April 21, 2023

Representative Liz Olson, Chair
House Ways and Means Committee
75 Rev. Dr. Martin Luther King Jr. Blvd.
Saint Paul, Minnesota 55155

Dear Chair Olson and Members of the House Ways and Means Committee,

The Minnesota Society Clinical Oncology Society (MSCO) and the Association for Clinical Oncology (ASCO) are committed to supporting policies that reduce cost while preserving access to quality cancer care. However, we are concerned that the Upper Payment Limit portion of the Prescription Drug Affordability Board - **SF 2744 – Section 21**, if passed, would jeopardize access to necessary care for Minnesota patients with cancer. We appreciate your commitment to lowering costs and would like to work with you on the best path forward for patients who face this life-threatening disease.

MSCO is a professional organization whose mission is to facilitate improvements for Minnesota physician specialties in both hematology and oncology. MSCO members are a community of hematologists, oncologists, and other physicians who specialize in cancer care. ASCO is a national organization representing physicians who care for people with cancer. With more than 45,000 members, our core mission is to ensure that cancer patients have meaningful access to high quality, equitable cancer care.

Life-saving treatments for cancer often include use of high-cost drugs, the very ones targeted by the upper payment limit section of SF 2744. Cancer patients are uniquely vulnerable and often have a narrow window of time for a successful outcome. If doctors and patients must endure a 60-day appeal to access treatments subject to an upper payment limit, some of Minnesota's sickest patients will suffer severe consequences.

Oncologists do not set or control drug prices; they offer their patients the most appropriate, evidence-based treatment that will ensure the best outcome for an individual cancer patient and their specific disease.

We are concerned that over time, the upper payment limit as proposed could impact access to care. Under the upper payment limit proposal, physician practices will be reimbursed the amount they pay to purchase the drug, with no reimbursement to cover the significant costs associated with drug treatments in physicians' offices, including the cost of procuring, storing, preparing, and handling the drugs. We recommend that the bill include an add on payment to help offset the actual costs incurred for procuring, storing, preparing, and handling highly toxic agents.

We are eager to discuss other solutions we think could control appropriate utilization of the highest cost drugs and protect cancer patients at that same time, including the use of value-based clinical pathways.

ASCO and MSCO are concerned that the upper payment language in SF 2744 will have a harmful impact on cancer practices in Minnesota and the patients they treat. We urge you to consider the unintended consequences of this legislation. For a more detailed understanding of our recommendations on this issue, we invite you to read the ASCO Position Statement on Addressing the Affordability of Cancer Drugs. If you have questions or would like assistance on any issue involving the care of individuals with cancer, please contact Sarah Lanford at Sarah.Lanford@asco.org.

Sincerely,

Amrit Singh, MD
President
Minnesota Society of Clinical Oncology

Lori J. Pierce, MD, FASTRO, FASCO
Chair of the Board
Association for Clinical Oncology

POLICIES TO HELP PATIENTS PAY LESS FOR THEIR MEDICINES

PhRMA
RESEARCH • PROGRESS • HOPE

America's biopharmaceutical companies agree that, for too many Americans, the health care system is not working and needs to change. While medical innovation has made the United States a world leader in the discovery of new medicines, these treatments won't benefit patients who can't get them.

There are no easy solutions, but patients need real leadership from everyone involved in our health care system to make it work better. That's why our companies are calling for everyone in the health care system to join us in supporting common-sense reforms to make insurance work like insurance and ensure that patients can access and afford the medicines their doctors prescribe.

We believe the following policies are the best way to achieve these goals and make sure that *patients pay less* for their medicines.

1 Share the Savings

On average, nearly half of spending on brand medicines goes to health insurers, PBMs, the government and others, not the manufacturer that researched and developed the medicine. However, patients often do not benefit from these significant discounts in the form of lower out-of-pocket costs for their medicines. That's not right, and it needs to change. If insurance companies and middlemen don't pay the full price for medicines, patients shouldn't have to either. These rebates and discounts must be directly shared with patients at the pharmacy counter.

2 Make Coupons Count

In some cases, health insurance companies are not allowing the coupons manufacturers provide to patients to count towards deductibles or other cost sharing requirements, meaning patients could be paying thousands more at the pharmacy than they should be. We need to end this practice so that patients are getting the full benefit of programs meant to help them access their medicines.

3 Offer Lower, More Predictable Cost Sharing Options

Actual spending on medicines is growing at the slowest rate in years. Unfortunately, it doesn't feel that way for patients. Insurers are increasingly using high deductibles and coinsurance that result in patients paying more for certain medicines out of pocket. Patients should have more choices when it comes to their medicine coverage. Every state should require health insurers to offer at least some health plan options that exclude medicines from the deductible and offer set copay amounts instead of forcing patients to pay an amount based on the full list price of their medicines.

4 Cover Medicines from Day One

Insurers increasingly require patients to pay high deductibles before receiving coverage of their medicines. This can lead to patients rationing or not taking their medicines, which can result in devastating consequences to their health. Policymakers can help patients from day one by requiring all plans to cover certain medications used to treat chronic conditions with no deductible. Additionally, insurers should be mandated to offer some plans that cover all medicines from day one.

5 Cap Patient Cost Sharing

Many commercially insured patients are being exposed to high out-of-pocket costs due to increasing use of deductibles and coinsurance. High cost sharing is a barrier to prescription medicine access, especially for patients with chronic, disabling or life-threatening conditions, who shoulder the largest share of the burden. Cost sharing should not be so burdensome that it prevents patients with insurance from accessing necessary prescription medicines.

April 21, 2023

Re: Patients stories in support of a Prescription Drug Affordability Board (SF2744)

Dear Chair Olson and Members of the Committee:

Please see the attached stories of Minnesota patients for affordable prescription drugs.

Ramae Harmin, Bemidji, MN

In 2018, I was Ramae Harmin — a 47-year-old single mother, long distance runner, and high school math teacher. Then I was diagnosed with an incurable blood cancer called multiple myeloma. Now, for the rest of my life, I will be a cancer patient. I took a leave of absence from my job as a teacher to undergo several surgeries, radiation, an induction chemotherapy regimen, and a stem cell transplant. My slow recovery from the transplant coupled with the intense fatigue from my daily maintenance regimen has prevented me from returning to work. I have just enough energy to take care of myself and my son.

I also have just enough money to live. For now, I receive long-term disability from my former employer and from SSDI. I am currently still on my private insurance plan through Cobra, but I will make the switch to Medicare at the end of the year. My only income is 60% of my former teaching salary and some child support that will end when my son turns 18. I also have two college-aged daughters that I help to support as well. Other than a high yearly deductible and the monthly Cobra premiums, I have paid very little out-of-pocket for my medical treatments and medications. My maintenance drug, Revlimid, is not fully covered by my insurance plan, but I do qualify for $25 copays through my drugmaker's assistance program. The drug maker charges my insurer between $15,000 and $25,000. My assistance will evaporate once I start on Medicare. I'm terrified. Myeloma patients on Medicare are paying as much as $3,000 out-of-pocket per month for Revlimid and other drugs. There are grants available for some, but not all qualify. I don't know if I will qualify or if the grant money will be there when I need it. What I do know is that I won't be able to afford this monthly cost without selling my home and using every penny I've managed to save — and even that will only last so long.

Margaret, MN

My name is Margaret and I'm from Minnesota. When I was 19 years old, I was diagnosed with Crohn's Disease. Because I was on my parents' insurance, I had no clue how to navigate insurance coverage for my care and medications. For a number of years, the price of my drugs never crossed my mind. But when I turned 26 and was no longer eligible for my family's insurance plan, things got tricky.

I was ultimately added on to my husband's insurance, but the switch was far from seamless. In addition to switching insurance I had moved to a new state, and my first infusion in California came with a copayment of $6,000. When I called to see why my patient assistance program wasn't paying for the drug, I was told that my membership had lapsed. While I eventually regained membership, Janssen Pharmaceuticalswon't January 2023 retroactively cover that first infusion — meaning I'm stuck with a bill for $6,000 that is rapidly accumulating interest.

$6,000 per dose is a number no patient should have to pay just to control their debilitating symptoms. The price of my drugs is high, and that's without even mentioning the high cost of my other medical care, like trips to the Mayo Clinic and appointments with chronic care specialists. Because of these expenses, I've been forced to move back to Minnesota and go back to living with my parents at the age of 30. This isn't the life I imagined for myself — but it's something many patients are experiencing because the medications we need are simply too expensive to keep up with.

Years after my initial experience with the drug Remicade, I've been switched to Stelara and am once again struggling to get Janssen Pharmaceuticals to cover that medication through patient assistance. Drug companies advertise patient assistance programs, but the hoops I've had to jump through clearly show that even with these programs, patients are slipping through the cracks and ending up in debt.

This issue is difficult for me to rehash — it triggers a lot of depression and anxiety for me to talk about what I went through and continue to go through. But I think it's important to speak up. Statistically, many young girls like me get diagnosed with Crohn's Disease in college, when they have financial support from family and health insurance. It gets more complicated once you turn 26, and I want more patients to know how to work as their own advocates. This issue is serious, and it's impacting a lot of people.

Travis Paulson, Eveleth, MN

My name is Travis Paulson and I am from Eveleth, Minnesota. I have been a Type 1 diabetic for many years, but affording insulin wasn't that difficult as a child — it was about $8 a vial. The problems came when I was in my late twenties and early thirties. I was working in finance full-time and going to college full time, and my insurance had a deductible of $7,500. Insulin at the time ranged from $300 to $350 a vial, and I required about five vials a month. There were times I couldn't scrape together $5 and was just plain poor due to these costs. On several occasions I starved myself and took less insulin than I was supposed to so my vial would last longer. Unfortunately, even doing that, I would run out of insulin. I wasn't involved in diabetes groups and knew no other diabetics. I don't even think there was a name for rationing insulin at the time. I thought I was in a unique situation, so I didn't reach out for help.

All those years of rationing insulin have caused diabetes retinopathy, insulin resistance, and long-term complications that never would have occurred if I had access to affordable insulin. I would stay in bed and call into work sick until my paycheck cleared the bank. I'd then force

myself up and get to a pharmacy and get insulin. It's really hard to move when your blood sugar is that high. I remember feeling like I wasn't going to make it, but somehow I did. Ten years ago, I had never heard of anybody dying from rationing insulin, so I figured that while it wasn't a good thing, it wouldn't go so far as to kill me. I've learned since then that I was just very lucky at the time — I easily could have died.

It was during the financial crisis of 2007 to 2008 that I was forced to ration insulin again. Times were tough for lots of people. I remember camps of ex-financial services workers living in tents. But aside from just finding housing during the financial crisis, I had an additional problem: I had to afford my insulin. I traveled around the country working odd jobs to afford insulin and rationed what I had, living a meager existence and working warehouse jobs wherever I could.

It was after I came back home to Minnesota to get back on my feet that I decided I would no longer tolerate the abuse and hold on my life Big Pharma had. I realized I could get insulin from Canada for less than a tenth of the price I was paying in the U.S. From then on, I have been getting my insulin in Canada and helping others to do the same. The unfortunate thing is that all those years of rationing insulin have caused diabetes retinopathy, insulin resistance, and long-term complications that never would have occurred if I had access to affordable insulin. My health is what paid the price.

Additionally, it brought attention to the thousands of people every year who travel to other countries just to afford their life-saving medications.

When it comes to cheaper insulin prices, Canada isn't an outlier. Their prices could be our prices here in the United States. If our lawmakers allowed Medicare to negotiate with drug manufacturers as the Canadian public insurance does, the price would decrease significantly. We need lawmakers with the courage to prioritize patients and work to decrease the cost of prescription drugs like insulin.

Because of our advocacy in Minnesota, some insurers in our state have capped their prices, allowing some people to only pay $25-30 a month for insulin. Additionally, we passed the Alec Smith Insulin Affordability Act which provides a safety net for Minnesotans who can't afford their insulin. But this is not enough. Insulin is just one drug. We need solutions both at the state and national levels to address the system-wide greed of drug companies. Drug companies continue to charge ridiculous prices, further exacerbating already existing racial and economic inequities in our health care and prescription drug systems. High prices disproportionately affect black and brown communities, the same people hit hardest by the COVID-19 pandemic. In such a critical moment in our country, I'm inspired to refocus my activism and continue advocating for a more just system.

Contact: robert@takeactionminnesota.org

RE: Support for Prescription Drug Affordability Board and Stopping Price-Gouging of Prescription Drugs (SF2744, Article 2, Sec. 12-22)

April 24, 2023

Dear Chair Olson and Members of the Committee:

We write to express our strong support for policy to establish a Prescription Drug Affordability Board and stop price-gouging of the medicines Minnesotans rely on every day included in SF2744 (Senate companion to HF2680).

In Minnesota, we believe everyone deserves access to affordable medicine they need to be healthy and well. Today, nearly half (45%) of Minnesotans are worried about prescription drug costs, and one in five Minnesotans (21%) has rationed prescription medicine in recent years due to cost (Healthcare Value Hub, Nov. 2020). Data shows pharmaceutical companies are continuing to hike up the price of certain drugs without good reason for an increase.

Access to affordable medicine can be a matter of life and death and affects all of us. The costs show up in health insurance premiums—prescription drugs account for about 25% of premium costs—we pay a public health toll when our community members can't afford medicine they need, and Minnesotans across the state are paying the price with their lives and livelihoods.

The Prescription Drug Affordability Board will be a watchdog with the authority to set fair upper payment limits for out-of-control prescription drug costs, helping Minnesota patients, payers, purchasers, and providers address the increasing challenge of high cost drugs. The PDAB, along with increased authority to prohibit excessive price-gouging of generic prescription drugs, will ensure Minnesotans can afford the medications they need.

These solutions were recommended to the Legislature by the Attorney General's Task Force on Lowering Pharmaceutical Drug Costs. The task force included patients, experts, and a bipartisan group of legislators from the House and Senate. Five states have already enacted similar Prescription Drug Affordability Boards.

As Minnesotans continue to be harmed by out-of-control prescription drug costs, the state has the responsibility to take meaningful action, and broad public support to do so. Eighty-seven percent of Minnesotans support this commonsense action. (Health Care Value Hub, Nov. 2020).

We urge you to stop price-gouging of prescription drugs and pass a Prescription Drug Affordability Board into law this session to lower costs and save lives.

Signed,

AARP Minnesota
AFSCME Council 5
Committee to Protect Health Care
ISAIAH
Land Stewardship Project
Main Street Alliance
Minnesota Nurses Association
MN Farmers Union
SEIU Healthcare Minnesota & Iowa
TakeAction Minnesota
We Make MN

DID YOU KNOW?

PBMs, Plans and Wholesalers Continually Rank Higher on Fortune 500 Lists than Biopharmaceutical Companies

THE TOP 10

2022
Fortune 500 Rankings

1. Walmart
2. Amazon
3. Apple
4. CVS Health
5. UnitedHealth Group
6. Exxon Mobil
7. Berkshire Hathaway
8. Alphabet
9. McKesson
10. AmerisourceBergen

Health Plan, PBM, Pharmacy
Health Plan, PBM
Wholesale Distributor

FORTUNE

https://fortune.com/ranking/fortune500/2022/search/

PBMs, Plans and Wholesalers Continually Rank Higher on Fortune 500 Lists than Biopharmaceutical Companies

TOP RANKED PBMS AND PLANS

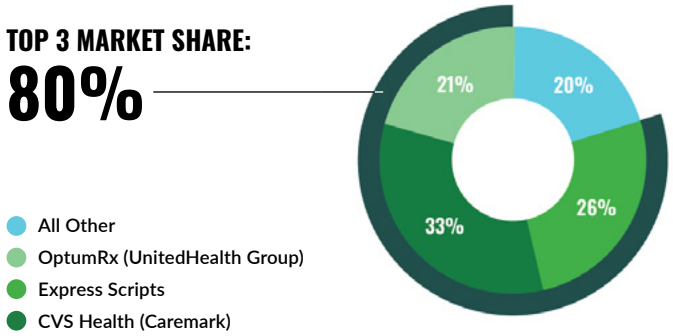
4. CVS Health (Caremark and Aetna)
5. UnitedHealth Group (OptumRx)
12. Cigna (Express Scripts)

TOP RANKED BIOPHARMA COMPANIES

37. Johnson & Johnson
43. Pfizer
63. AbbVie

Insurers and PBMs Control Access to Pharmacies and Leverage for Medicine Costs

TOP 3 MARKET SHARE:
80%



INSURERS DETERMINE:

FORMULARY
if a medicine is covered

TIER PLACEMENT
patient cost sharing

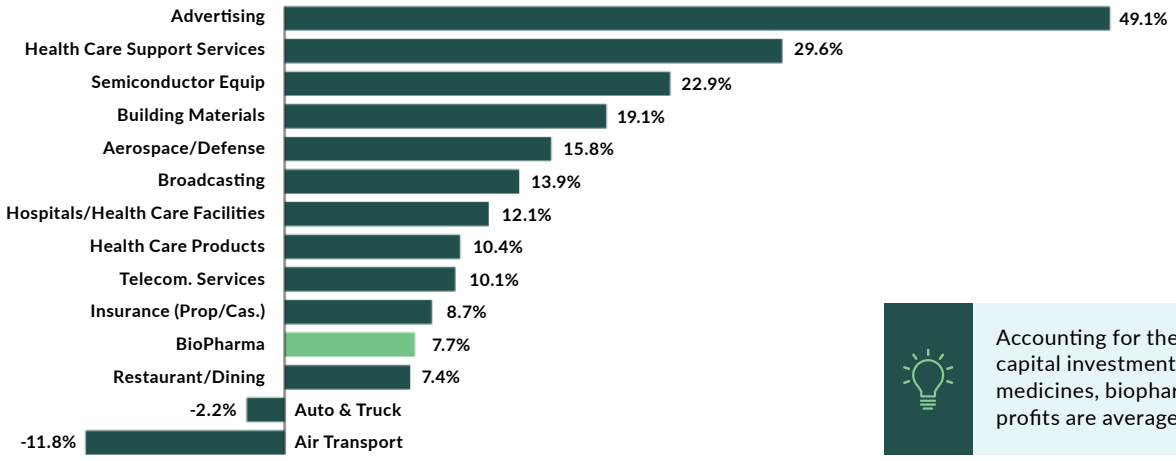
ACCESSIBILITY
utilization management through prior authorization or fail first

PROVIDER INCENTIVES
preferred treatment guidelines and pathways

HOW DOES THE BIOPHARMACEUTICAL INDUSTRY COMPARE TO OTHER INDUSTRIES?

Biopharmaceutical Profits Are in Line With Those of Other Industries

AVERAGE ECONOMIC PROFIT FOR SELECTED INDUSTRIES, 2019-2021*



Accounting for the significant risk and capital investments required to develop medicines, biopharmaceutical industry profits are average among industries.

*Economic profits are accounting profits minus capital expenses.

†Represents the weighted average of pharmaceuticals (8.2%) and biotechnology (2.2%), which are listed as separate industries in the source data.

Source: Adapted from R. Manning and A. Subramaniam, Intensity, LLC. Economic Profitability of the Biopharmaceutical Industry, 2022. https://intensity.com/news/economic-profitability-of-the-biopharmaceutical-industry-2022

COMMITTEE TO PROTECT
HEALTH CARE

Minnesota Medical Professionals Support Passage of a Prescription Drug Affordability Board

To Chair Olson and Members of the Committee:

As medical professionals across Minnesota, we urge the Minnesota House to pass legislation to create a Prescription Drug Affordability Board (PDAB) and stop price-gouging of generic drugs (SF2744, Art. 2, Sec. 12-22) without delay.

In our decades of experience across medical specialties, we're acutely aware of how critical prescription drugs are in helping keep patients healthy and managing their medical conditions. We see each and every day how, when patients take medications as prescribed, their quality of life improves and they're able to keep more serious complications at bay.

Unfortunately, we also see what happens when patients don't take the medications we've prescribed them. They deal with unnecessary pain and discomfort. Their health conditions, which are often manageable, worsen, becoming more difficult, expensive, and painful to treat. Too often, patients forgo or ration their prescribed medications simply due to cost. Even with health insurance, high prices put needed medications out of reach for too many.

That's why medical professionals are calling on the Legislature to act on Prescription Drug Affordability Board legislation. HF17 and SF168 will help limit costs for certain drugs and stop the price-gouging of generic drugs. These measures will benefit patients, health care providers, and both public and private payers.

Powerful pharmaceutical corporations of course will use every play in the book to block this legislation to protect their enormous profits. Spending more money on lobbying and advertising than research and development, they have ample opportunity to sow doubt.

They'll spread fear, claiming that they won't be able to afford to produce new medicines, even as their profits break record after record. They'll use front groups, even shamelessly hiding behind patient groups for rare diseases, claiming they won't be able to access the medicines they need. Their goal is to cause fear and inaction.

But patients know the real truth, which is that medicine isn't accessible if you can't afford it. And medicine doesn't work when people can't afford it.

The current system is broken, and with each passing day without legislative action, patients' health deteriorates, people suffer, and lives are put at risk — all unnecessarily. We are proud of the physicians leading this work at the Capitol. Lawmakers must take action now, and the best action they can take today is to pass a Prescription Drug Affordability Board.

Signed:

Alfredo Beltran, MD; Internal Medicine (New Brighton)

Eleanor Beltran, MD; Internal Medicine (Saint Paul)

Elizabeth Bildsoe, RN (Remer)

Mirna Boumitri, MD; Nephrology (Minneapolis)

Mark Brakke, MD; Family Medicine (Minneapolis)

Jessica Braun, APRN, CNP; Family Medicine (Saint Peter)

Rachel Bui, RN; Psychiatry (Shakopee)

Frank Bures, MD; Dermatology (Winona)

Melissa Chin, CNM, APRN; OB/GYN (Minneapolis)

Heather Dale, PA-C (Saint Peter)

Mary Dao, NP; Family Medicine (Brooklyn Park)

Karen Terese Dorn, MD; Hospital Medicine (Burnsville)

Ann Dougherty, RN; Psychiatry (Saint Paul)

Dimitri Drekonja, MD, MS; Infectious Diseases (Minneapolis)

Peter Eckman, MD; Cardiology (Saint Paul)

Dawn Ellison Jordan, MD; Emergency Medicine (Dent)

Amy Engebretson, MD; OB/GYN (Saint Paul)

Bernadine Engeldorf, RN; Mental Health (Saint Paul)

Ken Engelhart, MD; Internal Medicine (Minneapolis)

Katie Esse, MD; Neurology (Saint Paul)

Jennifer Exo, DO; Pediatrics (St Louis Park)

Rumi Faizer, MD; Surgery (Little Canada)

Susan Fee, MD; Maternal Fetal Medicine (White Bear Lake)

Masood Ghazali, MD; Neurology (Minneapolis)

Jane Hess, DO; Family Medicine (Little Canada)

Ron Jankowski, MD; Family Medicine (Anoka)

Mary Kemen, MD; Anesthesiology (Chanhassen)

Amy Kelly, MD; Pediatrics (Saint Paul)

Sarah Lawrence, MD; Internal Medicine (Rochester)

Kacia Lee, MD; Internal Medicine (Minneapolis)

Helen Line, RN (Roseville)

Becky Lohnes, LPN; Family Medicine, OB/GYN (Minneapolis)

Sahar Lotfi-Emran, MD, PhD; Rheumatology (Minneapolis)

Kate Lynch, LPN; Family Medicine, Pediatrics (Roseville)

Mary Lynch, RN (Minneapolis)

Kathy Messenger, RN; Urology (Duluth)

Jodi Metz, PA-C; Family Medicine (Minneapolis)

Enrico Ocampo, MD; Internal Medicine (Tyler)

Leena Ranade, MD; Psychiatry (Minneapolis)

Brian Randall, MD; Radiology (Chanhassen)

Emily Rath, NP; Family Medicine (Sartell)

Natalie Rosen, DNP; Psychiatry (South Haven)

Paul Andrew Ruth, MD; Family Medicine (Fairmont)

Louis Carl Saeger, MD; Interventional Pain Management (Edina)

Catherine Sanders, RN; Psychiatry (Burnsville)

Janet Schmitt, MD; Family Medicine (Minneapolis)

Sandra Schraut, RN; Psychiatry (Brooklyn Center)

Sue Schroeder, RN, LMFT; Psychiatry (Minneapolis)

Daniel Townsend, DO; Internal Medicine (Saint Paul)

Kristine Venaglia, RN (Brooklyn Park)

Jane Vujovich, RN (Saint Paul)

Lindsay Williams Palaniappan, MD; Family Medicine (Minneapolis)

Vignesh Williams Palaniappan, MD; Internal Medicine (Minneapolis)

Saida Yassin, MD; Internal Medicine, Geriatrics (Minneapolis)

[The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026]

IQIVA • April 21, 2022

Key Findings

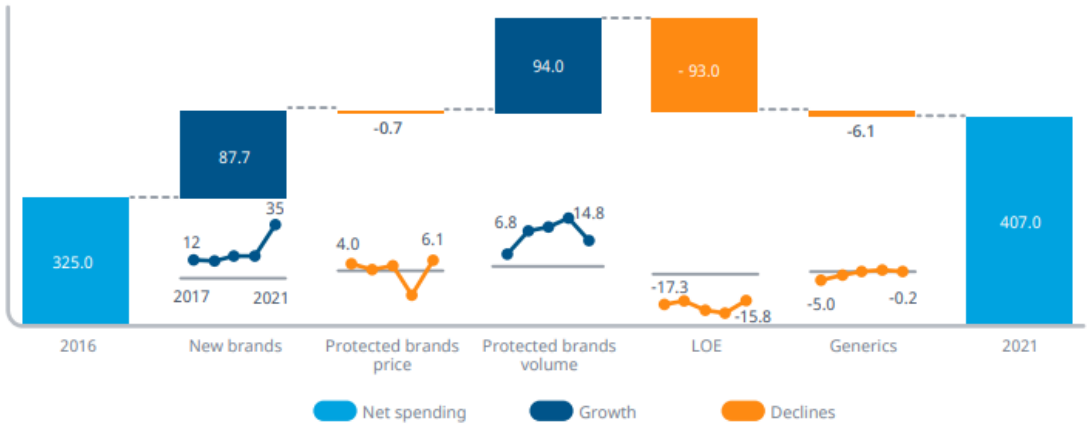
- Net prices for brand medicines increased 1.0% in 2021, below the rate of inflation for the fifth year in a row. Looking ahead, net price growth is projected to be 0% to -3% per year through 2026.
- Overall net spending on medicines (net manufacturer revenue) increased 12.1% in 2021, driven by the "unprecedented contribution" of the COVID-19 vaccine and treatments. Excluding spending on COVID-19 vaccines and treatment, spending on medicines increased just 4.9% in 2021.
- Excluding spending on COVID-19 vaccines and treatment, net per capita spending on medicines *declined* by 1% in 2021.
- Looking ahead, net spending growth is projected to return to pre-pandemic trends, increasing 1% to 4% per year, on average, through 2026.
- Brand medicine net prices are, on average, 49% lower than their list price.
- Savings from loss of exclusivity (LOE) totaled $93 billion between 2016 and 2021, more than offsetting the $87 billion spent on newly launched brand medicines over this period.

Full Summary

Medicine Spending

- Total net manufacturer revenue on medicines increased 12.1% in 2021, driven by the "unprecedented contribution" of the COVID-19 vaccine and treatments, reaching $407 billion.
    - Excluding spending on COVID-19 vaccines and treatment, spending on medicines increased 4.9% in 2021.
- Total net manufacturer revenue on medicines is projected to increase 1-4% per year, on average, through 2026.
- Real per capita net medicine spending (net manufacturer revenue) grew by 5.8% in 2021 when factoring in COVID-19 spending.
    - Excluding spending on COVID-19 vaccines and treatment, real per capital net medicine spending would have *declined* by 1% in 2021.
    - Medicine spending per capita has increased just $204 since 2011, a 1.8% compound annual growth rate, from $1,028 to $1,232.
- Total net spending on medicines increased by $82 billion from 2016 to 2021, driven by new products and increased utilization
    - COVID-19 vaccines and treatments accounted for $29 billion of this growth
    - Savings from loss of exclusivity (LOE) totaled $93 billion between 2016 and 2021, more than offsetting the $87 billion spent on newly launched brand medicines
    - Between 2016 and 2021, changes in brand medicine prices *reduced* total spending on medicines by $700 million.

Exhibit 22: Spending and growth at estimated net manufacturer prices 2015–2020, all channels, US$Bn



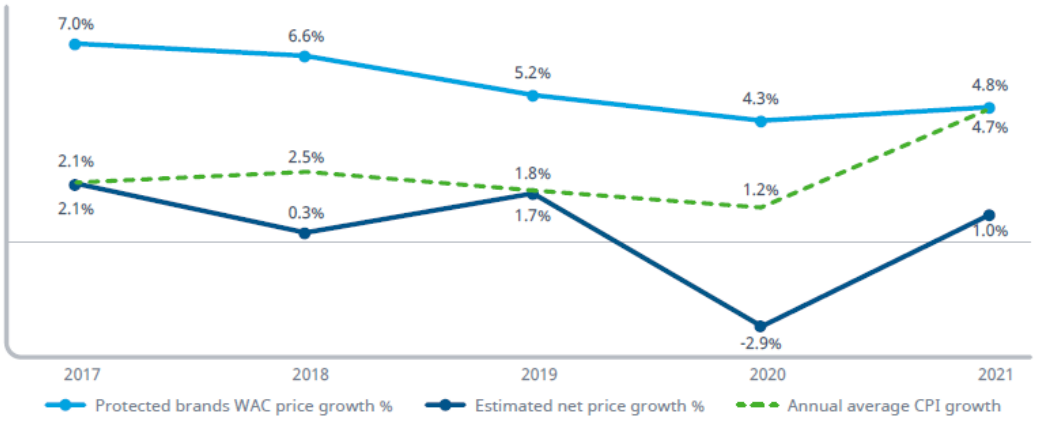
Source: IQVIA Institute, Mar 2022.

- Specialty medicines accounted for 55% of total medicine spending in 2021 but accounted for 3% of total prescription volume.

Medicine Prices

- Net prices for brand medicines increased 1.0% in 2021, below the rate of inflation for the fifth year in a row. Looking ahead, net price growth is projected to be 0% to -3% per year through 2026.
- Brand medicine net prices are, on average, 49% lower than their list price.
- List prices for brand medicines increased 4.8% in 2021, below the rate of inflation.

Exhibit 24: Wholesaler Acquisition Cost (WAC) growth and net price growth for protected brands

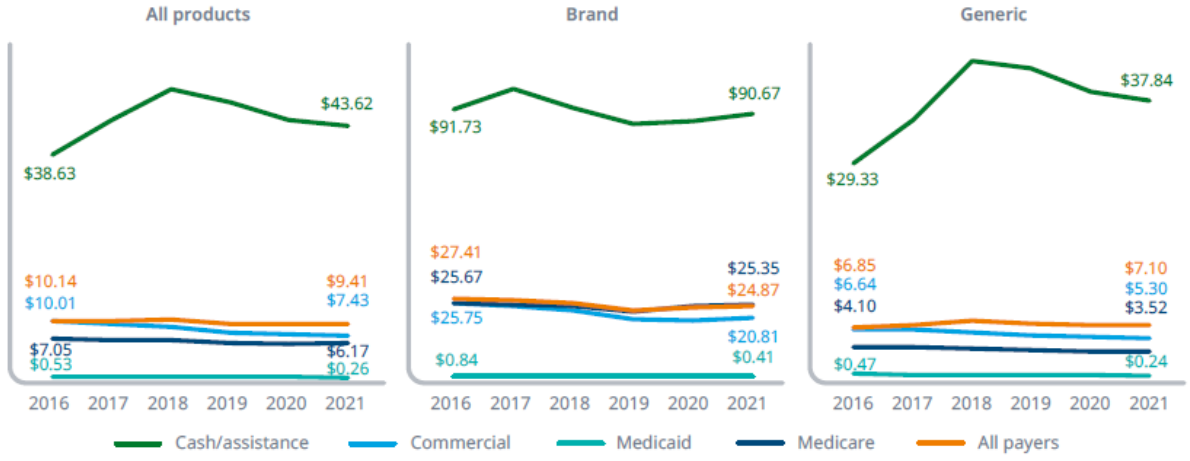


Source: IQVIA Institute, National Sales Perspectives, Dec 2021; Bureau of Labor Statistics, Annual Average Monthly CPI Growth, Dec 2021.

Patient Out-of-pocket (OOP) Spending

- The average OOP cost per retail prescription was $9.41 in 2021 (down from $10.14 in 2016)
- The average OOP cost per brand retail prescription was $24.87 in 2021 (down from $27.41 in 2016)

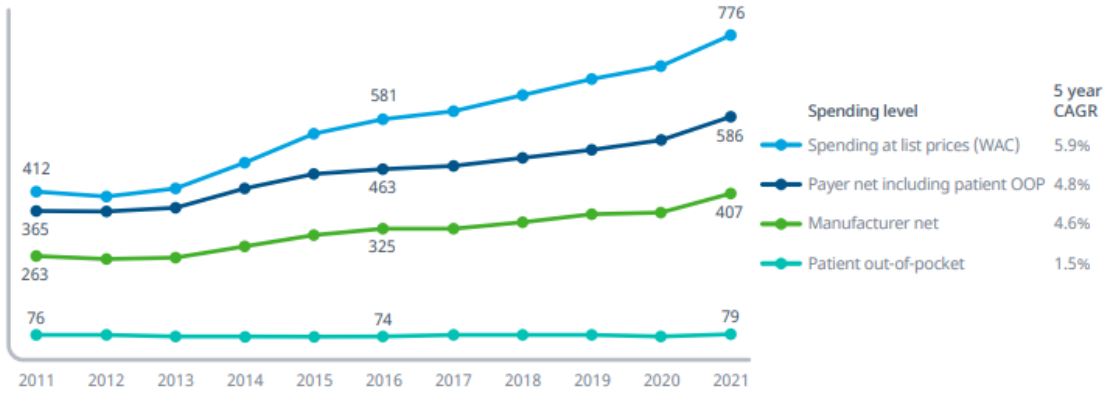
Exhibit 31: Average final out-of-pocket cost per retail prescription by product type and method of payment, 2016–2021



Source: IQVIA LAAD Sample Claims Data, Dec 2021.

- Across all patients, 29% had no annual medicine OOP costs, 8% reached annual OOP costs above $500, and 2.1% paid more than $1,500 OOP in 2021.
    - Among Medicare beneficiaries, 22% had no annual medicine OOP costs, 16% reached annual OOP costs above $500, and 4% paid more than $1,500 OOP.
    - Among commercially insured patients, 23% had no annual medicine OOP costs, 7.3% reached annual OOP costs above $500, and 1.6% paid more than $1,500 OOP.
- Over 92% of total prescriptions (brand and generic) had a final OOP cost below $20 in 2021, while 0.9% (totaling 64 million prescriptions) had a final OOP cost above $125.
- 73% of brand prescriptions had a final OOP cost below $20 in 2021, while 4% had a final OOP cost above $125.
- Coupons and debit cards provided by brand manufacturers totaled $12 billion in 2021.
- Total patient OOP spending increased by an average of 1.5% per year over the past five years, slower than the growth rate of payer spending on medicines, manufacturer net revenue growth, and spending at list price.

Exhibit 17: Medicine spending at selected reporting levels, US$Bn



Source: IQVIA Institute, Mar 2022; CMS National Health Expenditures (NHE), Dec 2020.

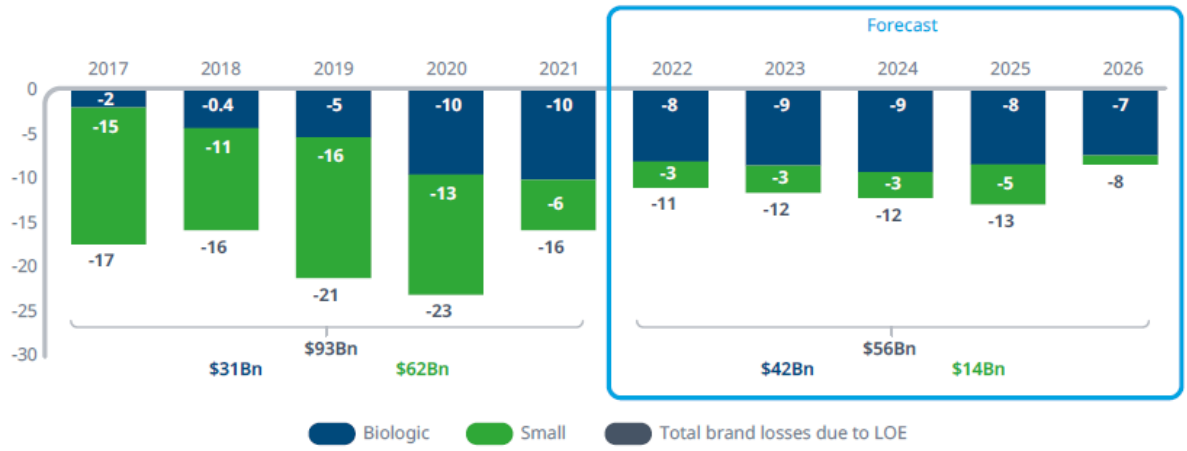
Abandonment

- Patients starting a new therapy abandoned 81 million prescriptions in total at the pharmacy in 2021.
- 61% of patients did not fill their new prescription when OOP costs exceeded $250, while just 7% of patients abandoned their prescriptions when OOP costs were less than $10.
- Abandonment of medicines to treat chronic conditions resulted in 5.3 billion fewer patient days of therapy in 2021.

Market Dynamics

- There were 72 novel active substances (NAS) launched in 2021, including emergency use authorizations (EUA) for COVID-19.
- Over the next five years, a projected 250–275 NAS will enter the market but are anticipated to represent an average 6–7% of brand spending compared to 11% in the past five years.
- LOE reduced net spending on brand medicines by $93 billion over the past five years, with a $62 billion savings from small molecules and $31 billion savings from biologics
- LOE is expected to lower brand spending by $56 billion from 2022 to 2026, with $41.6 billion from reduced spending on biologics.

Exhibit 42: U.S. impact of brand losses of exclusivity 2017–2026, US$Bn



Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Mar 2022.

Medicine Use

- Medicine utilization, measured by days of therapy, grew by 3.3% in 2021
- In total, dispensed prescriptions increased by an average of 2.1% per year over the past five years, driven mainly by the aging population.
- Retail drugs currently represent 86% of medicine use (by days of therapy), with non-retail accounting for the remaining 14%.

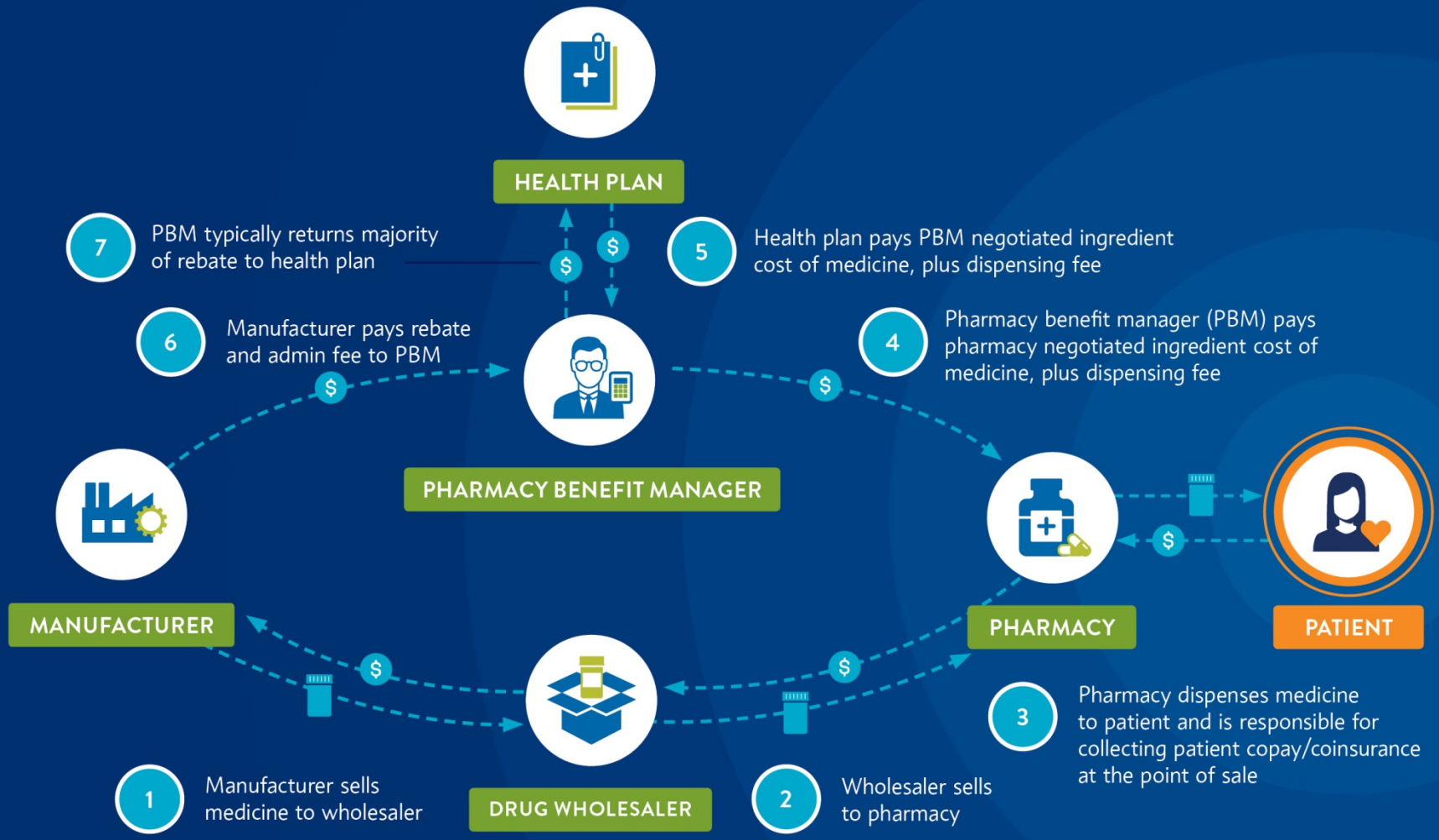
Condition Specific Findings

- Oncology
  - Oncology spending is projected to exceed $113 billion by 2026, with annual growth slowing to 9% due to competitive pressure from biosimilars
  - Net prices for brand oncology products are, on average, 7% lower than the list price.
- Cell, Gene, or RNA Therapies
  - There are currently 33 cell, gene or RNA-based therapies launched globally to-date, with 18 currently marketed in the U.S.
  - An additional 55–65 new therapies are expected to launch globally by 2026
  - “Even considering the large numbers of these products, they will not be more than 20% of all new drugs expected to be launched in the next five years and less than 10% of the spending on new drugs in the same period.”
  - Spending on these treatments is projected to reach $11 billion by 2026, estimates range under different assumptions ($7 to $20 billion).
- Diabetes
  - Net prices for brand diabetes products are, on average, 78% lower than the list price.
  - Total OOP costs paid by patients with insulin prescriptions amounted to $1.27 billion in 2021
    - 44% of this total is from the 20% of prescriptions that cost patients more than $35
  - Insulin OOP costs have declined by $500 million since 2018

        - If insulin OOP costs were capped at $35, patient spending would have been further decline by $555 million.
    - Net spending (manufacturer revenue) on diabetes medicines is projected to decline 12% through 2026, while list prices are estimated to grow 10-13% annually
- Autoimmune
    - Net prices for brand autoimmune products are, on average, 49% lower than the list price.
    - Net spending on autoimmune disorder treatments is expected to exceed $70 billion by 2026, slowing after 2022 due to key biosimilars

Distribution and Financial Flow

FOR RETAIL BRAND DRUGS



Source: Adapted from Pembroke Consulting

April 21, 2023

Chair Liz Olson
100 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, Minnesota 55155

Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

Re: House File 2680

Dear Representative Olson,

Eli Lilly and Company (Lilly) opposes Minnesota House File 2680 (HF 2680) 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."

HF 2680 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 HF 2680,[1] we focus our comments in this letter on the provisions of HF 2680 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 nationwide network of wholesalers, almost none of which are located in Minnesota. These wholesalers,

[1] For example, HF 2680 Article 2 Sections 23 through 28 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.

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 HF 2680 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]

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

[4] Although HF 2680 Section 36, Subd. 2(c) 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, HF 2680 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, HF 2680 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

---

[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. HF 2680 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 HF 2680 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 HB 768 (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 HF 2680 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. HF 2680 inappropriately relies on other legislation.

HF 2680 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. HF 2680 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 HF 2680 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. HF 2680 is simply premature in light of this other state legislation.

STATES SHOULD IMPLEMENT POLICIES THAT MORE DIRECTLY BENEFIT PATIENTS

As described above, we believe HF 2680 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.

* * * * * * *

We appreciate the opportunity to express our views on HF 2680. Given HF 2680 does not advance patient drug affordability goals and raises serious concerns under the United States Constitution, we respectfully request that you oppose.

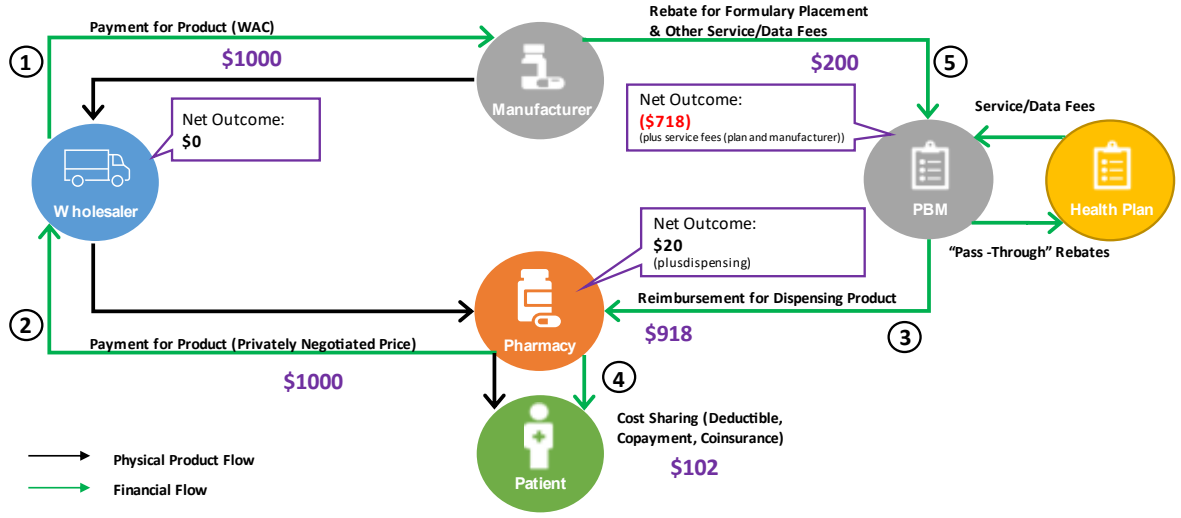
Sincerely,

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)

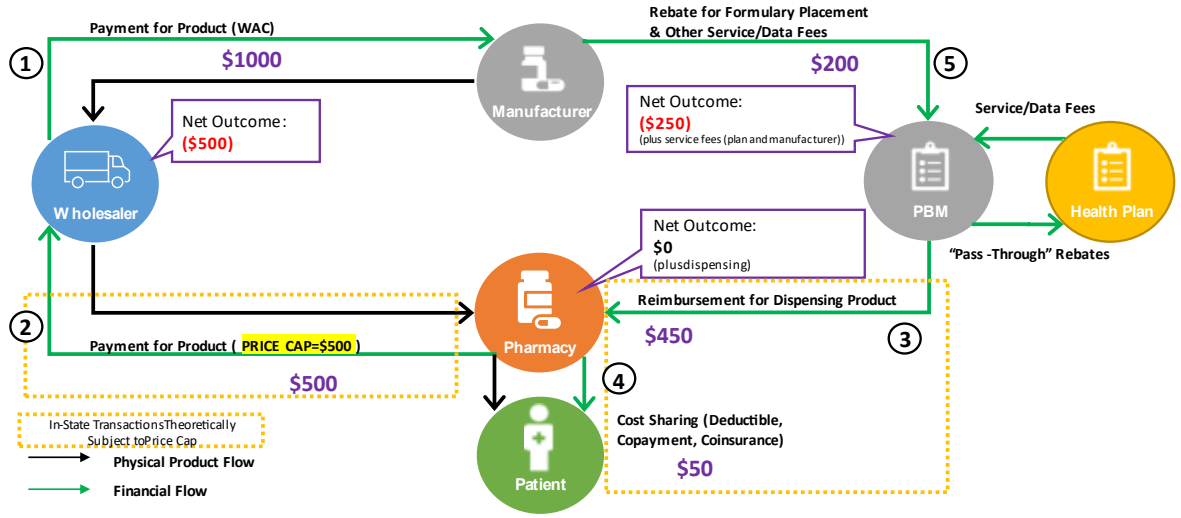
Hypothetical Drug X: Product & Financial Flows in Retail Channel (Before Price Control)



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).

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to Prescription Drug Affordability Board and Upper Payment Limit in Minnesota House File 2680, House Commerce Omnibus Bill

Updated March 27, 2023

Position: PhRMA respectfully opposes the prescription drug affordability board and upper payment limit provisions in the House Commerce Omnibus Bill, House File 2680 (HF 2680). PhRMA believes that discussions about the affordability of medicines are important, but the intention of this bill is for the government to decide drug prices, which could limit the prescription options available to Minnesotans. HF 2680 shortsightedly targets drug spending in ways that likely will have long-term, harmful effects on innovation and the development of new, life-saving therapies.

Specifically, HF 2680 implements a government-appointed Board to review prescription drug costs and value with the goal of setting price limits by way of an "upper payment limit" (UPL) for the entire drug supply system. Regulating drug prices in-state could lead to a shortage of or limit access to medicines for patients. Specifically, if a pharmacy or provider cannot obtain a medicine at the government price, the medicine will not be available to Minnesota residents. Further, the legislation also requires onerous disclosure of pricing information which will not benefit patients and could jeopardize the competitive market. By disincentivizing the development of innovative treatments, this legislation could threaten the positive effect that the biopharmaceutical industry has on Minnesota's economy.

Price controls on brand medicines raise constitutional concerns.

Application of this price control to patented medicines raises constitutional concerns under the Supremacy Clause because it would restrict the goal of federal patent law, which is to provide pharmaceutical patent holders with the economic value of exclusivity during the life of a patent. Congress determined that this economic reward provides appropriate incentive for invention and Minnesota is not free to diminish the value of that economic reward. Specifically, in the case of *BIO v. District of Columbia, 496 F.3d 1362 (2007)*, the U.S. Court of Appeals for the Federal Circuit overturned a District of Columbia law imposing price controls on branded drugs, reasoning that the law at issue conflicted with the underlying objectives of the federal patent framework by undercutting a company's ability to set prices for its patented products. The bill raises due process concerns as it provides broad authority to the Attorney General and the Prescription Drug Affordability Board (PDAB), with very few standards or safeguards to ensure that authority is exercised in a consistent manner. The bill gives the PDAB the authority to determine which products will be subject to a cost review, and which products will ultimately have a UPL imposed on them, but provides no clear and consistent standard for how the Board will conduct price reviews or set UPLs. The bill also raises concerns under the Dormant Commerce Clause, which precludes the States from regulating commercial activity beyond their own borders. See Association for Affordable Medicines v. Frosh, 887 F.3d 664 (4th Cir. 2018). And, by allowing the board to take prices in Canada into account in setting the upper payment limit, the bill raises questions under the Foreign Commerce Clause.

The use of Medicare Maximum Fair Price (MFP) as the UPL is premature as the federal government is still in the stages of implementation.

For prescription drugs identified by the Board as "creating an affordability challenge" and subject to the Medicare MFP, HF 2680 requires the Board to set the UPL at the MFP. Medicare MFP is a price-setting mechanism recently enacted as part of the federal Inflation Reduction Act ("IRA"). Implementation of the IRA statute and the complex framework of its MFP provisions is at an early stage, and many operational and legal issues remain to be sorted out.[1] PhRMA believes it is premature to incorporate the MFP as the UPL because the Centers for Medicare and Medicaid Services (CMS) has not issued guidance or parameters describing how the MFP will be calculated. Including the MFP within the process for UPL determinations, in the absence of these important details, risks creating a UPL-setting process that will be influenced in a manner that the Board cannot have considered until CMS has completed MFP implementation, which could ultimately conflict with requirements in the statute. In light of the work that still needs to be done at the federal level to shape the IRA's MFP provisions, MFP should not be used as a consideration for the UPL.

The Minnesota Department of Health's (MDH) first prescription drug price transparency report notes significant limitations in the data used for cost reviews to set a UPL.

In 2020, the Minnesota Legislature passed the Minnesota Prescription Drug Price Transparency Act (Act), which required drug manufacturers to report specific information for new prescription drugs, newly acquired prescription drugs and prescription drug price increases that meet the criteria outlined in the Act. As part of the Act, the MDH is required to publish an annual report of findings from the data submitted by drug manufacturers. The first report was published on February 21, 2023.

The Prescription Drug Price Transparency Report from MDH on drug manufacturer data noted significant limitations of the data for use in analysis, including:

> *Unfortunately, in its current design, the Act's impact is limited because:*[2]
> - *The focus is on list prices instead of net prices, and therefore does not represent the actual income manufacturers earn from the sale of their products.*
> - *The focus is only on manufacturers rather than the full supply chain. Other downstream entities—like pharmacy benefit managers, wholesalers, pharmacies, and payers—also contribute to the final price paid by consumers.*
> - *Reporting requirements treat drug pricing as if there is one market functioning under a single set of practices, which does not reflect the complex factors—such as incentives, economic environments, and business arrangements—driving pricing and rebate practices.*

HF 2680 requires the Commissioner of Health provide the Board information reported by drug manufacturers under the Act for use in their duties of identifying prescription drug products for a cost review that can result in the establishment of a UPL. The limitations the MDH notes in the report raise concerns that the data being used to identify prescription drug products for costs reviews has significant flaws and should not be used for cost reviews or to set a UPL until the limitations of these data are addressed.

[1] See Establishment of the Medicare Drug Rebate and Negotiations Group Within the Center for Medicare (CM), 87 Fed. Reg. 62433, 62433 (Oct. 14, 2022) ("The work required to implement and administer these new programs will be novel and differ significantly from the Medicare functions that CMS performs today ... Moreover, the scope and complexity of these new programs ... require that a new, dedicated organization be established to ensure that CMS is able to implement these programs successfully and on time.").

[2] Minnesota Department of Health. Minnesota Prescription Drug Price Transparency Report to the Minnesota Legislature. February 2023.

This legislation ignores that there are meaningful policies for addressing affordability without utilizing government price setting that could reduce treatment options.

PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $236 billion in 2021,[3] do not make their way to offsetting patient costs at the pharmacy counter. Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy, such as making monthly costs more predictable, making cost-sharing assistance count toward a plan's out-of-pocket spending requirements, and sharing negotiated savings on medicines with patients. These policies can be done without utilizing international price setting, which can reduce the options available to treat patients.

This legislation does not account for insurance benefit design issues that prevent discounts from flowing to patients, and HF 2680 assumes incorrectly that the price a patient pays is determined solely by drug manufacturers.

This legislation singles out the biopharmaceutical industry and ignores the variety of stakeholders involved in determining what consumers ultimately pay for a medicine, including insurers, pharmacy benefit managers (PBMs), wholesalers, and the government. The important role that these entities play in determining drug coverage and patient out-of-pocket costs is overlooked by the requirements of this legislation. For example, PBMs and payers—which dictate the terms of coverage for medicines and the amount a patient ultimately pays—negotiate substantial rebates and discounts.

According to research from the Berkeley Research Group (BRG), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year, while the share received by manufacturers has decreased over time. In 2020 manufacturers retained only 49.5% of brand medicine spending while members of the supply chain retained 50.5%.[4] Increased rebates and discounts have largely offset the modest increases in list prices and reflect the competitive market for brand medicines.

The growth of net price prices, which reflects rebates and discounts, has been in line with or below inflation for the past five years. Specifically, brand medicine net prices increased 1.0% in 2021.[5] This, of course, does not necessarily reconcile with what patients are feeling at the pharmacy counter, which is why looking at the whole system is so important. For example, despite manufacturers' rebates and discounts negotiated by health plans, nearly half of commercially insured patients' out-of-pocket spending for brand medicines is based on the medicine's list price rather than the negotiated price that health plans receive.[6]

In FFY2020, only 3.6% of Minnesota's Medicaid budget was spent on prescription drugs, including both brands and generics. Specifically, in FFY2020, pharmaceutical manufacturers paid more than $632 million in brand and generic rebates, which is 55% of the total Medicaid spending on drugs, on Minnesota's Medicaid drug utilization alone.[7]

---

[3] Fein, A. "The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2022.
[4] BRG: The Pharmaceutical Supply Chain 2013-2020. January 2022.
[5] IQVIA Institute for Human Data Science. The Use of Medicines in the U.S. 2022. Published April 2022. Accessed January 2023. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022
[6] IQVIA Institute for Human Data Science. Medicine spending and affordability in the United States. Published August 2020. Accessed August 2020. https://www.iqvia.com/insights/theiqvia-institute/reports/medicine-spending-and-affordabilityin-the-us
[7] Menges Group analysis of FFY2020 CMS Financial Management Reports (FMR) and State Drug Utilization (SDU) data files. Brand/generic expenditure totals net of rebates. Data predominantly derived from CMS FMRs. Brand/generic prescription drug costs derived through tabulations performed by Menges. Pre-rebate expenditures tabulated using FFY2020 CMS SDU data files and CMS brand/generic indicators for each NDC. Statutory rebates and fee-for-service supplemental rebate information obtained from CMS FMRs. MCO supplemental rebates available in FMRs for several states and estimated in remaining states at similar percentages as the published FMR data indicate. Generic rebates assumed to always be at the statutory 13% level –no supplemental rebates assumed. Total brand rebates are therefore derived as the difference between total rebates and the generic statutory rebates. Post-rebate expenditures derived through Menges tabulations using above information.

The biopharmaceutical industry is heavily regulated and discloses significant information to the public.

The biopharmaceutical industry is one of the most heavily regulated industries in the United States. Companies already report extensive information to the federal government about costs, sales, clinical trials, and total research and development (R&D) expenditures. HF 2680 goes further and focuses on the costs of approved medicines while ignoring a large portion of the drug discovery and development process—failure. Specifically, requiring information on production and distribution costs for individual products may not be feasible, as R&D is a long-term process, and manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Accounting for these related discovery costs could be nearly impossible.

Much of the information that HF 2680 requires to be disclosed is considered proprietary and confidential trade secret information, which is protected by state and federal law. The Federal Trade Commission (FTC) has repeatedly acknowledged that disclosure of competitively sensitive information could undermine beneficial market forces within the pharmaceutical industry.[8] In a letter to the New York legislature in 2009, the FTC's Office of Policy and Planning, Bureau of Competition and Bureau of Economics cautioned that disclosure of information similar to what is requested in HF 2680 could jeopardize the competitive market by impacting incentives to provide discounts and additional rebates, which "…may increase pharmaceutical prices."[9]

This legislation could harm Minnesota's economy.

On average, it takes more than 10 years and $2.6 billion to research and develop a new medicine. Just 12% of drug candidates that enter clinical testing are approved for use by patients. Efforts to impart price controls on innovative manufacturers could chill the research and development of new medicines by taking away the incentives that allow manufacturers to invent new medicines. Price controls also could severely reduce Minnesota patients' access to medicines, as is seen abroad.

The biopharmaceutical sector is committed to bringing new treatments and cures to patients. This commitment to innovation supports high-quality jobs and is a vital part of Minnesota's economy and its economic competitiveness. The biopharmaceutical sector directly accounted for 11,733 jobs in Minnesota in 2020 and supported another 50,036 jobs in Minnesota for a total of 61,769 jobs. These jobs generated over $1.1 billion in state and federal tax revenue for in 2020. This bill could place these jobs, and tax revenue, in jeopardy.

PhRMA recognizes the access challenges faced by patients in Minnesota with serious diseases. We stand ready to work with the Minnesota legislature to develop market-based solutions that help patients better afford their medicines at the pharmacy counter. We believe this bill would not help patients better access breakthrough, innovative medicines and respectfully oppose the passage of HF 2680.

We urge you to vote no for HF 2680 for these reasons.

[8] FTC Letter to Terry G. Kilgore, Member, Virginia House of Delegates, re: H.B. 945 (Oct. 2, 2006); FTC Letter to Representative Patrick McHenry, re: North Carolina Bill 1374 (July 15, 2005); FTC Letter to California Assembly Member Greg Aghazarian, re: AB 1960 (Sept. 7, 2004). FTC Letter to The Honorable Mark Formby, Mississippi House of Representatives, re: SB 2445 (March 22, 2011).
[9] FTC Letter to Senator Seward, re: SB 58 (March 31, 2009).

MINNESOTA NEWSPAPER ASSOCIATION

Re: Minnesota Age-Appropriate Design Code Act in SF 2744/HF 2680

Dear Members of the House Ways & Means Committee,

I write on behalf of Minnesota's newspapers and magazines to express concerns about language in the Age-Appropriate Design Code Act included in the House Commerce Omnibus bill (SF 2744/HF2680). Although the legislation is not focused on professional news organizations, we believe the bill would impact them nonetheless. Some provisions, particularly the definitions – or lack thereof – introduce ambiguity that would make compliance difficult and could limit the ability of professional news organizations to provide valuable information to the public they serve. This could produce very adverse consequences for the state's news media and, consequently, its citizens and communities.

It is our understanding this bill is about protecting children's privacy, a worthy goal. However, the bill contains provisions that appear to go beyond data protection. We appreciate the author's intention to delete the direct reference to content, but provisions remain that create a significant risk of limiting access to news content even if that content is not otherwise subject to the bill's restrictions. For example, the language in Section 2 ("Construction") requires consideration of "the best interests of children" when providing an online service, product, or feature. For the news media, the product provided is quite literally the news, so this provision amounts to a requirement to regulate truthful content in the public interest.

Because a news organization's product differs from those entities the bill seeks to target, compliance with this legislation is likely to be difficult. Consider the requirement that a data protection impact assessment be completed before "any new online services, products, or features are offered to the public." It is unclear what is considered "new" for the purposes of a news organization's website. News content changes by the hour, stories and features are being added and adjusted all the time. Does every story require a new data protection impact assessment? Does the creation of a new regular Sunday column or a new multi-part investigative series trigger a new data protection impact assessment? Because the proposal was crafted using terms common to tech platforms, whose business is distinct from professional news organizations, there is a lack of clarity for our industry. We are concerned that Minnesota news organizations will find compliance challenging.

The impact of this proposal goes beyond national and regional media companies. Any newspaper that collects subscriber information, does business in Minnesota, and has gross annual revenues of more than $25 million must comply with this bill. As many of Minnesota's local newspapers are part of larger parent news organizations, they would be subject to these requirements despite a significantly smaller individual revenue footprint.

Subjecting professional news organizations to a proposal aimed at social media and tech companies will provide no public benefit but is likely to have unintended negative consequences on our ability to deliver news to the public. Because of these concerns, we have requested the addition of language to clarify that professional news organizations are exempt from this Act. We appreciate Chair Stephenson and Rep. Bahner's willingness to talk with us and consider our suggested language. We are hopeful we can find some agreement before this proposal becomes law.

Minnesota Newspaper Association | 10 South Fifth Street, Suite 1105 | Minneapolis, MN 55402-1502
P: 612-332-8844 E: Member@mna.org W: www.mna.org

MINNESOTA NEWSPAPER ASSOCIATION

High-quality, professional journalism plays an important role in the democratic process, and in supporting local communities. Millions of Minnesotans – including young readers – rely on the state's news organizations and their associated websites and apps to stay up to date on the latest local, domestic, and international news, political developments, culture and society, and specific topics related to their hobbies, sports, activities, or areas of interest. We look forward to working with you to ensure Minnesota's news organizations will not be inhibited in performing this vital role.

We very much appreciate your consideration.

Lisa Hills
Executive Director