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March 11, 2025

VIA ELECTRONIC SUBMISSION

Senator Judy Lee, Chairman Human Services Committee

North Dakota State Capitol 600 E. Boulevard Ave Bismarck, ND 58505

Re: House Bill 1473

Dear Chair Lee and Members of the Human Services Committee:

Bristol Myers Squibb ("BMS") strongly opposes HB 1473 that includes provisions on the federal 340B program. These provisions would enable unchecked growth in abuses of the federal 340B Program in North Dakota and would not help vulnerable patients but rather enhance profits of big-chain pharmacies and others who exploit the 340B program for financial gain.

At BMS, we are inspired by a single vision—transforming patients' lives through science. We are in the business of breakthroughs—the kind that transform patients' lives through lifesaving, innovative medicines in areas such as hematology, oncology, immunology, cardiovascular, and neuroscience. Our talented employees come to work every day dedicated to the mission of discovering, developing, and delivering innovative medicines that help patients prevail over serious diseases. In North Dakota, we partner with patients and scientific experts on the ground to conduct clinical studies across multiple therapeutic areas to help patients with chronic conditions.

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In 1992, the United States Congress created the federal 340B program with the worthy goal of supporting uninsured, low-income, and other vulnerable patients by ensuring that certain providers (known as "covered entities") receive discounts on outpatient drugs for the benefit of those patients. Unfortunately, the 340B program has since become subject to vast profiteering and abuse, all at the expense of the vulnerable patients Congress meant to help. Not just covered entities, but other enterprising intermediaries, including for-profit entities known as "contract pharmacies," have exploited the program for their private gain. Indeed, national big-chain pharmacies have publicly disclosed that 340B is "material" to their bottom line, signaling that recent program integrity measures to keep widespread abuse in check is a risk to their pursuit of profits over patient benefit. Legislation like the provisions in HB 1473 will only further exacerbate these problems.

For the reasons set forth below, we respectfully request that you consider the serious negative implications that could result from the implementation of the 340B provisions in HB 1473 and continued abuses of the 340B program in North Dakota and oppose this legislation.

The 340B provisions in HB 1473 seek to regulate a pharmaceutical manufacturer's participation in the federally regulated 340B program in a way that both conflicts with the federal 340B statute and, even more importantly, enhances the profiteering and abuse that has undermined Congressional purpose. Rather than helping push back against the exploitation of the 340B program (e.g., requiring actual direct support of vulnerable patients in affording outpatient medicines), the provisions would instead protect and expand such exploitation through the unlimited and unregulated use of contract pharmacies, all without consideration of any common-sense measures to combat well-documented abuses.

Indeed, **contract pharmacies have become a vehicle to dramatically expand the scope and scale of their sale of drugs purchased with 340B program discounts**, allowing them to retain the resulting profits or deploy them for purposes unrelated to the 340B program's goal of supporting uninsured and other vulnerable populations in affording outpatient drugs. The contract pharmacies themselves, which benefit from lucrative contracts to provide access to discounted drugs, are often large, for-profit national pharmacy corporations, with two of America's largest pharmacies providing more than 60 percent of contract pharmacy services.¹ In fact, since 2019, in-state contract pharmacy arrangements increased 83% while out-of-state arrangements for in-state 340B covered entities grew 104%.²

Reports from the Government Accountability Office (GAO) and the Department of Health and Human Services Office of Inspector General (OIG) highlight the many troubling issues with the program. For example, the GAO found that a lack of adequate oversight and transparency and the "identified noncompliance at contract pharmacies raises questions about now the effectiveness of covered entities' current oversight practices."³ The GAO further found that "operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."⁴ The OIG has raised similar concerns and has testified before Congress stating that there are "a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements."⁵

After over a decade of growing unlawful and documented abuses fostered by runaway nonadherence, manufacturers established permissible practices setting forth reasonable conditions on contract pharmacy arrangements for the purchase of their 340B outpatient

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¹ Adam Fein, Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?, *Drug Channels* (July 14, 2020), available at: https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html.

² Analysis of HRSA OPAIS data.

³ GAO, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement." (2018). https://www.gao.gov/assets/gao-18-480.pdf

⁴ U.S. Government Accountability Office (GAO), "Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement." (2011). GAO-11-836 Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement.

⁵ HHS OIG, "Examining Oversight Reports on the 340B Drug Pricing Program. Testimony of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections before the United States Senate Committee on Health, Education, Labor and Pensions." (2018). Examining Oversight Reports on the 340B Drug Pricing Program (05/18) (hhs.gov).

drugs. Federal court decisions have since confirmed the legality of these practices.⁶ In fact, the United States Court of Appeals for the DC Circuit recently joined the 3rd Circuit Court of Appeals by upholding the reasonable conditions set by manufacturers stating that "[S]ection 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities." Now, the 340B interests—which themselves may be funded by discounts meant to go to vulnerable patients—are seeking to use state legislation as an alternative path to profit from contract pharmacy arrangements—without actual regard for the vulnerable patients meant to benefit from 340B-discounted purchasing. But as a federal appellate court explained when upholding manufacturer practices supporting program integrity: "Though covered entities cannot squeeze as much revenue out of [the 340B Program] as they once could, drug makers need not help them maximize their 340B profits." By contrast, the 340B provisions in HB 1473 would seek to disallow the reasonable conditions allowed under federal law and seek instead to encourage the maximizing of 340B "profits."

We at BMS are committed to meaningful and common-sense reforms that will protect the 340B program and ensure that its benefits reach those patients it was intended to serve. By contrast, the 340B provisions in HB 1473 would do nothing to address these issues. To the contrary, the legislation, if enacted, would allow current abuses of the program to continue to grow unchecked while increasing costs to North Dakota employers and workers by more than \$67 million annually.⁷

We respectfully urge you to oppose HB 1473.

Sincerely,

/s/ Genevieve Plumadore

Director, State & Local Government Affairs Upper Midwest Region Bristol Myers Squibb

⁶ See, Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs., Nos. 21-3167 & 21-3379 (3d Cir. Jan. 30, 2023).

⁷ IQVIA, "The Cost of the 340B Program to States. (February 2025), available at: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cost-of-340b-to-states-whitepaper-2025.pdf.