

Congress of the United States

Washington, DC 20515

June 29, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human
Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Thomas J. Engels
Administrator
Health Resources and Services
Administration
U.S. Department of Health and Human
Services
5600 Fishers Lane
Rockville, MD 20857

Dear Secretary Kennedy and Administrator Engels:

We write to express our serious concern regarding the recent action by Eli Lilly and Company (Lilly) terminating 340B pricing for covered entities' (CE) that do not comply with its in-house claims data policy. We urge the Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) to take immediate action that will ensure Lilly's compliance with its pricing obligations under the 340B statute and reinstate 340B pricing for all CEs impacted.

As you are aware, Lilly and a growing number of other pharmaceutical companies have announced policies that threaten to bar access to 340B discount pricing for their drugs unless the CE shares claims-level data from in-house pharmacies, including from mixed-use pharmacies for drugs administered in the hospital to outpatients. Lilly notified some CEs that it planned to tell wholesalers within five business days of June 1, 2026, that those CEs were no longer eligible for 340B pricing unless the CEs acceded to Lilly's data demands. On June 18, 2026, Lilly terminated access to 340B pricing for select hospitals, forcing those hospitals to either purchase Lilly drugs at their high list prices or accede to Lilly's data demands. Lilly notified HRSA of its plans to send similar letters to additional CEs in the coming months. All the while, these CE's eligibility for the program has not changed, only Lilly's demands.

Congress established 340B to enable safety-net providers to stretch scarce federal resources, expand access to care, and furnish more comprehensive services to vulnerable patients. The statute requires participating drug manufacturers to offer covered outpatient drugs to eligible covered entities at or below the statutory ceiling price as a condition of their participation in the Medicare and Medicaid programs. Congress did not authorize manufacturers to unilaterally impose additional reporting mandates or data-sharing requirements as a prerequisite for obtaining those discounts.

Lilly's actions effectively condition participation in the 340B program on compliance with manufacturer-imposed requirements that extend beyond the statutory framework established by Congress. Such actions create significant administrative and operational burdens for covered entities, requiring hospitals, health centers, and clinics to devote substantial resources toward

collecting, validating, and transmitting claims information rather than providing patient care. We believe this to be in direct opposition to the intention of the program.

Even more troubling, the suspension of 340B pricing will have immediate and far-reaching consequences for safety-net providers and the patients they serve. Many covered entities rely on 340B savings to support uncompensated care, rural health services, oncology programs, behavioral health treatment, pharmacy services, and other essential programs that would otherwise be difficult to sustain. Disruption to their access to 340B pricing threatens the financial stability of these providers and undermines access to care for underserved communities.

An additional issue with this move is the pretext upon which Lilly is predicating its push for claims data submissions. Lilly, along with other drug manufacturers currently engaged in this same pursuit, is arguing that recent court decisions in the U.S. Court of Appeals for the Third and D.C. Circuits give them the authority to demand access to medical claims data from covered entities as a condition for 340B discount pricing.^{1,2} Their interpretation of these court decisions is an inaccurate reading of what these circuit courts found in their rulings. The decisions in these cases only apply to contract pharmacy claims because the 340B statute does not explicitly cover the issue of contract pharmacy; they do not apply to the in-house pharmacy claims that Lilly is demanding through its threats to cut off 340B pricing. Even within the context of its specific ruling on contract pharmacy, the D.C. Circuit decision specifically acknowledged that while some restrictions on 340B could be considered lawful, it is also possible that some could be so onerous and restrictive toward covered entities' continued participation in the program that they would be unlawful as a result. The push for in-house pharmacy claims data submission would qualify as especially onerous and restrictive.

Lilly also refers to the claims-level data that it is requiring under its in-house policy as “standard information” that covered entities already transmit to others, including payers, relying on guidance published by HRSA in 1994 to support its ability to “request standard information” from covered entities as a “condition” of 340B pricing.^{3,4} 340B hospitals have never routinely submitted to manufacturers the set of claims-level information Lilly demands. Lilly alleges in its letter to HRSA that 70% of covered entities purchasing Lilly medications, or 2,350 entities, are submitting data to Lilly. There are 12,585 covered entities registered in the states that are not exempt from Lilly's policy due to state 340B laws.⁵ If only 2,350 of those entities are submitting data, that means that more than 80% of covered entities in the applicable states are not providing data, demonstrating that Lilly's data requirements are not customary.

The 1994 guidance clearly states that manufacturers may not “single out covered entities” for “restrictive conditions that would undermine the [340B] statutory objective,” but “may include provisions in their contracts with covered entities that address customary business practice, request standard information, or include other appropriate contract provisions.”⁶ The guidance also explicitly prohibits manufacturers from requiring CEs to provide assurances that they comply with 340B provisions as a condition of receiving 340B pricing.⁷ The guidance does not

1. Novartis Pharmaceuticals Corp. v. Johnson (formerly Novartis Pharmaceuticals Corp. v. Becerra) No. 21-5299, U.S. Court of Appeals for the D.C. Circuit. <https://law.justia.com/cases/federal/appellate-courts/cadc/21-5299/21-5299-2024-05-21.html>

2. Sanofi Aventis U.S. LLC v. U.S. Department of Health & Human Services, No. 21-3167, U.S. Court of Appeals for the Third Circuit. <https://www2.ca3.uscourts.gov/opinarch/213167p.pdf>

3. Letter from Eli Lilly and Co. to Thomas J. Engels, Adm'r, Health Res. & Servs. Admin. (June 1, 2026), <https://www.lilly.com/news/stories/lilly-in-house-claims-data-requirement-upcoming-action>.

4. *Id.* Footnotes 2, 5.

5. HRSA Office of Pharmacy Affairs, 340B OPAIS, “Covered Entities”, <https://340bopais.hrsa.gov/SearchCe>

6. 59 Fed. Reg. 25,110, 25,114 (May 13, 1994) (appearing in a section titled “Manufacturer's Contracts Regarding 340B Compliance.”).

7. *Id.*

support manufacturer demands for data that CEs may share with payers or other third parties pursuant to entirely different business relationships that were established over decades.

Congress has consistently supported the integrity of the 340B program and its role in strengthening the health care safety net. Allowing manufacturers to condition statutory discounts on compliance with unilateral reporting requirements risks establishing a precedent that could fundamentally alter the operation of the program without congressional authorization.

Accordingly, we respectfully request that HRSA and HHS take immediate action to reinstate covered entities' uninterrupted access to 340B pricing for eligible drugs and use all available enforcement authorities to ensure manufacturers comply with their obligations under Section 340B of the Public Health Service Act. HRSA and HHS should clarify that manufacturers may not threaten access to 340B pricing based on the submission of claims data or other requirements not expressly authorized by statute.

The 340B program remains a critical tool for supporting hospitals, health centers, and other providers that serve vulnerable populations. We appreciate your prompt attention to this matter and look forward to your response.

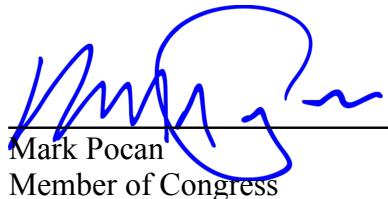
Sincerely,



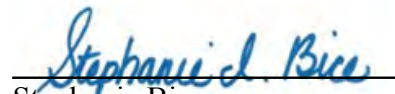
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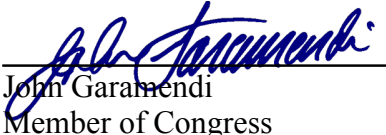
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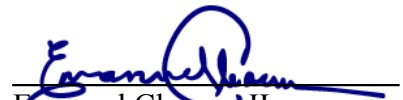
John Garamendi
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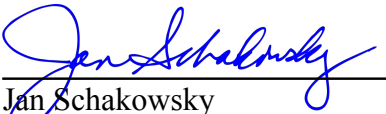
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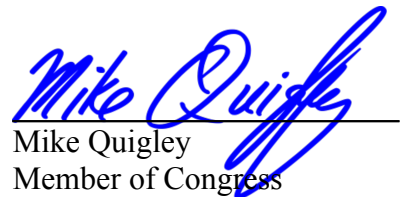
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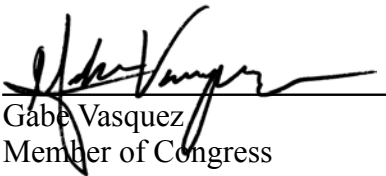
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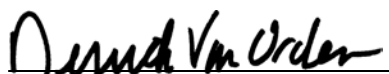
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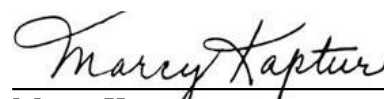
Donald Norcross
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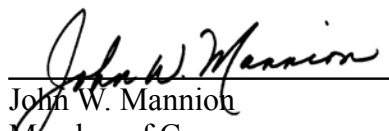
Mike Thompson
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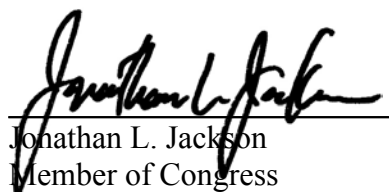
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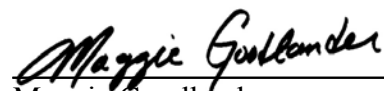
Jonathan L. Jackson
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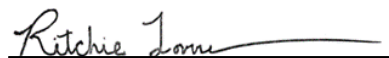
Gwen S. Moore
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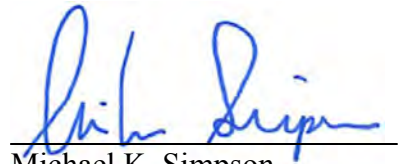
Ritchie Torres
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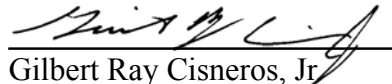
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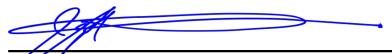
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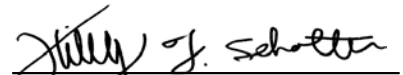
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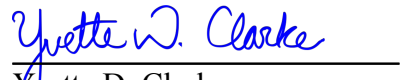
Jefferson Van Drew
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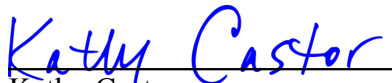
Hillary P. Scholten
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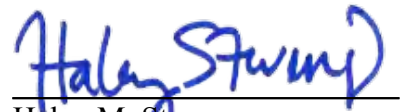
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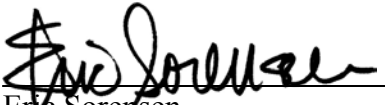
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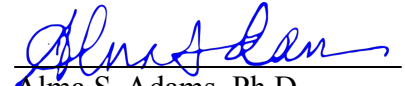


Stephen F. Lynch
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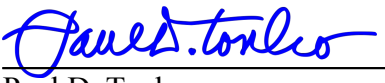
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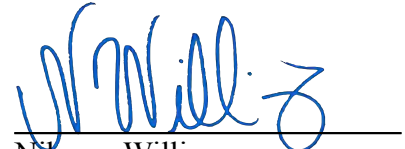

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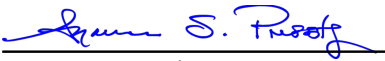

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George Latimer
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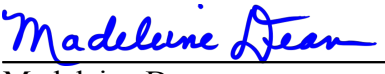

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Paul D. Tonko
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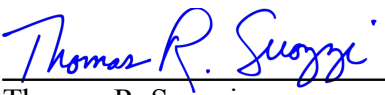

Nikema Williams
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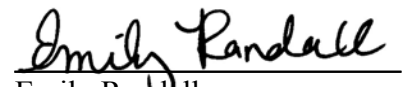

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Madeleine Dean
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Raja Krishnamoorthi
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Thomas R. Suozzi
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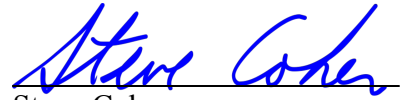

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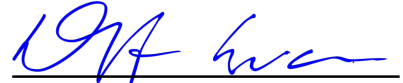
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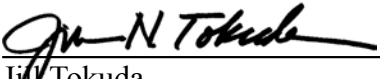
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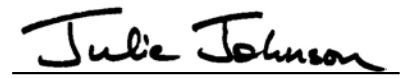
Mary Gay Scanlon
Member of Congress



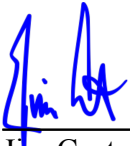
Dwight Evans
Member of Congress



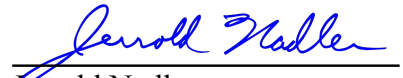
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Julie Johnson
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Jim Costa
Member of Congress



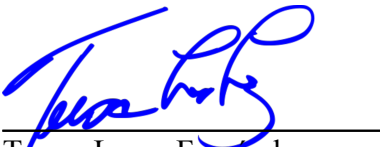
Ferrol Nadler
Member of Congress



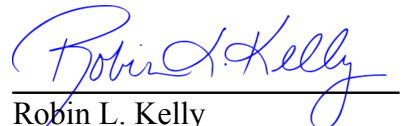
Randy Beestra
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Chris Deluzio
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Teresa Leger Fernandez
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Robin L. Kelly
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