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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

September 23, 2024

VIA ELECTRONIC TRANSMISSION

David A. Ricks
Chair and Chief Executive Officer
Eli Lilly and Company
Lilly Corporate Center
893 S. Delaware Street
Indianapolis, IN 46285

Mr. Ricks:

I write to request information regarding your company's participation in the 340B Drug Pricing Program (340B Program). The 340B Program was designed to allow covered entities, like certain hospitals, clinics, and community health centers, to "obtain lower prices on the drugs that they provide for their patients," and to "enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] As a condition of participation in Medicaid, pharmaceutical manufacturers are required to sell drugs at a significant discount to covered entities to allow those entities to use these savings to care for America's most vulnerable patients, by either offering discounted drugs or by providing charity care to patients.

In 2010, the Health Resources and Services Administration (HRSA), the agency charged with administration and oversight of the 340B Program, issued new guidance that allowed covered entities to enter into agreements with an unlimited number of contract pharmacies.[2] As a result, the number of contract pharmacies participating in the 340B Program has skyrocketed. To illustrate, between 2009 and 2022, the number of retail pharmacies participating in the 340B Program grew exponentially from 789 to 25,775—a 3,166 percent increase in less than 15 years.[3] While HRSA intended for its 2010 guidance to "create wider patient access by having more inclusive arrangements in their communities,"[4] its decision to significantly expand the program has led to allegations that covered entities are using the 340B Program to generate profits for themselves rather than invest in programs for low-income or the uninsured patients.

[1] H.R. REP. NO. 102-384, pt. 2, at 7, 12 (1992).
[2] Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).
[3] Sayeh Nikpay et al., *Trends in 340B Drug Pricing Program Contract Growth Among Retail Pharmacies From 2009 to 2022*, JAMA HEALTH FORUM (Aug. 4, 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10403775/.
[4] Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010).

Recently, a number of pharmaceutical manufacturers, including Eli Lilly, announced restrictions on covered entities that use more than one contract pharmacy to distribute 340B drugs. Manufacturers claim that the growth of contract pharmacies resulted in an increase in unlawful duplicate discounts and the dispensing of 340B drugs to ineligible patients (or, diversion). Manufacturers further claim that HRSA does not conduct adequate oversight over contract pharmacies and that their restrictions are necessary to prevent abuses in the 340B Program. Eli Lilly, in particular, has alleged that distributing 340B drugs to an unlimited number of contract pharmacies has caused "thousands of duplicate Medicaid discounts with refusal to issue refunds for agreed-upon amounts, gaming of Lilly's [distribution policies] and general lack of accountability for vendors and third-party administrators used by covered entities."[5]

On September 1, 2020, Eli Lilly announced its Pharmacy Limited Distribution System, saying that it would no longer distribute 340B drugs directly to contract pharmacies and that it would distribute these drugs only to covered entities and their child sites and to contract pharmacies wholly owned by the covered entity.[6] A little over a year later, on December 10, 2021, Eli Lilly announced it would again permit 340B drugs to be distributed directly to an unlimited number of contract pharmacies so long as certain claim-level data was submitted by covered entities back to Eli Lilly.[7] However, on November 6, 2023, Eli Lilly reverted to its previous September 2020 policy of limiting 340B drug distribution to only covered entities and their child sites and to wholly-owned contract pharmacies.[8] Most recently, on June 19, 2024, Eli Lilly announced further restrictions, prohibiting 340B drug distribution to wholly-owned contract pharmacies and thus only allowing 340B drugs to be distributed directly to covered entities and their child sites.[9] Covered entities that do not have an in-house retail pharmacy may designate a single contract pharmacy to which340B drugs may be distributed.[10]

The exception to this policy is for "penny priced" insulin products, which Eli Lilly continues to distribute to an unlimited number of contract pharmacies as long as: (1) 340B patients can acquire the insulin through the contract pharmacy at the 340B acquisition price, (2) neither the covered entity nor the contract pharmacy marks up or charges a dispensing fee, and (3) no insurer or payer is billed for the insulin.[11] Eli Lilly sells many of its insulins for pennies per milliliter (mL) to 340B

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[5] *Update to Lilly's Contract Pharmacy Limited Distribution System*, ELI LILLY & COMPANY (June 19, 2024), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/20240619-lilly-claims-requirement-eff-20240701.pdf.

[6] *Limited Distribution Plan Notice for Eli Lilly and Company Products*, ELI LILLY & COMPANY (Sept. 1, 2020), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/200901-eli-lilly-and-company_limited-distribution-plan_public-notice.pdf.

[7] *Update to Eli Lilly and Company Contract Pharmacy Policy*, ELI LILLY & COMPANY (Dec. 10, 2021), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/lilly-340b-announcement--updated-010321.pdf.

[8] *Notice of Reinstatement of Lilly's Prior Contract Pharmacy Limited Distribution System*, ELI LILLY & COMPANY (Nov. 6, 2023), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/2023116-update-eff-20231116.pdf.

[9] *Update to Lilly's Contract Pharmacy Limited Distribution System*, ELI LILLY & COMPANY (June 19, 2024), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/20240619-lilly-claims-requirement-eff-20240701.pdf.

[10] *Id.*

[11] *Update to Lilly's Contract Pharmacy Limited Distribution System*, ELI LILLY & COMPANY (June 19, 2024), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/20240619-lilly-claims-requirement-eff-20240701.pdf.

covered entities, for example, selling Humalog for 10 cents per vial.[12] However, it alleges that covered entities are not passing these savings to low-income and uninsured patients. In fact, in 2023, the company offered an example to the Connecticut General Assembly that contract pharmacies mark up the price of its insulins over 330,000 percent, charging one uninsured patient over $500.[13]

Furthermore, the increase in use of GLP-1 drugs, including Eli Lilly's Mounjaro, has led to diabetes drugs experiencing huge growth in the 340B Program.[14] Diabetes drugs had 40 percent 340B year-over-year growth in 2023, accounting for $9 billion in 340B sales.[15] Of these 340B sales, GLP-1 drugs were nearly $5 billion in 2023, compared to about $1 billion in 2021.[16] Unlike insulin, Mounjaro is one of Eli Lilly's highest grossing drugs each year, generating $5.2 billion in sales in 2023,[17] and estimated to hit $34 billion in sales by 2029.[18] Also unlike insulin, Mounjaro is subject to Eli Lilly's Pharmacy Limited Distribution System, meaning that Eli Lilly will only distribute the drug to covered entities and their child sites (or the above-mentioned designated single contract pharmacy) in the 340B Program.

In order to better understand how Eli Lilly is participating in the 340B Program and the impact of its policies regarding the distribution of insulin and Mounjaro in the 340B Program, please respond to the following questions on a question-by-question basis, no later than October 15, 2024. I ask that all documents be unredacted, produced in electronic form, and Bates stamped.

1. For each year beginning in 2018, please produce an Excel document with a detailed accounting of Eli Lilly's participation in the 340B Program, including the following information per calendar year:

    a. A list of full packages, identified by National Drug Code (NDC), of drugs sold to covered entities at the 340B ceiling or sub-ceiling price;
    b. The price of each of the packages identified in question (1)(a) at the wholesale acquisition cost (WAC);
    c. The amount of the 340B price concessions given to covered entities for each of the drug sales identified in question (1)(a);

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[12] *How Lilly is Helping Discounts Reach People With Diabetes in 340B*, ELI LILLY & COMPANY (July 26, 2021), https://www.lilly.com/news/stories/lilly-helps-discounts-reach-people-with-diabetes-in-340B.
[13] Letter from Kathy Bilotas, Senior Director State Government Affairs, Eli Lilly & Company, to Sen. Anwar et al (Mar. 13, 2023), https://www.cga.ct.gov/2023/phdata/TMY/2023HB-06669-R000313-Bilotas,%20Kathy,%20Senior%20VP%20of%20Government%20Affairs-Eli%20Lilly-Opposes-TMY.PDF.
[14] Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023*, IQVIA 4 (2024), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/iqvia-update-on-size-of-340b-program-report-2024.pdf.
[15] *Id.*
[16] *Id.* at 5.
[17] Press Release, Eli Lilly & Company, Lilly Reports Strong Fourth-Quarter 2023 Financial Results and Provides 2024 Guidance (Feb. 6, 2024), https://investor.lilly.com/static-files/fd0ef78b-4c48-4a15-b65b-8bf9b6ed26d2.
[18] *Eli Lilly's double impact: Mounjaro and Donanemab set to outshine market rivals, says GlobalData*, GLOBALDATA (Apr. 17, 2024), https://www.globaldata.com/media/pharma/eli-lillys-double-impact-mounjaro-donanemab-set-outshine-market-rivals-says-globaldata/.

d. The 340B price paid as a percentage of WAC for each of the drug sales identified; and
e. A denotation of whether each drug was distributed to covered entities and their child sites, wholly-owned pharmacies, or contract pharmacies for each drug sale identified.

2. For each calendar year beginning in 2018, please produce the above information separately for all 340B drugs sold to the following covered entities: Cleveland Clinic, Bon Secours Mercy Health, Sun River Valley, and Yakima Valley Farm Workers Clinic.

3. Please provide all internal communications and documents related to Eli Lilly's decision to impose restrictions on distribution of 340B drugs to contract pharmacies and how these policies were created and implemented.

    a. Please provide numerical data, on a month-by-month basis, on how this policy has affected the volume of your 340B sales since the date of implementation.
    b. Please provide numerical data and specific examples of how this policy has resulted in fewer duplicate discounts or diversion of 340B drugs to ineligible patients.

4. Currently, the vast majority of covered entities purchase 340B drugs through the virtual inventory/replenishment model. Please explain any difficulties this model has for Eli Lilly and if there is a different model that would be more efficient for the sale and distribution of 340B drugs.

    a. How does Eli Lilly identify which purchases are made through 340B under this model?
    b. How does the use of contract pharmacies versus the use of in-house pharmacies affect this model?

5. Please describe Eli Lilly's policies and procedures for identifying duplicate discounts with Medicaid and diversion to ineligible patients.

    a. What has been the company's experience in resolving these issues with covered entities, state Medicaid agencies, and/or HRSA?
    b. Please provide the financial impact of the identified duplicate discounts and diversions in your response.

6. How does your company intend to monitor that 340B pricing is not duplicated with the Inflation Reduction Act's introduction of the Maximum Fair Price and inflation rebate penalties?

7. How has HRSA's 2010 guidance allowing for an unlimited number of contract pharmacies affected how Eli Lilly conducts compliance audits on covered entities to monitor the occurrence of duplicate discounts and diversion under the 340B Program?

8. Please explain the actions that Eli Lilly takes when instances of duplicate discounts and/or diversion are identified. What are the procedures and process by which covered entities remit payments to manufacturers in instances of duplicate discounts and/or diversion?

9. Has Eli Lilly undertaken any internal 340B audits on the company's participation in the 340B Program over the past five years? If so, please explain the results in detail. If not, please explain why you did not perform any internal audits.

10. Please explain how the requirements of the 340B Program affect Eli Lilly's contracts with Pharmacy Benefit Managers (PBMs) and the rebates offered outside of the 340B Program.

Thank you for your attention to this important matter.

Sincerely,

Bill Cassidy, M.D.

Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health,
Education, Labor, and Pensions