



Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005

April 16, 2024

Chair Klein and Members of the Senate
Commerce and Consumer Protection Committee
MN Capitol Building
St. Paul, MN 55115

RE: Opposition to SF 5301: 340B Mandate

Dear Chair and Commerce Committee Members

I am writing today on behalf of the Biotechnology Innovation Organization (BIO), a national trade association for the biotechnology industry, representing over 1000 companies and academic institutions involved in the research and development of innovative healthcare, agriculture, industrial, and environmental biotechnology products. BIO and its members would like to express our opposition the 340B provisions incorporated in the senate commerce omnibus bill as it distorts the 340B program beyond the scope of federal statute and erroneously mischaracterizes manufacturers' responsibilities within the distribution process.

SF 5301 would codify the practice of pharmacies contracting with 340B covered entities, which is not included in the federal 340B statute and is the subject of current litigation.

Contract pharmacies have contributed to exponential growth in the program. In 2014, discounted purchases under the 340B Drug Discount Program totaled roughly \$9 billion.¹ In 2021, the program reached approximately \$44 billion, equating to approximately 14% of gross US sales of brand-name drugs.² According to an October 2020 study, the number of contract pharmacy arrangements in the program grew by 4,228% from 2,321 in 2010 to 101,469 in 2020,³ and as of July 2023 this number increased to 194,016.⁴ Additionally, the number of unique pharmacy locations has grown from approximately 1,300 in 2010 to roughly 33,000 in 2023.⁵ According to one analysis, "the average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72% compared with just 22% for non-340B medicines dispensed through independent pharmacies."⁶ This

¹ Fein, Adam, "New HRSA Data: 340B Program Reached \$29.9 Billion in 2019; Now Over 8% of Drug Sales," Drug Channels, June 9, 2020. Accessed: <https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html>

² Fein, Adam, "The 340B Program Climbed to \$44 Billion in 2021—With Hospitals Grabbing Most of the Money," Drug Channels, August 15, 2022. Accessed: January 4, 2023. <https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html#:~:text=For%202021%2C%20discounted%20purchases%20under,of%20these%20skyrocketing%20340B%20purchases.>

³ Vandervelde, Aaron, et al., "For-Profit Pharmacy Participation in the 340B Program," BRG Group, October 2020. <https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/> (Accessed: April 25, 2023)

⁴ Fein, Adam, "Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market," July 11, 2023. Accessed July 13, 2023. <https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html>

⁵ Ibid.

⁶ Vandervelde, October 2020.

explosive growth has occurred because it is extremely profitable for pharmacies to share in the 340B discount provided to covered entities. A contract pharmacy's average gross profit margin on a 340B medicine dispensed at a contract pharmacy is estimated at 72%, compared to just 22% when dispensed by an independent pharmacy.⁷ SF 5301 would further legitimize and expand contract pharmacy arrangements, which would benefit contract pharmacies and covered entities, not the vulnerable patients the 340B program seeks to protect and serve.

SF 5301 prohibits manufacturers from withholding 340B-discounted drug products from a pharmacy that has contracted with a 340B covered entity. The issue of contract pharmacy is currently being litigated in several federal courts, as there is no statutory requirement for manufacturers to extend 340B prices to contract pharmacies. Contract pharmacy was created through federal guidance. A sub-regulatory guidance that the Health Resources and Services Administration (HRSA) – the agency that issued it— itself has acknowledged is legally unenforceable.⁸ We oppose legislation to address federal 340B issues, especially those that are not in the federal statute and are subject to pending litigation.

Further, SF 5301 contains language that erroneously implies manufacturers can select which pharmacies can participate as a 340B contract pharmacy. Manufacturers are not involved with contracts between pharmacies and another provider, including a 340B covered entity. The 340B program's requirement is for manufacturers to provide discounted drugs to 340B covered entities, and they are not required to facilitate distribution to their contract pharmacies. Therefore, it is not appropriate for legislation to dictate whether a manufacturer must allow for distribution of drugs to any pharmacy regardless of participation in the 340B program.

For these reasons, BIO opposes the 340B provisions included in the senate commerce omnibus bill. Please do not hesitate to contact us for any further information.

Sincerely,

/S/

Patrick Plues
Vice President, State Government Affairs
The Biotechnology Innovation Organization (BIO)

⁷ Ibid.

⁸ "HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable," 340B Report. AAFCPAs, July 9, 2020.