the 340B price by 340B-eligible providers to be delivered to contract pharmacies, unless the 340B provider submits the same type of data that Merck is requesting. In mid-August, Novartis made similar changes.[12] AstraZeneca also began distributing a letter indicating that it would not ship its products to more than one contract pharmacy per 340B covered entity.[13]

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[4] 340B Drug Pricing Program, Health Resources and Services Administration, Retrieved at: https://www.hrsa.gov/opa/index.html
[5] Health Resources and Services Administration, as cited.
[6] Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs, Eli Lily, Health Resources and Services Administration, Retrieved at: https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf
[7] No discounts for Cialis? Drug sparks spat between 340B Coalition and Eli Lilly, Fierce Healthcare, Retrieved at: https://www.fiercehealthcare.com/hospitals/340b-coalition-combats-moves-by-merck-and-eli-lilly-to-curtail-contract-pharmacies
[8] See 42 U.S. Code § 254b(a)(1): "...the term "health center" means an entity that serves a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing, by providing, either through the staff and supporting resources of the center or through *contracts* or cooperative arrangements…"
[9] Eli Lilly Dramatically Escalates Efforts to Restrict Access to 340B Pricing, 340B Report, Retrieved at: https://340breport.substack.com/p/eli-lilly-dramatically-escalates
[10] Recent Actions by Drug Manufacturers Merck and Eli Lilly Pose a Threat to Safety-Net Provider's Ability to Access Drugs at 340B Prices, RWC-340B, Retrieved at:
[11] Health Centers Seek Meeting With Merck About its 340B Contract Pharmacy Data Request, 340B Report, https://340breport.substack.com/p/health-centers-seek-meeting-with?r=3g59t&utm_campaign=post&utm_medium=email&utm_source=twitter
[12] BREAKING: Novartis the Latest to Seek 340B Contract Pharmacy Claims Data, 340B Report, Retrieved at: https://340breport.substack.com/p/breaking-novartis-the-latest-to-seek?r=3g59t&utm_campaign=post&utm_medium=email&utm_source=twitter
[13] BREAKING: AstraZeneca Raises the Ante in Drug Industry Push Against 340B Contract Pharmacy, 340B Report, Retrieved at: https://340breport.substack.com/p/breaking-astrazeneca-raises-the-ante?r=3g59t&utm_campaign=post&utm_medium=email&utm_source=twitter

Data reporting requirements are not automatically a violation of 340B program requirements; however, if they become too burdensome or are unrelated to 340B compliance, then this quickly changes. CHCs are currently required to report data on their programs at least annually to the Department of Health and Human Services, and this information is available to manufacturers in the program as well. Also, if manufacturers can demonstrate "reasonable cause" for suspecting that a 340B provider may be violating the statute, they may request approval from HRSA to audit that provider.[14] The data requirements of your member companies do not fit into that category and likely violate the 340B law.

Restrictions on the number of contract pharmacies that a manufacturer will provide drugs to is also a likely violation of the 340B statute. The 340B statute places no limitations on manufacturers' obligation to offer drugs to covered entities at the 340B price.[15] For example, it does not allow manufacturers to decide whether to sell 340B-priced drugs to covered entities based on where they are to be shipped. If implemented, this policy will make it more difficult for patients to access prescription drugs and prevent CHCs from working with contract pharmacies, which would hinder their ability to serve their communities.

If our health centers lose the benefits of the 340B discounts, low-income patients will lose access to vital medications, putting their health at risk. Our CHCs have neither the capacity nor the ability to make up the budget shortfalls that will result if your member companies decide to pursue these unconscionable policies. We understand that there have been calls for additional oversight of the 340B program in recent years. Multiple hearings have been held and various legislative proposals have been put forward. Additional oversight of the program may be needed to maintain its integrity, but the fact remains that these new actions to undercut and damage the 340B program are not a legal or viable solution, nor are they necessary.

The COVID-19 pandemic has created new challenges for many in our healthcare system, but our pharmaceutical companies are far from the hardest hit. With this in mind, we have been surprised and disappointed by the steps your member companies have taken to effectively withdraw from the 340B program's future. We ask you to work with your membership to require them to stop these changes and to immediately reverse course.

Because Sanofi has set an October 1, 2020 deadline for implementing many of the most harmful changes, and others, like Eli Lilly, have already begun to undermine the program, this issue is incredibly urgent. As such, we ask that you reply to this letter by September 17, 2020. Thank you for your attention to this important issue, and we look forward to hearing from you.

Very Truly Yours,

KATIE PORTER
Member of Congress

ROSA DeLAURO
Member of Congress

ALAN LOWENTHAL
Member of Congress

PETER WELCH
Member of Congress

[14] 42 U.S. Code § 256b
[15] 42 U.S. Code § 256b

GILBERT R. CISNEROS, JR.
Member of Congress

ANDY LEVIN
Member of Congress

GWEN MOORE
Member of Congress

SUSAN WILD
Member of Congress

MAX ROSE
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ADAM B. SCHIFF
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MARK DeSAULNIER
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DEBBIE DINGELL
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BOBBY L. RUSH
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