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DATE: March 13, 2025

TO: The Honorable Brenda Dietrich
Members of the Senate Committee on Financial Institutions & Insurance

FROM: Jannie Oosthuizen, President, Merck Human Health, U.S.

RE: Written Opponent Testimony on SB 284

Thank you for the opportunity to submit written testimony in opposition to Senate Bill 284.

Merck, as a U.S. headquartered health care company that delivers innovative health solutions through our prescription medicines, vaccines biologic therapies, and animal health products, respectfully opposes SB 284, a bill that would require pharmaceutical manufacturers to offer 340B pricing to all pharmacies that contract with 340B covered entities. As a large employer in Kansas, with over 500 employees across three sites in the state, the growth and misuse of the 340B program has a critical impact on our ongoing investment in our operations.

Merck is a strong supporter of the program as a mechanism for helping safety net facilities provide health care services to the vulnerable populations they serve. However, we continue to believe the program has grown well beyond its intended purpose and is in desperate need of greater transparency, oversight, and accountability to ensure it continues to serve these patients and remains sustainable for the long term.

Congress established the 340B Program in 1992.[1] Manufacturers of prescription drugs and biologicals, such as Merck, are required to participate in the 340B Program as a condition of having their products covered and reimbursed under state Medicaid programs and the Medicare Part B program.[2] Manufacturers enter into the 340B Program by signing a form agreement with the HHS Secretary—the

[1] *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602(a), 106 Stat. 4943, 4967 (Nov. 4, 1992) (adding Section 340B to the Public Health Service Act, codified at 42 U.S.C. § 256b).

[2] 42 U.S.C. § 1396r–8(a)(1), (a)(5).

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Pharmaceutical Pricing Agreement (PPA)—that is used nationwide for all manufacturers participating in the program.[3]

The 340B statute requires participating manufacturers to charge no more than a statutorily calculated "ceiling price" when their covered outpatient drugs are purchased by a 340B covered entity for use by the covered entity's patients.[4] The 340B statute enumerates the categories of healthcare providers that qualify as "covered entit[ies],"[5] generally focusing on "specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans."[6] This enumerated list of covered entity types does not include, and never has included, third-party pharmacies. But in 2010, nearly 20 years after the 340B Program's inception, the U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA), which administers the 340B Program, issued non-binding guidance purporting to permit 340B covered entities to enter into unlimited "contract pharmacy" arrangements with third-party, for-profit pharmacies.[7] Subsequently, the 340B Program has experienced explosive growth, with massive proliferation of contract pharmacy arrangements and transactions. For example, in 2018 the Government Accountability Office (GAO) found that the use of contract pharmacies had "increased more than fifteen-fold, from about 1,300 to approximately 20,000" since 2010.[8] Another analysis found that, from 2010 to 2020, such arrangements grew by more than 4,000%, from 2,321 to 100,451 nationwide.[9] In Kansas alone, 340B covered entities have 1,123 contract pharmacy arrangements, with almost 50% of them located out-of-state. The 340B Program "is now unambiguously the second-largest government pharmaceutical program, based on net drug spending," surpassing even the Medicaid Drug Rebate Program.[10] Numerous government reports and audits have found that these contract pharmacy arrangements lead to increased instances and risks of statutorily prohibited diversion and duplicate discounts.

The question of whether manufacturers can be required to ship 340B drugs to contract pharmacies is currently being litigated in several courts across the country. In January 2023, the U.S. Court of Appeals

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[3] 42 U.S.C. § 256b(a)(1); *see also Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) ("PPAs are not transactional, bargained-for contracts. They are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS.").

[4] 42 U.S.C. § 256b(a)(1), (a)(4), (a)(5)(B), (b)(1).

[5] *See* 42 U.S.C. § 256b(a)(4).

[6] H.R. Rep. No. 102-384(II) at 12 (emphasis added).

[7] Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

[8] GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 10 (June 2018), https://www.gao.gov/assets/700/692697.pdf.

[9] Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program*, BRG, at 4 (Oct. 2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRGForProfitPharmacyParticipation340B_2020.pdf.

[10] Adam Fein, *Exclusive: The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023), https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-.

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for the Third Circuit specifically found that the federal statute "does not require delivery to an unlimited number of contract pharmacies" and "Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies."[11] Legal activity around this issue involving the federal government and states is ongoing, which is why we believe it was prudent of the Kansas Legislature to let the courts decide these issues before implementing its own state policy.

SB 284 is enormously problematic from a public policy perspective. It purports to compel manufacturers to honor unlimited contract pharmacy arrangements in the 340B Program—arrangements that, as noted, dramatically increase the risks for diversion and duplicate discounts that are expressly prohibited by the federal 340B statute[12] and that very often do not result in any benefits for patients.[13] It should be noted that eighty percent (80%) of 340B hospitals in Kansas are below the national average for charity care spending. These contract pharmacy relationships

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[11] Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs., 58 F.4th 696 (3d Cir. 2023)
[12] 42 U.S.C. § 256b(a)(5)(A)–(B).

[13] *See, e.g.*, GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836, at 28 (Sept. 2011), *available at* https://www.gao.gov/assets/gao-11-836.pdf ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."); HHS, Office of Inspector General (OIG), *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 1–2 (Feb. 2014), *available at* https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf (finding that "contract pharmacy arrangements create complications in preventing diversion" and "duplicate discounts"); *id.* at 2 ("[W]e found that some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies" and "that most covered entities in our study do not conduct all of the oversight activities recommended by [the federal government]"); GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 44 (June 2018), *available at* https://www.gao.gov/assets/700/692697.pdf (concluding that "[t]he identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices"); *id.* at 30 (reporting that, of the 55 340B covered entities that responded to GAO's questionnaire, about half of them ***did not offer any discounts*** to patients—including low-income, uninsured patients—on 340B drugs dispensed at their contract pharmacies); HHS OIG, Testimony of Ann Maxwell Before the U.S. Senate Committee on Health, Education, Labor, and Pensions, Examining Oversight Reports on the 340B Drug Pricing Program, at 5 (May 15, 2018), *available at* https://oig.hhs.gov/testimony/docs/2018/maxwell-testimony05152018.pdf (stating that the HHS OIG "has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements"); HHS, Centers for Medicare & Medicaid Servs. (CMS), Centers for Medicaid and CHIP Services (CMCS), CMCS Informational Bulletin, *Best Practices for Avoiding 340B Duplicate Discounts in Medicaid*, at 3 (Jan. 8, 2020), *available at* https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf (discussing and describing "challenges with avoiding duplicate discounts on 340B drugs dispensed by 340B contract pharmacies"); HRSA, 340B Drug Pricing Program, Program Integrity, Audits of Covered Entities – Results by Fiscal Year, *available at* https://www.hrsa.gov/opa/program-integrity/index.html (last visited Apr. 24, 2023).

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siphon off manufacturer discounts that should be used to benefit patients and instead use them to increase the revenues of third-party, for-profit pharmacies.[14]

Merck has maintained a strong commitment to the 340B Program since its inception. We continue to strongly support the mission of the 340B program and efforts to make sure it helps the patients it was designed to assist. As a supporter of the 340B program with concerns about the long-term viability of the program we oppose this bill. Thank you for your attention to this issue. Please reach out if you have any questions and our team in Kansas is available to discuss further.

Sincerely,

CC:
Jordan Feuerborn
Riley Scott

[14] *See, e.g.*, Ltr. from Adam J. Fein, Drug Channels Inst., to Hon. Lamar Alexander, Chair, U.S. Sen. Committee on Health Educ., Labor, & Pensions, and Hon. Greg Walden, Leader, U.S. House of Reps. Committee on Energy & Commerce at 1–2 (Oct. 30, 2020) (noting that "there is . . . zero transparency around the profits earned by billion-dollar public companies that dominate 340B pharmacy networks," and that occur "at the expense of needy and uninsured patients"), http://drugchannelsinstitute.com/files/AdamFein-DrugChannels-340B-30Oct2020.pdf; *see also* Adam J. Fein, Wall St. J., *The Federal Program That Keeps Insulin Prices High* (Sept. 10, 2020); Amicus Brief of 340B Expert Aaron Vandervelde, Berkeley Research Group (BRG), in *AstraZeneca Pharmaceuticals LP v. Becerra, et al.*, Case No. 1:21-cv-00027-LPS, Dkt. 46 at 2 (Apr. 16, 2021) ("These health conglomerates have captured a large share of the 340B margins and are generating hundreds of millions of dollars in 340B profits each year." (citing Eric Percher et al., Nephron Research, *The 340B Program Reaches a Tipping Point: Sizing Profit Flows & Potential Disruption*, at 7 (Dec. 2020))).