March 30, 2023

Senator Kelly Morrison
Commerce Committee Chair Matt Klein
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Re: Senate File 2744

Dear Senators Morrison and Klein,

Eli Lilly and Company (Lilly) opposes Minnesota Senate File 2744 (SF 2744) which purports to "prohibit[] excessive price increases" of drugs as well as authorize certain "remedies," including capping the price of certain prescription drugs, to address "affordability challenge[s] [to] the state health care system."

SF 2744 raises significant legal and policy issues yet does not actually improve patient affordability challenges. As drafted, the bill is vulnerable to legal challenges on multiple grounds, and practically could lead to private revenue transfers from innovative drug manufacturers, wholesalers, and out-of-state pharmacies to pharmacy benefit managers (PBMs), health plans, and financial intermediaries, all without providing meaningful benefit to patients.

Although Lilly opposes other sections of SF 2744,[1] we focus our comments in this letter on the provisions of SF 2744 that purport to lower the cost of prescription drugs by authorizing a Prescription Drug Affordability Board (Board) to impose an arbitrarily determined "upper payment limit," i.e., a price control, on the purchase price and reimbursement rate for purchases within, and dispensed to patients in, Minnesota. These attempts to control a drug's price will harm patients' access to medicines, both in the short and long term. In fact, other state attempts to implement similar legislation have not resulted in any tangible patient benefit. Moreover, these provisions raise significant constitutional problems.

We urge Minnesota to consider alternative policies that would both provide meaningful out-of-pocket relief to patients and comply with law.

UPPER PAYMENT LIMITS HARM PATIENTS AND BENEFIT FOR-PROFIT PAYERS AND FINANCIAL INTERMEDIARIES

1. State imposed price controls on drug purchases and reimbursements can create immediate drug access challenges for patients.

Although the legislature purports to impose "upper payment limits" (UPLs) to benefit patients through lower prescription drug costs, this legislation may have the opposite effect. As shown in the diagrams in Attachment A to this letter,[2] many manufacturers, including Lilly, only sell their products to a

[1] For example, SF 2744 Article 2 Sections 8 through 13 prohibit "excessive price increases" of certain drugs and prescribe certain enforcement authorities for the Attorney General. These provisions, which attempt to regulate the nationwide list price for drugs, directly violate the Commerce Clause of the United States Constitution. Moreover, these provisions provide limited direct patient benefit, as they do not impact the prices faced by patients at the pharmacy counter.

[2] The pharmaceutical supply chain is complicated and varies based on the product's characteristics, among other things. For example, a product could be sold through a number of separate and distinct channels (e.g., retail pharmacy, specialty pharmacy, physician office, inpatient or outpatient hospital pharmacies, etc.). For simplicity in Attachment A, we have described the potential impact of a $500 UPL on a hypothetical drug in the retail channel. We would be happy to meet with you to describe different supply chain flows and the potential impacts of this bill in each channel.

nationwide network of wholesalers, almost none of which are located in Minnesota. These wholesalers, in turn, sell the products to their customers, including retail pharmacies, specialty pharmacies, physician offices, or hospitals, that may or may not be located within the state. In other words, manufacturers may not sell drugs into Minnesota, but other supply chain entities, like wholesalers and out-of-state pharmacies, do.

This bill would authorize the Board nonetheless to impose an arbitrary ceiling on the price of certain drugs when sold into the state. However, as shown in the Attachment, assuming out-of-state transactions stay constant, and manufacturers continue to sell their products to wholesalers at the Wholesale Acquisition Cost (WAC), i.e., the *nationwide list price* defined in federal law,[3] wholesalers or their downstream out-of-state customers will be faced with a Hobson's choice: continue selling the product into the state at a loss or stop selling the product into the state entirely.

We are concerned that a rational economic actor, located out-of-state, may cease selling or dispensing medicines to end purchasers in Minnesota, which in turn would create immediate access challenges for selected drugs and impose significant harm on patients in your state.

2. State imposed UPLs on drug purchases and reimbursements can result in revenue shifting from one entity in the drug supply chain (e.g., wholesalers, pharmacies) to payers and financial intermediaries, with minimal impact on patient out-of-pocket costs.

As noted above, if and when drug price controls are imposed, out-of-state sellers or dispensers will either have to sell or dispense the selected drug into Minnesota at a loss or cease providing the drug in the state entirely. The legislature seems to assume that these supply chain entities will choose the former, even though that choice is contrary to their own economic interests. However, *if* that assumption holds true, then the legislature would essentially be implementing a private wealth transfer from manufacturers or wholesalers on the one hand to payers and financial intermediaries on the other, with only marginal if any benefit to patients. Because SF 2744 authorizes a ceiling *not only* on an in-state purchaser's purchase rate, *but also* on reimbursements, the legislature will be removing pharmacies' remaining ability to negotiate a reasonable payment rate with payers, lowering payers' costs, while forcing pharmacies or other entities in the supply chain to "break even" or sell or dispense at a loss.

At best, this wealth transfer is likely to provide only marginal benefit to patients.[4] For example, most payers impose certain cost sharing obligations on their members. Thus, a patient who currently has a 10% coinsurance for their drugs would likely continue to pay 10% post-UPL implementation. Assuming the patient's cost sharing will be based on the amount of arbitrary price control, the patient's out-of-pocket will go down slightly, but the majority of the benefit—indeed, 90% in this example—will accrue to the payer, which in turn will have no specific obligation to provide that benefit to patients at the pharmacy counter or pass those savings on to the payer's employer clients. These savings can thus be absorbed as additional payer revenue.[5]

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[3] *See* 42 U.S.C. § 1395w-3a (c)(6)(B).

[4] Although SF 2274 Section 21, Subd. 2(d) requires that health plans and PBMs "report annually . . . how cost savings resulting from the [price cap] have been used . . . to benefit enrollees," there is no actual requirement that payers "pass on" savings from the UPLs to patients.

[5] As we note further in this letter, this wealth transfer implicates the Fifth Amendment Takings Clause of the United States Constitution.

In totality, SF 2744 disrupts the competitive market that exists between entities in the supply chain today,[6] benefiting some entities over others and providing only minimal benefit to patients. Because payers already receive substantial rebates and fees from manufacturers that rarely appear to be passed through to the patient, we encourage the legislature to implement other legislative options, including those identified below in this letter, to lower patient out-of-pocket costs.

3. Government imposed price controls could impact the rate at which the biopharmaceutical industry is able to bring forward innovative new medicines.

Research shows that significant government price controls will damage pharmaceutical innovation and opportunities for future cures.[7] Experts estimate a price control that results in a 50% decrease in the price of medicines would result in a 25% to 60% decrease in the number of new drugs in the pipeline.[8] Additionally, the pharmaceutical industry conducts more research in the U.S. than in other countries, and more research overall than other U.S. industries.[9] One study found that when looking at research and development intensity by industry, U.S. pharmaceutical companies dedicated 43.8 percent of their total gross value added in 2014 back into R&D, ahead of both air and spacecraft, and electronic and optical products.[10] In 2022, Lilly increased our investment in R&D to $7.2 billion, which is over one-quarter of Lilly's 2022 revenue.[11]

The impact that price controls have on pharmaceutical innovation will ultimately affect patient access to medicines. Looking to other countries as a reference, in those where governments set medicine prices, patients have access to fewer treatment options. U.S. patients currently get earlier and less restrictive access to new therapies. For example, the U.S. has access to nearly 85% of all medicines launched between 2012 and 2021, while just 61% are available in Germany, 59% in the U.K., 51% in Japan, 52% in France, 45% in Canada, and 34% in Australia.[12]

4. Other states that have implemented similar legislation have yet to see any patient benefit, and many have incurred significant costs.

Based on the experiences of other states, SF 2744 is likely to require significant state expenditures to "start up" the Board, with minimal or no short-term benefit to patients. For example, Maryland's Prescription Drug Affordability Board (PDAB) legislation (HB 768) passed in 2019. Estimated implementation costs to the state since 2019 are approximately $2.5 million, while the PDAB has resulted

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[6] For example, manufacturers and PBMs/payers negotiate rebates for drug placement on the PBM's formulary, wholesalers and pharmacies negotiate purchase prices, and PBMs and pharmacies negotiate reimbursement rates. SF 2274 would arbitrarily supersede these negotiations while failing to provide meaningful patient benefit.

[7] J. Kennedy, *The Link Between Drug Prices and Research on the Next Generation of Cures*, Information Technology & Innovation Foundation (Sept. 9, 2019), *available at* https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures.

[8] Abbot, T. and Vernon, J., *The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions. National Bureau of Economic Research* (Feb. 2005), *available at* https://www.nber.org/papers/w11114; Civan, A. & Maloney, M., *The Effect of Price on Pharmaceutical R&D*, The B.E. Journal of Economic Analysis & Policy, 9(1) (2009).

[9] J. Kennedy, *The Link Between Drug Prices and Research on the Next Generation of Cures*, Information Technology & Innovation Foundation (Sept. 9, 2019), *available at* https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures.

[10] *See id*. ("R&D intensity by industry, measured as business R&D spending as a percentage of the gross value added of an industry.")

[11] Eli Lilly and Company 2022 Form 10-K, *available at* https://investor.lilly.com/static-files/a9c648f1-eae8-490a-904c-822806275f92.

[12] PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration, European Medicines Agency, Japan Pharmaceuticals and Medical Devices Administration, Health Canada and Australia Therapeutic Goods Administration data. Note: Sample includes new active substances launched globally from January 1, 2012 to December 31, 2021. Updated June 2022.

in zero savings for patients.[13] To date, the Maryland PDAB has not successfully designed nor implemented a UPL. Maine's PDAB legislation (LD 1499) passed in 2019. No policy has been implemented that has reduced patient out-of-pocket spending on prescription drugs. New Hampshire's PDAB legislation (HB 703) passed in 2020; however, two bills have been introduced in 2023 that would repeal the PDAB (HB 172 and HB 130). Finally, Colorado's PDAB legislation (SB 21-175) passed in 2021. Colorado has experienced significant delays in their attempts to establish a UPL for a single prescription drug, and it is unclear when a UPL may be determined.

Given that other states that have enacted similar legislation to SF 2274 have spent millions to set up their PDAB and have not lowered patient out-of-pocket costs, we encourage Minnesota to invest state resources in policy solutions that provide more immediate and more direct benefit to patients.

ATTEMPTS TO REGULATE A DRUG'S PRICE RAISE CONCERNS UNDER THE UNITED STATES CONSTITUTION

1. Wealth transfers from out-of-state wholesalers and pharmacies to payers and financial intermediaries are unconstitutional under the Fifth Amendment Takings Clause of the United States Constitution.

The practical impact of this bill will be a transfer of revenues from out-of-state entities (e.g., wholesalers or pharmacies) to payers and PBMs. However, a state's attempt to mandate such a private wealth transfer—and in a manner that requires entities to give away products at under-market prices—would violate, among other things, the Takings and Due Process Clauses in the Fifth and Fourteenth Amendments of the United States Constitution. States simply lack the constitutional authority to force private parties to directly fund or subsidize other private parties.

2. Forcing changes to a manufacturer's price for a drug violates various constitutional principles, including under the Takings Clause, the Supremacy Clause, and the Commerce Clause of the United States Constitution.

The legislature may anticipate that impacted supply chain entities will behave economically rationally, and that these entities will not choose to sell or dispense drugs into the state at a loss. The bill tries to address this point by forcing manufacturers to change the price of the drug to solve the very drug access problem the bill creates. But by doing so, the bill again raises serious constitutional issues.

First, forcing a private wealth transfer from innovative manufacturers to payers raises the same Takings concern described above. Second, such action violates the Supremacy Clause of the United States Constitution, as state price controls on branded drugs conflict with federal patent laws that allow patent holders the economic value of exclusivity during the life of a patent. In fact, in *BIO v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 1997), the court overturned a District of Columbia law imposing price controls on innovator drugs, reasoning that the D.C. law at issue conflicted with the underlying objectives of the federal patent framework by undercutting the inventor's ability to set prices for its patented product.

Third, attempts to regulate the list price of a manufacturer's product violate the Constitution's Commerce Clause. A manufacturer's WAC is a nationwide price, defined by Congress and applied uniformly across the country.[14] WAC is used by insurers, including in some instances the Medicare and

[13] Maryland HB768 (2019). Fiscal and Policy Note. http://mgaleg.maryland.gov/2019RS/fnotes/bil_0008/hb0768.pdf
[14] *See* 42 U.S.C. § 1395w-3a (c)(6)(B).

Medicaid programs, to set reimbursement rates. A state cannot dictate a company's nationwide selling price consistent with the Constitution, and a state more generally may not regulate transactions that occur entirely outside of the state's borders. Yet, that is precisely what SF 2274 would do here. Moreover, setting a drug's UPL *below* the drug's "Best Price," as defined in the federal Medicaid Drug Rebate Act, could result in setting a new nationwide Best Price, which in turn would impact the manufacturer's nationwide liability in the federal Medicaid Drug Rebate Program and would set a new nationwide Ceiling Price in the federal 340B drug pricing program.[15] Again, a state cannot regulate activity outside of its borders.

3. SF 2274 inappropriately relies on other legislation.

SF 2274 authorizes the Board to take certain actions based on existing state and federal law. Most concerning is the bill's reference to the Medicare Maximum Fair Price (MFP), a concept created in the federal Inflation Reduction Act (IRA), signed into law a mere seven months ago. SF 2274 mandates that the Board *must* set the price cap of a selected drug equal to the MFP if such MFP exists. But doing so would upend the balance that Congress carefully struck when it determined the scope and breadth of transactions subject to an MFP. The more that states or commercial entities seek to treat the MFP as a "benchmark" price, the less likely manufacturers are to continue to participate in federal healthcare programs or to continue marketing a product at all.

Not only is the federal MFP determination process too early in its infancy to render it practically useful to the Board, but attempting to commandeer this rate would create direct tension with federal law.

We also note that SF 2274 directs the Board to review certain information reported by manufacturers to the Minnesota Commissioner of Health under the Minnesota Prescription Drug Price Transparency Act (Act). However, although the Act was passed in 2020, the first report to the Minnesota Legislature was just released in February and represents incomplete analysis. Throughout the report, the Department of Health (DOH) makes multiple references to the preliminary and incomplete nature of its findings.[16] Moreover, the DOH specifies that its ability to provide meaningful recommendations is limited given the need for more transparency requirements across the supply chain. SF 2274 is simply premature in light of this other state legislation.

STATES SHOULD IMPLEMENT POLICIES THAT MORE DIRECTLY BENEFIT PATIENTS

As described above, we believe SF 2274 is likely to raise serious policy and constitutional issues, while providing little benefit to patients. Lilly believes that other state actions, including the below policies, would be more impactful solutions that promote affordable access to medicines, particularly insulins:

- **First dollar coverage:** Similar to other preventive medicines, exempting insulin from insurance deductibles to lower out-of-pocket costs and make them more predictable.
- **Copay caps at the pharmacy:** Limiting out-of-pocket costs for commercially insured patients.
- **Cost sharing based on net price (rebate pass through):** Requiring pharmacy benefit managers and health plans to share manufacturer rebates directly with beneficiaries at the point of sale to offset out-of-pocket costs.

[15] We note these impacts also raise concerns under the Supremacy Clause, as noted above.
[16] Minn Dept of Health, Minnesota Prescription Drug Price Transparency 7 (Feb 2023). ("[T]he analysis reported here should be considered preliminary."). *See also id.* at 11 ("This [legislative report] contains . . . preliminary analyses of reported data [and a] preliminary discussion of the effectiveness of the Act."); *id.* at 18 ("This section provides a preliminary summary of prescription drug prices . . . the summary and analysis presented in this report is preliminary.").

- **Affordability program awareness:** Policies that ensure people are aware of and enroll in applicable state and federal health care programs to enable affordable access to medicines.
- **Cost-sharing assistance:** Polices that ensure patients fully benefit from manufacturer cost-sharing assistance at the pharmacy counter.

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We appreciate the opportunity to express our views on SF 2274. Given SF 2274 does not advance patient drug affordability goals and raises serious concerns under the United States Constitution, we respectfully request that you oppose.

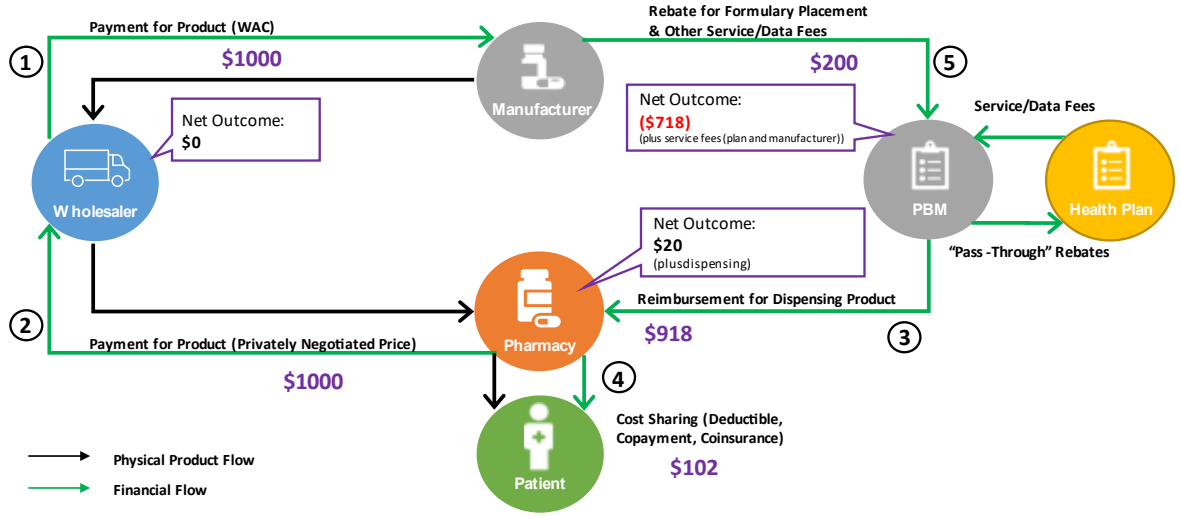
Sincerely,

William S. Reid
Vice President, State Government Affairs

CC: Diane Hilligoss, Assistant General Counsel – Eli Lilly and Company
Derek Asay, Senior Vice President, Government Strategy – Lilly USA

ATTACHMENT A – POTENTIAL IMPACT OF PRICE CONTROL WITHIN DRUG SUPPLY CHAIN (RETAIL)

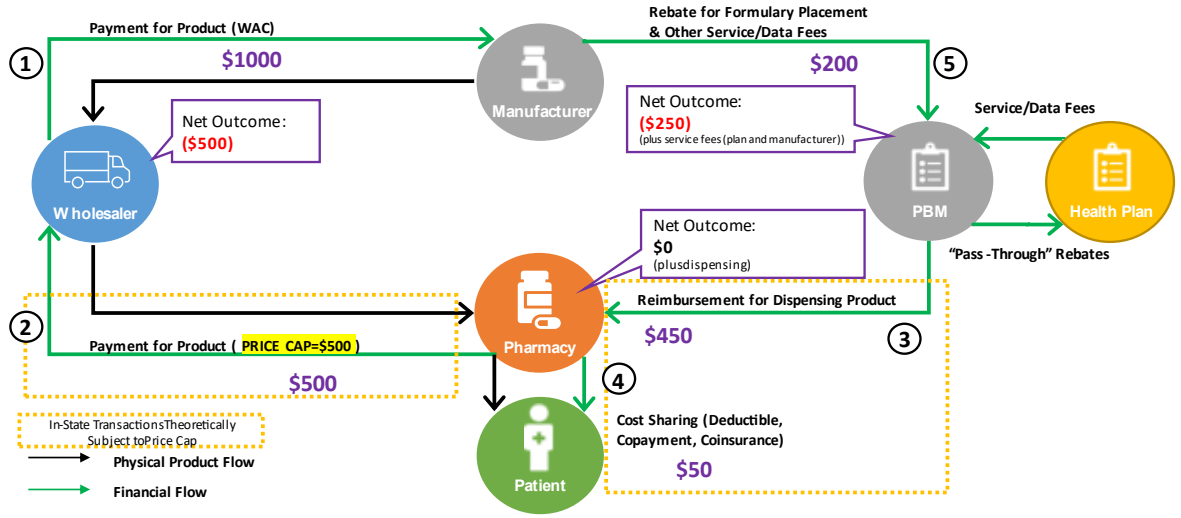
Hypothetical Drug X: Product & Financial Flows in Retail Channel (Before Price Control)



Hypothetical Assumptions:

1. Manufacturer sells to wholesaler at WAC ($1000).
2. Wholesaler sells to in-state pharmacy at WAC ($1000).
3. PBM and pharmacy negotiate a reimbursement rate of 2% above WAC ($1020), 90% of which is owed by PBM ($918).
4. Given patient's benefit design, patient owes 10% of negotiated rate ($102).
5. Manufacturer pays PBM a rebate of 20% of WAC for covered status ($200).

Hypothetical Drug X: Product & Financial Flows in Retail Channel (After Price Control)



Hypothetical Assumptions:

1. Manufacturer sells to wholesaler at WAC ($1000).
2. Wholesaler sells to in-state pharmacy at UPL ($500).
3. Pharmacy reimbursed at UPL ($500), 90% of which is owed by PBM ($450).
4. Given patient's benefit design, patient owes 10% ($50).
5. Manufacturer pays PBM a rebate of 20% of WAC for covered status ($200).