United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

September 23, 2024

VIA ELECTRONIC TRANSMISSION

Robert A. Bradway
Chairman and Chief Executive Officer
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320

Mr. Bradway:

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 Amgen, 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 conduct adequate oversight over contract pharmacies and that their restrictions are necessary to prevent abuses in the 340B Program.

On December 1, 2021, Amgen announced that it would no longer distribute 340B drugs to contract pharmacies for non-federal grantee covered entities, and that it would only distribute the drugs directly to the covered entities.[5] Federal grantee covered entities were exempt from this policy and non-federal grantees without an in-house pharmacy location were able to select one contract pharmacy where 340B drugs could be distributed to.[6] Then, on February 23, 2024, Amgen announced that federal grantees were no longer exempt from these restrictions and that it would only distribute 340B drugs directly to covered entities or their single designated contract pharmacy, if eligible.[7] However, Amgen's policy only applies to six of its self-administered drugs.[8]

Enbrel, a drug used to treat rheumatoid arthritis, is one of the drugs included in Amgen's 340B policy restricting distribution directly to contract pharmacies. Enbrel is Amgen's highest grossing drug in the United States, accounting for $3.7 billion in sales in 2023.[9] Anti-arthritic drugs (including Enbrel), as a drug class, experienced 10 percent 340B year-over-year growth in 2023 and represented $6 billion in 340B sales.[10] Enbrel and other immunosuppressants also accounted for 16 percent of 340B spending at hospital-based facilities in 2021.[11]

In order to better understand how Amgen is participating in the 340B Program and the impacts of its policies regarding the distribution of Enbrel, 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 Amgen's participation in the 340B Program, including the following information per calendar year:

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[5] Letter from Jennifer Norton, Vice President, US Value and Access, Amgen, to Amgen Customers (Dec. 1, 2021), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/amgen-letter-with-340b-ndcs.pdf.
[6] *Id.*
[7] Letter from David Zimmer, Vice President, US Value and Access, Amgen, to Amgen Customers (Feb. 23, 2024), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/20240223-federal-grantee-eff-20240319.pdf.
[8] *Id.*
[9] *Amgen Reports Fourth Quarter and Full Year 2023 Financial Results*, AMGEN (Feb. 6, 2024), https://www.amgen.com/newsroom/press-releases/2024/02/amgen-reports-fourth-quarter-and-full-year-2023-financial-results.
[10] 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.
[11] Rebecca Sachs & Joshua Varcie, *Spending in the 340B Drug Pricing Program, 2010 to 2021*, CONGRESSIONAL BUDGET OFFICE (June 17, 2024) (on file with Committee).

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 those 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);
d. The 340B price paid as a percentage of WAC for each of those sales; 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 year beginning in 2018, please produce the above information separately for any 340B drugs you 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 Amgen'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 it was implemented.
    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 Amgen and if there is a different model that would be more efficient for the sale and distribution of 340B drugs.

    a. How does Amgen 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 Amgen'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 unlimited numbers of contract pharmacies affected how Amgen 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 Amgen takes when it identifies instances of duplicate discounts and/or diversion. What are the procedures and process by which covered entities remit payments to manufacturers in instances of duplicate discounts and/or diversion?

9. Has Amgen undertaken any internal 340B audits on the company's participation in the 340B Program in 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 affects Amgen'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