

Report of the Minnesota Attorney General's Advisory Task Force on Lowering Pharmaceutical Drug Prices

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Minnesota Attorney General Keith Ellison
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Foreword

From Attorney General Keith Ellison

My job as Attorney General is to help Minnesotans afford their lives and live with dignity and respect. But the cost of prescription drugs is so high that far too many Minnesotans are having to choose between affording their lives and staying alive.

Take insulin, a life-saving drug for people with diabetes. The researchers who discovered it almost 100 years ago sold the patent for it for \$1, because they wanted it to save lives. So why has the price of insulin gone up more than 1,100% in the last 20 years? Why does the same drug cost 90% less in Canada?

Take Tysabri, a drug that Rep. Rod Hamilton, who served on the Task Force, takes to control his muscular sclerosis. The price has doubled and now costs \$15,000 a month. Why? Who sets that price, anyway, and how?

And why do Minnesota families *with* health insurance pay on average \$5,000 in out-of-pocket costs each year?

These are the kind of questions Minnesotans want answered and the kind of problems Minnesotans want solutions to. They affect every single one of us, because every single one of us has taken or will take a prescription drug. And none of us can wait any longer for answers and solutions.

This is why I created a Task Force to gather in the best thinking in order to understand why the costs of prescription drugs are so high — in some cases, unconscionably so — and come up with legislative, legal, regulatory, and community-based strategies to bring them down. Task Force members heard hundreds of hours of testimony, read thousands of pages of studies and reports, and spent many more hours debating and coming up with recommendations. The 15 people who served on the Task Force have brought a great diversity

of experience, knowledge, and perspective. I thank each one of them, especially co-chairs Nicole Smith-Holt and Senator Scott Jensen.

This thorough, eye-opening report first answers the overall question of why the pharmaceutical-drug market doesn't work for people and drives prices so high. Then it proposes 14 recommendations that will put less-expensive drugs in people's hands and give us stronger tools for bringing more transparency and public accountability to the industry.

This isn't the end of the Task Force's work — it's the beginning of the work that all of us now have to do to implement these recommendations and bring drug prices down so that Minnesotans can not only afford their lives, but can afford to live with dignity and respect.



Table of Contents

Executive Summary	6
The Impact of High Drug Prices	6
Causes and Contributors to High Drug Prices	7
The Task Force’s 14 Recommendations	9
Next Steps.....	10
1. Introductions and Overview of the Advisory Task Force on Lowering Pharmaceutical Drug Prices	11
1.1 Structure and Membership of the Task Force.....	11
1.2 The Scope of This Report and Its Intended Audience.....	12
2. Understanding the Drug Industry, How it Works, and How Its Structure and Dynamics Permit and Incentivize High Drug Prices.	14
2.1 Understanding and Quantifying the Problem.....	14
2.2 The Entities Involved In the Distribution and Pricing of Pharmaceuticals.	20
2.3 The Current Federal and State Legal Landscape Regarding Prescription Drugs.....	24
2.4 Examples of Problematic Drug Pricing Practices.	29
2.5 How High Drug Prices and Price Increases Affect Minnesotans.....	31
3. Significant Causes And Contributors Resulting In High Prescription Drug Prices.	36
3.1 The Misuse and Abuse of Patent, Exclusivity, and Related Laws to Insulate Drug Manufacturers From Competition Significantly Contributes to High Prescription Drug Costs.....	36
3.2 Patients’ Inability to Access More Affordable Sources of Medications Through Safe, Vetted Importation Programs Contributes to High Prescription Drug Costs.	39
3.3 Anticompetitive Conduct in the Drug Industry Significantly Contributes to High Prescription Drug Costs.....	40
3.4 Deceptive and Other Unlawful Marketing Practices in the Drug Industry Significantly Contribute to High Prescription Drug Costs.	42
3.5 The Opacity of, and Conflicts of Interest Present in, PBMs’ Business Models Significantly Contributes to High Prescription Drug Costs.	43
3.6 Perverse Economic Incentives that Result in High-Cost Drugs Being Used Even When Generic Alternatives Are Available Significantly Contribute to High Prescription Drug Costs.....	44
3.7 The Lack of Transparency Regarding How Drugs Are Priced and Paid For Significantly Contributes to High Prescription Drug Costs.	47



4. Selected Past and Current Legislative, Regulatory, and Law Enforcement Strategies That Have Attempted to Address High Prescription Drug Prices.	49
4.1 Selected Past and Current Federal and State Legislative and Regulatory Strategies to Address High Drug Prices.	49
4.2 Selected Past and Current Law Enforcement Strategies to Address High Drug Prices.	52
5. Recommendations of the Minnesota Attorney General's Advisory Task Force on Lowering Pharmaceutical Prices.	53
5.1 Create a "Prescription Drug Accountability Commission" to Oversee Drug-Industry Pricing Practices in Minnesota.	54
5.2 Import Critical-Access Drugs Into the State on a Trial Basis.	56
5.3 Enact Legislation Defining and Prohibiting Price-Gouging Related to Prescription Drugs.	57
5.4 Strengthen Deceptive Trade Practices and Advertising Laws Related to Drug Pricing Information.	58
5.5 Enact a State Anti-Kickback Law, and Prohibit Copay Coupons and Similar Practices When a Generic Version of a Drug is Available.	59
5.6 Strengthen Laws Targeting Anticompetitive Behavior in the Drug Industry.	60
5.7 Advocate for Reform of Certain Federal Patent and Exclusivity Laws Governing the Drug Industry.	61
5.8 Optimize and Expand Use of the 340B Drug Pricing Program.	62
5.9 Create An Inventory of All Government Entities to Determine Whether They Purchase Drugs Directly or Indirectly, and Identify Their Annual Expenditures.	63
5.10 Optimize Use of MMCAP INFUSE Program and Further Expand It to Provide Similar Savings to Minnesota Patients.	64
5.11 Minnesota Should Robustly Regulate PBMs and Their Business Practices, Building on the PBM Legislation Enacted in 2019.	66
5.12 Minnesota Should Encourage and Facilitate Price Transparency for Prescription Drugs.	67
5.13 Assure Patient Access To Pharmacists' Services for Effective Medication Use.	68
5.14 Support More Research on Prescription Drug Prices & Drug Benefits.	70
Conclusion and Next Steps.	71
Glossary of Terms.	72
Committee Members.	73
Endnotes	75



Executive Summary

The market for prescription drugs in Minnesota and the United States is exceedingly complex, opaque, rife with anticompetitive and other problematic business practices, and the laws governing the industry are often misused and abused. In short, the market for prescription drugs is dysfunctional and the prices of them are far too high. Significant reforms to how such drugs are regulated, distributed, and paid for are necessary to rein in the skyrocketing cost of these often life-saving medications. The goal of this report is to propose solutions that if properly implemented, will lower the cost of prescription drugs for the many Minnesotans who struggle to pay for the medications they desperately need.

The Impact of High Drug Prices

Everyone will take a prescription drug at one point in their lives. Currently, 58% of non-senior adults and 86% of seniors were prescribed a medication in the last year. Minnesotans, like Americans everywhere, spend a lot of money on them: in 2017, Minnesota spent nearly \$5.2 billion on retail prescription drugs. If prescriptions administered in medical settings (e.g., a hospital) are taken into account, this number approaches \$8.7 billion. And the cost is rising far more quickly than the rate of general inflation: according to data compiled by the Minnesota Department of Health, prescription drug spending in Minnesota rose by 28.6% between 2013 and 2017.

But the market for prescription drugs does not function like markets for other goods and services for many reasons that are unique to the pharmaceutical industry. (See Section 2.1.1.) The prescription drug market is also fragmented between different types of drugs that are subject to different regulatory requirements, and involves scores of entities in an exceedingly complex distribution chain that are all fixated on maximizing their own profits through the sale or administration of the drug at issue. (See Sections 2.1.2-.3.) These circumstances have led to prices and price increases for drugs that are staggering, with the cost of some of the more expensive prescription drugs now exceeding \$60,000 per month. (See Sections 2.1.5-.6.)

The high cost of many pharmaceutical drugs has forced some people to spend less on groceries, postpone paying bills, get a second job, or even declare bankruptcy. Indeed, some Americans—8% in one recent survey—have resorted to crossing the border into Canada or Mexico to purchase drugs at a small fraction of the price that they cost in the United States. (See Section 2.1.7.) Further, the high cost of prescription drugs has created significant



barriers to patients' adherence to their prescribed medication regimes: almost one in ten Minnesotans, more than half a million people have not filled a prescription in the last year due to its prohibitive cost. (See Section 2.1.8.)

The price of insulin illustrates how increases in the price even of old drugs whose original patents expired long ago can cause financial strains on Minnesota families. Insulin was first discovered in 1922. About 330,000 people, or nearly 8% of Minnesota residents, have diabetes today. But the price for some insulin products has increased more than 1,100% over the last two decades. Diabetics' insulin costs doubled between 2012 and 2016 alone and now average about \$5,705 a year. As a result, the Minnesota Attorney General's Office has a pending lawsuit against the three major manufacturers of insulin over pricing practices it alleges are deceptive, fraudulent, and unlawful. (See Section 2.4.)

Causes and Contributors to High Drug Prices

Section 3 of this report details numerous causes and contributors to the high drug prices that Minnesotans are forced to pay. These causes and contributors include:

1

First, the misuse and abuse of federal patent and exclusivity laws by drug manufacturers has led to high-cost branded drugs being insulated from generic competition for years—if not decades—beyond the initial patent and exclusivity periods. For example, AbbVie created a “patent thicket” for Humira, which is used to treat arthritis and is the top-selling drug in the world, by securing 132 patents for the drug, which resulted in 39 years of patent protection. (See Section 3.1.)

2

Second, partly as a result of misuse and abuse of patent and exclusivity laws, the U.S. now spends more money per capita on prescription drugs than any other high-income country and this gap is continuing to grow. For example, Crestor, a medication used to lower high cholesterol, costs between 169% to 336% more in the United States than it does in Canada, France, or Japan. Minnesotans' inability to safely access and import drugs at the often dramatically cheaper prices found in other countries is another impediment to lower drugs costs. (See Section 3.2.)

3

Third, various anticompetitive practices are also pervasive in the drug industry. One such practice is called “product hopping,” where a branded drug manufacturer makes minor changes to some aspect of a drug besides its active ingredient. After doing so, the manufacturer secures additional patent or exclusivity rights to the “new” version of the drug, and stops selling the prior version, extending its monopoly power.

Another anticompetitive practice is “pay for delay” arrangements where a branded drug manufacturer pays a generic competitor to delay the launch of its rival generic drug, ostensibly to settle patent litigation.





4

Fourth, certain industry marketing practices drive up demand for expensive, branded pharmaceuticals. “Direct-to-consumer” advertising of drugs—which has increased dramatically since it was largely deregulated in the 1990s and which is permitted in only one other country in the world—significantly contributes to high drug costs. The same is true regarding the “off-label” marketing of drugs for conditions they are not approved to treat. (See Sections 3.3-4.)

5

Fifth, the business practices of pharmacy benefit managers (“PBMs”), which are middle men in the drug sales chain further drive up the cost of prescription drugs in various manners. Chief among them are PBMs’ rebate practices, which incentivize drug manufacturers to increase the price of their drugs so these manufacturers can offer PBMs larger rebates—which is an important source of revenue for PBMs—without affecting manufacturers’ bottom line. These same rebate practices also incentivize PBMs to sell more expensive branded medicine through their pharmacy networks, as opposed to cheaper generics, because the rebates offered on branded drugs are generally larger than those offered on generic ones. PBMs lack of transparency into their business practices and how they are reimbursed for drugs further obscures critical data that could be used to lower drug costs. (See Section 3.5.)

6

Finally, perverse economic incentives that drug manufacturers offer patients can result in a patient choosing a more expensive branded drug even when a cheaper generic is available. Things such as “patient discount coupons” or “patient assistance programs” may lower a patient’s upfront copay or other costs somewhat, but they incentivize a patient to use a more expensive branded drug instead of an equivalent generic one, which their health plan must ultimately pay for, thereby driving up patients’ monthly insurance premium. (See Section 3.6.)



The Task Force's 14 Recommendations

Over the course of 2019, the Task Force conducted a thorough review of materials and information presented to it by numerous speakers, consulted with various experts and other people knowledgeable about the drug industry, and engaged in extensive discussion and debate about the best manner to address high drug prices. This resulted in the Task Force formulating 14 policy proposals that, if satisfactorily adopted and implemented, it believes will lower the cost of prescription drugs for all Minnesotans.

The Task Force's 14 Recommendations

1

Create a “Prescription Drug Accountability Commission” to address drug pricing and related practices in Minnesota. This commission would have the power to investigate, review, and publish information on prescription drug prices. It would also have power to take action to hold drug companies accountable for unreasonable or unlawful pricing practices, including by “capping” or setting maximum reimbursement prices for drugs under certain circumstances or referring the matter to the Minnesota Attorney General’s Office for potential enforcement actions.

2

Import, through a prime vendor, four critical access drugs—insulin, EpiPen, Truvada, and naloxone. This would be done on a trial basis initially, with the potential for expansion of the program if it is successful. These four drugs should be imported for use in Minnesota at affordable prices consistent with global market rates for the products.

3

Enact drug price-gouging legislation that prohibits drug manufacturers from charging or causing to be charged an unconscionable price—that is, a price that cannot be reasonably justified—for essential prescription drugs that are sold in Minnesota.

4

Strengthen Minnesota’s consumer fraud laws as they relate to deceptive and misleading marketing, as well as other problematic business practices utilized in the drug industry.

5

Enact a state anti-kickback law that applies to both government programs and the private sector, including prohibiting copay coupons or equivalent programs when a generic version of the branded drug at issue is available.

6

Strengthen Minnesota’s antitrust laws to prohibit specific, anticompetitive practices present in the drug industry, such as product hopping and pay-for-delay settlements.



7

Minnesota's federal and state lawmakers—and other policy leaders—should strongly advocate for reform of federal patent and drug exclusivity laws that are being misused and abused to block competition from cheaper generic drugs.

8

Optimize and expand Minnesota's use of the federal 340B Drug Pricing Program, which allows health care providers to purchase drugs at dramatically reduced prices under certain circumstances, and then make the pricing discounts received through this program available to more Minnesota patients.

9

Quantify how much all Minnesota government entities spend on prescription drugs, to enable these entities to better pool and utilize their bulk purchasing power to obtain additional pricing concessions from drug manufacturers when buying drugs.

10

Optimize and better utilize Minnesota's bulk purchasing power through MMCAP INFUSE, including by expanding the pricing discounts this buying program receives to everyday Minnesotans, or create a parallel program that would do so.

11

Robustly regulate PBMs and their business practices, building on the PBM legislation enacted in 2019, and further increase transparency into the rebates they receive.

12

Enact additional measures to increase transparency into how drugs are priced and reimbursed throughout the drug sales chain.

13

Ensure patient access to pharmacists for effective medication use.

14

Support additional research into prescription drug pricing and drug benefits.

Next Steps

The Task Force views this report as only the end of the beginning. It will be up to lawmakers, agencies with rulemaking authority, advocates, and other policymakers, including not least the Minnesota Attorney General's Office, to continue to advocate for and lend their expertise to turning the Task Force's recommendations into action. Only if all stakeholders act with the urgency that this issue requires will the spotlight remain appropriately focused on the life-or-death issue of lowering the skyrocketing cost of prescription drugs for Minnesotans.



1. Introductions and Overview of the Advisory Task Force on Lowering Pharmaceutical Drug Prices

1.1 Structure and Membership of the Task Force.

The Advisory Task Force on Lowering Pharmaceutical Drug Prices (hereinafter “Task Force”) was established in February 2019 by the Office of the Minnesota Attorney General, Keith Ellison. The Task Force consists of 15 members. Its members include experts on pharmaceutical drug prices, patients and their family members, medical practitioners, a representative of the Minnesota Board of Pharmacy, and Minnesota legislators.¹ The full Task Force first met on April 23, 2019, and seven more times thereafter, with the final meeting taking place on January 14, 2020. The Task Force also formed three working groups that met numerous additional times.

The Task Force was comprised of the following members:



In support of the Task Force, three working groups were established: Working Group #1 was tasked with determining the role of federal and state legislative and regulatory actions in lowering drug prices;² Working Group #2 focused on identifying root causes and contributing factors to the increase in pharmaceutical drug prices; and Working Group #3 conducted a comprehensive analysis of various strategies that have been, and could be, undertaken to lower drug prices. The working groups met numerous times throughout the spring, summer, and early fall of 2019.

Advisory Task Force Working Groups		
<p style="text-align: center;">Working Group #1 Legislative Regulatory Action</p> <p>Task: Determine the role of the federal and state legislative and regulatory actions in lowering drug prices</p> <p>Members: Sen. Matt Little Rep. Rod Hamilton Cody Wiberg Shirlynn LaChapelle Nicole Smith-Holt</p>	<p style="text-align: center;">Working Group #2 Causes & Contributors</p> <p>Task: Identify the root causes and contributing factors to the increase in pharmaceutical drug prices</p> <p>Members: Dr. Stephen Schondelmeyer Dr. Leonard Snellman Rose Roach Rep. John Lesch Christy Kuehn</p>	<p style="text-align: center;">Working Group #3 Past, Current, and Future Strategies</p> <p>Task: Conduct a comprehensive analysis of various strategies that have been, and could be, undertaken to lower drug prices</p> <p>Members: Phu Huynh Nazie Eftekhari Jessica Braun Elo Alston Sen. Scott Jensen</p>

Bylaws governed the operations of the Task Force.³ Public participation was also welcomed at every stage of the Task Force process. All meetings were open to the public, with dates, times, and locations of meetings posted online in advance.⁴ Time was also allocated for public testimonials at all full Task Force meetings.⁵ Both the full Task Force and working groups brought in numerous experts, advocates, industry members, and state officials to provide them information and advice on addressing high drug prices.⁶ Listening sessions attended by various members of the Task Force and Attorney General Ellison were further held throughout the state.

1.2 The Scope of This Report and Its Intended Audience.

It was not the Task Force’s goal to write a report simply cataloging the problem of high drug prices. To comprehensively summarize the legions of issues discussed by or presented to the Task Force and its working groups would require a report so voluminous that it would be of limited use to all but drug-industry experts. The Task Force’s purpose was instead to write a report easily understood by non-experts that can and will help everyday Minnesotans afford their lives and live with dignity and respect by allowing themselves, policy makers, and others to effectively advocate for measures to rein in the high cost of prescription drugs. The primary audience for this report was, correspondingly, those who must turn the Task Force’s recommendations into action, not drug-industry experts.

This report focuses on this audience in several ways. First, Section 2 provides a solid underpinning of information and examples to assist in understanding the many entities involved in the complex drug sales and distribution chain, the often-perverse economic and other incentives found throughout this chain, and how these dynamics result in ever-increasing drug prices. Section 3 builds on this foundation by specifically discussing and analyzing some of the major causes that drive drug prices higher, without attempting to list every possible contributor. Section 4 highlights selected past and current legislative and regulatory efforts to address high drug prices, so advocates and policymakers are aware of some of the initiatives to address drug prices that have been tried previously. Finally, Section 5 lays out a series of clear and understandable recommendations the Task Force believes will help address the problem of high drug prices. By structuring its report in this manner, the Task Force believes it can be an effective tool for Minnesotans and policymakers to use to understand the problem of high drug prices and be more effective advocates for change.



2. Understanding the Drug Industry, How it Works, and How Its Structure and Dynamics Permit and Incentivize High Drug Prices.

2.1 Understanding and Quantifying the Problem.

The Task Force's first step in coming up with recommendations to lower the high and continually increasing cost of prescription drugs, was examining a number of underlying factual circumstances that affect the cost and pricing of pharmaceuticals.

2.1.1 Traditional Economic Principles Are Often Distorted or Do Not Apply to the Prescription Drug Market⁷

In a number of ways, traditional economic principles break down in the pharmaceutical market. Unlike in a typical consumer market, the individual end-user of prescription drugs—the patient—has a limited ability to choose when, where, and what to purchase. This, in turn, distorts the interaction between buyers and sellers in the market that would ordinarily determine prices. In addition, competition in the pharmaceutical market is limited, both legally and artificially, which constrains the market forces that would otherwise drive down prices.

First, healthcare is different than other consumer goods because patients do not initiate the purchase or engage in the market directly. In a prescription drug purchase, “the patient is not a consumer in the traditional sense,” but typically learns of the need, evaluates options, and is directed to purchase a particular medicine by a third-party, such as a doctor.⁸ Patients often lack sufficient information or expertise to make fully-informed choices themselves about the drugs they use. Even basic information on drug pricing may be unavailable to allow patients to make fully-informed choices.

Patient also typically need a “permission slip”—in this case, a prescription—to purchase a drug. Unlike most markets, patients are legally barred from making their own choices even if they desired to do so. In other words, the health professional acts a “gatekeeper to the pharmaceutical market.”⁹ This health professional may also not know or even care about the price,¹⁰ as their primary objective is the health of the patient. In addition, the health professional may be subject to sales pressure from people marketing brand-name drugs.¹¹ Patients may also be unaware that in some instances—for example, in arrangements where doctors are compensated based on a percentage of the drug's cost such as Medicare Part B's 6% flat reimbursement rate—the doctor's incentive to prescribe a more expensive drug may be in direct conflict with the patients' economic best interests. There is little room in this dynamic for the patient's independent choice and power in making decisions about which drugs to use.

Pharmaceutical purchases are also unique because they are about health. Patients have a limited ability to make rational choices in the face of illness or life-or-death situations, where one's health compels the patient to make the purchase in a way that defies traditional ideas of choice. Additionally, the value of a drug to a patient—its health benefits—may not be felt until some unknown point in the future or the benefit will be in avoiding some future illness. In this way, drugs operate as a form of investment in one's future health, making it difficult for a patient to assess the value at the time of purchase. In short, when it comes to health, individuals' choices are influenced by motivations that upend the typical framework of rational economic choices by consumers that explain behavior in other markets.



Second, there is a lack of competition in the pharmaceutical market not found in other, more traditional markets. As discussed further below,¹² laws establish extensive periods of market protection through patents, exclusivities, and other methods. These protections grant substantial market and pricing power to manufacturers, who are then able to utilize their power to command higher prices. Compounding these effects, manufacturers sometimes abuse these protections to further extend their pricing power beyond the initial, intended period, through such tactics as product-hopping, ever-greening, and patent-thickets.

Indeed, some drug manufacturers take advantage of, or create, natural or artificial monopolies. Natural monopolies occur when high costs keep new entrants from the market, as well as in small markets where there is little incentive for competitors to enter, both of which allow a drug manufacturer to drive up prices. Companies can also create monopolies, and benefit from their resulting pricing power, by acquiring competitors or gaining control over the sources of a drug. Pharmaceutical companies may extend these advantages through further anticompetitive behavior, such as price collusion, shadow pricing, pay-for-delay arrangements, authorized generics, and sham petitions. Ultimately, drug companies are able to operate in an environment with limited competition and command higher prices. Compounded by the limited power of patients to shop for different drugs based on price, the pharmaceutical market exhibits a wide variety of market failures that defy traditional economic principles.

2.1.2 Not All Pharmaceuticals Are the Same—Branded Drugs, Generic Drugs, and Specialty Drugs.

Patients often view concerns over the pricing and cost of drugs as uniform across the entire spectrum of all pharmaceuticals. And from one perspective, they are correct. It does not matter to many patients why a drug costs so much, just that it does. But in order to take effective action to reduce the high cost of drugs, it is important to understand the basic differences between brand name drugs, generic drugs, and so-called “specialty” drugs.

Brand name drugs are prescription medications sold under a specific trade name. For example, “Zoloft” is the brand name of the generic name “sertraline”. Brand-name drugs are usually protected by a patent. During the time a branded drug is protected by a patent it is free from competition. Once the patent runs out on a brand-name drug, the United States Food and Drug Administration (“FDA”) can approve the sale of generic versions. For a new drug to come to the market, the FDA requires that a drug manufacturer demonstrate safety and effectiveness with laboratory, animal, and human testing of the drug. Oftentimes, drug manufacturers attempt to justify the high prices of their brand-name medications by arguing that they need to cover costs incurred during the research and development phase of bringing new drugs to the market.

Generic drugs are equivalent to their brand-name versions in active ingredients, dosage, safety, strength, route of administration, and quality. For a generic drug to come to market, the FDA requires that the manufacturer demonstrate that the generic alternative can be safely and properly substituted for the branded version of the drug. According to the FDA, about 88% of prescriptions in the United States are filled with generic medications.

What drugs fall within the term “**specialty**” drugs is not always clear. This is because there is no specific definition or classification for specialty drugs; instead, they are generally considered to be drugs with a high cost for a course of treatment. Specialty drugs are also often novel, treat rare conditions, or require distinctive handling or administration. Many, but not all, so-called specialty drugs are a type of drug known as “biologics,” which are drugs derived from living organisms or parts of living organisms.¹³ Often times, specialty drugs treat complex or chronic conditions, such as cancer, multiple sclerosis, or rheumatoid arthritis.¹⁴ Specialty drugs are frequently the most expensive drugs on the market, with the price-tag charged to patients for a regular course of treatment totaling in the tens to hundreds of thousands of dollars per year.¹⁵ The annual increases in prices for specialty drugs has also traditionally significantly outpaced the rate of inflation.¹⁶



2.1.3 Self-Administered Drugs Versus Physician-Administered Drugs.

Self-administered drugs—also sometimes referred to as out-patient prescription drugs—are generally those that a patient purchases at a pharmacy using a prescription and then takes as a health professional has instructed. Most research on drug prices has focused on self-administered drugs (“SADs”) when evaluating the causes of and solutions to the rising cost of drugs.¹⁷ These studies have found that SADs account for approximately 10% of all healthcare spending, both in Minnesota and nationally.¹⁸ In reality, however, this figure is artificially low and provides an incomplete picture of spending on drugs because it fails to measure the growing amount spent on what are known as physician-administered drugs (“PADs”).¹⁹

PADs and their costs are a far less studied and understood use of pharmaceuticals. PADs are drugs that are administered to patients—often in a single dose injection or infusion—by medical professionals in hospitals, clinics, and other health care facilities.²⁰ Unlike SADs, whose spending can be tracked by reviewing pharmacy claims data,²¹ the cost of PADs is often captured only in a larger “bundle” of medical claims data that also includes expenses for other healthcare services provided around the same time.²² This means that researchers—as well as employers and other entities that pay these claims—have no insight into what PADs (or their associated costs) are included in the medical claims that they are paying.²³ When spending on PADs is included, the true total amount of drug spending increases to at least 20% of all healthcare spending in Minnesota. That figure is twice the amount typically cited.²⁴

The use and costs of PADs has skyrocketed in recent years, and is a major contributor to the rise in overall health care spending.²⁵ For example, more than one-half (55%) of the increased spending on drugs in Minnesota from 2009 to 2013 was caused by the increased use of PADs, even though such claims only accounted for one-fifth (19%) of all drug claims.²⁶ During this same time period, the spending on PADs increased nearly three times as much as spending on SADs.²⁷ This is because PADs are usually for newer and higher-cost brand name drugs that do not have generic equivalents available.²⁸ As a result, PADs in Minnesota cost approximately \$180 per day, while SADs cost approximately \$2 per day.²⁹

2.1.4 The Prevalence of Prescription Drug Use Nationally and in Minnesota.

A significant number of Americans are prescribed one or more prescription drugs on a regular basis. The Centers for Disease Control and Prevention (“CDC”) estimated that, in 2017, 58% of adults age 18-64 years old were prescribed medications in the past year. The percentage jumps to 86% for those age 65 and older. In both age groups, women were prescribed medications at a slightly higher rate than men.³⁰

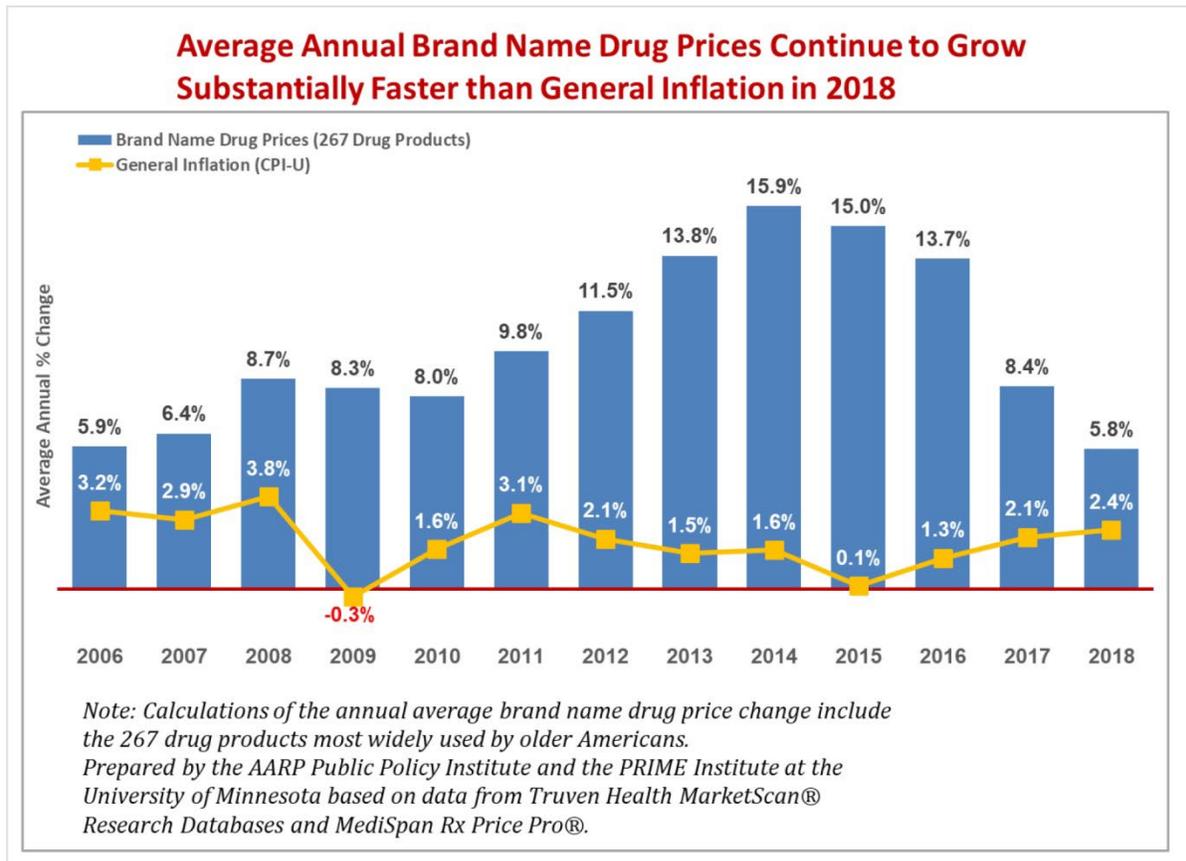
The CDC has also noted an increase in the number of prescription medications used per person over time. Between 1988 and 2014, the percentage of the population who took at least one prescription drug within the previous 30 days rose from 38% to 49%. In the same time period, the percentage of persons who took five or more prescription drugs within the previous 30 days rose from 4% to 12%.³¹

It is also important to consider the prevalence of prescription drug use among Minnesotans. The Minnesota Department of Health determined in a recent study that, as of 2013, 68% of insured Minnesotans filled at least one prescription at a pharmacy, and that number does not include Minnesotans who receive prescription drugs in a medical setting.³² The department also found that, between 2009 and 2013, Minnesotans averaged 12 prescription fills per year.³³ Among Minnesotans who filled at least one prescription, those individuals averaged 17 fills at the pharmacy in 2013.³⁴ When looking at prescription use by age, 88% of Minnesotans age 65 and older filled a prescription in 2013.³⁵



2.1.5 Drug Price Increases Have Significantly Outpaced Overall Inflation.

One reason patients notice the rise of prescription drug prices is because it often significantly outpaces general inflation as measured by the Consumer Price Index (“CPI”). For example, AARP’s Rx Price Watch Report provides pricing trend data for prescriptions widely used by older Americans. The report found that the “annual percent change in retail prices for brand name prescription drugs has consistently increased substantially faster than general inflation” at a “8.4% compared with 2.1%” rate.³⁶ The increase in the cost of prescription drugs when compared to the general inflation rate is stark:



Stephen W. Schondelmeyer and Leigh Purvis, Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2018, Rx Price Watch, AARP Public Policy Institute, November 2019; <https://doi.org/10.26419/ppi.00087.001>

AARP’s report also noted that the cost of an elderly American using 4.5 prescription drugs a month—the average for seniors—would be approximately \$30,000 annually, which exceeds the median annual income of Medicare beneficiaries of \$26,200.³⁷



2.1.6 Selected Examples of High Cost Prescription Drugs.

While troubling instances of high-priced generic drugs exist, generally the most egregious examples are found in the branded and specialty drug markets. As of May 2019, the world's most expensive drug was a newly approved gene therapy called Zolgensma, costing \$2.1 million, which treats spinal muscular atrophy in young children. Other examples of astronomically priced prescription drugs include: Myalept, which treats complications caused by leptin deficiency and costs about \$65,000 per month; Actimmune, which is approved for the treatment of chronic granulomatous disease and is priced at approximately \$48,000 per month; and Daraprim, which treats toxoplasmosis and is used for the prevention of other infectious diseases in AIDS and transplant patients is priced at approximately \$45,000 per month.

As detailed earlier in the report, some medications are administered to patients by medical professionals in a hospital or other infusion setting. Many examples of these high-cost infusion medications include those to treat cancer or autoimmune disorders. For instance, Herceptin, a common drug used to treat breast cancer, costs more than \$76,000 for a yearlong course of treatment. For those suffering from rheumatoid arthritis, the annual cost for Orencia infusions costs \$46,000: another popular infusion option, Remicade, costs \$37,000 annually. Yet other examples of drugs with high or significant price increases, which are discussed in depth below as case studies in the phenomenon, are EpiPen, insulin, lorazepam, clorazepate, and the business model of Valeant Pharmaceuticals (now known as Bausch Health Companies).

The high cost of prescription drugs affects all Minnesotans: it is likely that you or someone you know must take a prescription drug that is exceedingly expensive. Indeed, for example, Task Force member Representative Hamilton reported that one of the prescription drugs required to treat his multiple sclerosis—Tysabri—cost him about \$15,000 per month in 2018.

2.1.7 The Impact of High Drug Prices on Patients and Their Families.

A significant share of Americans' household income is being spent on prescription drug therapy. One recent study revealed, for example, that the average annual cost of drug therapy for the most widely used prescription drugs was nearly \$20,000 per year, or about one-third of the median U.S. household income in 2017 of \$60,336.³⁸ The share of household income spent on prescription drugs was even higher for those Americans who used a specialty prescription drug. In 2017, the average annual retail cost for drug therapy with specialty prescription drugs was nearly \$79,000 per year, almost \$20,000 more than the median U.S. household income.³⁹

Due to the high and rising costs of prescription drugs, many Americans have been forced to choose between paying for basic needs and paying for their medications. For example, 32% of Americans whose prescription drugs increased in price within the past year reported spending less on groceries so they could afford their medications. Of these people, 32% also reported spending less on their family, 21% postponing the payment of other bills, 12% reported postponing retirement, and 8% reported getting a second job, all just to pay for their medications.⁴⁰ Another recent poll found that 18% of Americans borrowed money from friends or family, took out a loan, or even declared bankruptcy to pay for their prescriptions.⁴¹

Increasing drug costs have also created a barrier to Americans' adherence to their prescribed drugs. Medication "adherence" is a term that describes the degree to which a patient takes their medications at the doses and times that their doctor has directed.⁴² A 2019 survey found that 29% of Americans reported that they did not take their medication at some point in the past year due to cost: this included 19% who did not fill a prescription, 18% who took an over-the-counter drug instead of their prescribed drug, and 12% who cut pills in half or skipped doses. Of those



who reported not taking a drug due to cost, 27% reported that their medical condition worsened as a result.⁴³ The consequences of a patient failing to adhere to their medication regimen range from disease progression, reduced functional abilities, increased hospital visits, and even death.

Americans have thus taken drastic measures just to afford their prescription drugs. Indeed, some Americans—8% in one recent survey—have resorted to crossing the border into Canada or Mexico to purchase drugs at a fraction of the price that they cost in the United States.⁴⁴ For example, while one person was in California to run the Los Angeles Marathon, she crossed the border into Mexico to purchase a supply of insulin for her son for \$600, which would have cost her \$3,700 in the U.S.⁴⁵ Similarly, a group of Minnesotans recently drove across the border to Canada to buy insulin for their families, where they paid \$1,200 for a supply of insulin that would have cost ten times as much in the United States.⁴⁶

2.1.8 The Burden that High Cost Prescription Drugs Impose on Minnesota.⁴⁷

The national trend of rising prescription drug costs affects Minnesota. According to data compiled by the Minnesota Department of Health, prescription drug spending in Minnesota rose by 28.6% between 2013 and 2017. In 2017, Minnesota spent nearly \$5.2 billion on retail prescription drugs. If prescriptions administered in medical settings (e.g., hospitals, doctors' offices, nursing homes, etc.) are taken into account, this number is even higher, approaching \$8.7 billion. Together, this volume of drug spending accounted for 17% of health care spending in Minnesota that year.

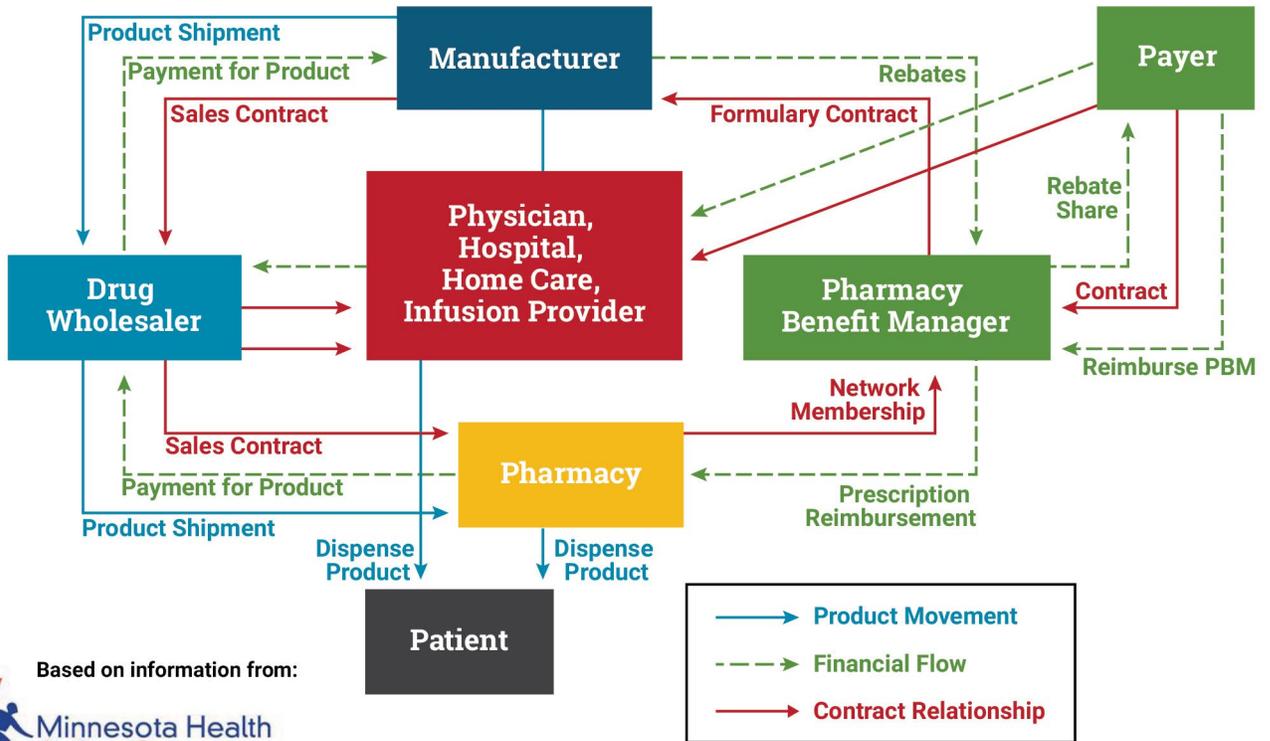
The high cost of prescription drugs has created significant barriers to Minnesotans' adherence to their prescribed medication regimes, as an estimated 9% of Minnesotans—or more than half a million people—had not filled a prescription due to cost in the preceding 12 months, according to the 2017 Minnesota Health Access Survey. For Minnesotans with one or more chronic conditions, this estimate was even higher at 16%.

Notwithstanding these troubling facts, Minnesota also still lacks satisfactory data into the details of the Minnesota patients who struggle to afford their prescription medications: where they live, which medications are not being adhered to, and what time of year they have the most difficulty taking their medication as prescribed. The wide-ranging opacity in the pricing of prescription drugs, which limits insight in Minnesota about how to reduce the cost of drugs, also extends to certain claims involving physician-administered drugs in hospital or other medical settings. The costs of such drugs are often “bundled” into a larger claim, making it difficult to assess spending trends and evaluate the effectiveness of prescribing patterns. Overall spending for these bundled medical claims rose 52% between 2009 and 2013. As a result, Minnesota is still ill-equipped to deal with the effects of expensive prescription drugs on patients in the demographic groups and in the geographic locations that need it and to support them in emergencies.



2.2 The Entities Involved In the Distribution and Pricing of Pharmaceuticals.

The sales and distribution chain for prescription drugs is maddeningly complex, with different companies involved in different aspects of the process, as this diagram shows:



Accordingly, attempting to divide the drug sales chain into discrete segments is an inexact science because some companies or persons simultaneously occupy multiple roles in the chain.⁴⁸ Generally speaking, however, there are 10 major participants in the drug sales chain, which are discussed below in the approximate order they appear within the chain.

2.2.1 Active Pharmaceutical Ingredient Suppliers.

Among their many ingredients, all drugs contain at least one active ingredient. For over-the-counter drugs, for example, the active ingredient is generally listed on the drug's packaging. Active pharmaceutical ingredient ("API") suppliers make the active ingredients contained in drugs from raw materials, using both physical and chemical processes. APIs may be manufactured in a different location from where the pill, liquid, or other final form of the drug is manufactured.⁴⁹ APIs are generally manufactured in bulk, and then sold to one or more drug manufacturers who use this active ingredient to make the final form of the drug. API suppliers' primary regulator in the United States is the FDA.



2.2.2 Drug Manufacturers.⁵⁰

Drug manufacturers make the drugs that are ultimately purchased by patients, health plans, and other third-party payers. As with API suppliers, drug manufacturers' primary regulator is the FDA, with which each must register.⁵¹ In Minnesota, drug manufacturers must also be licensed by the Minnesota Board of Pharmacy.⁵²

Some drug manufacturers physically manufacture the drugs themselves at their own facilities using ingredients purchased from API suppliers. Others do not engage in the actual physical manufacturing of drugs. Instead, such drug manufacturers sub-contract with other companies, called "contract manufacturing organizations," which do the physical manufacturing of the drug on their behalf. Yet other drug manufacturers, called "repackagers," simply repackage or relabel a drug that is physically manufactured by someone else and sell it as their own.

Importantly from a pricing standpoint, manufacturers set the initial sales price of their drugs. This initial price is often referred to as the manufacturer's "list price."⁵³ Equally important is that a manufacturer's list price is often the starting point—that is the benchmark for the price that others downstream in the sales chain charge when reselling the drug. Thus, if a manufacturer increases its list price, this will have ripple effects by increasing the price that wholesale distributors charge pharmacies and pharmacies charge patients, as well as the amount that health plans will reimburse when a plan member is prescribed the drug. Manufacturers also pay rebates and administrative fees to pharmacy benefit managers, which are middlemen that drive demand for their drugs, as discussed further below.

2.2.3 Wholesale Drug Distributors.⁵⁴

Wholesale drug distributors, often simply called "wholesalers," are the next step in the sales chain after drug manufacturers. They buy and physically receive drugs from drug manufacturers. Wholesalers then sell these drugs to retail pharmacies and health care facilities, which then in turn sell to patients. Some wholesalers also offer services such as drug repackaging and reimbursement support. Wholesale drug distributors who do business in Minnesota are required by state law to be licensed by the Minnesota Board of Pharmacy.⁵⁵

2.2.4 Pharmacy Benefit Managers.⁵⁶

Pharmacy benefit managers, or "PBMs," as they are more commonly known, are middlemen in the drug sales chain. PBMs typically never take physical possession of any drugs; instead, they only negotiate reimbursement, rebate, and distribution terms with others involved in the drug sales chain. PBMs first became a significant force in the health care industry in the late 1980s.

As further reflected in the above diagram, PBMs have relationships with three important entities in the sales chain: health plans, drug manufacturers, and retail pharmacies. PBMs are hired by health plans (e.g., Blue Cross Blue Shield, HealthPartners, Medica, etc.) to manage the drug benefit that is provided to plan members on the plan's behalf. PBMs do this, in part, by creating and managing what is known as a "formulary." Formularies are simply a list of drugs for which reimbursement will be paid by the health plan when the drug is prescribed to a health plan member. If a drug is not included on the formulary, a patient, even if insured, must generally pay for it out of pocket.⁵⁷

As part of overseeing health plan members' drug benefit, PBMs act on behalf of health plans in two important ways. First, PBMs contractually stitch together networks of retail pharmacies where a health plan's members can get the drugs they need. In building these pharmacy networks, PBMs negotiate with each participating pharmacy the amount that the health plan will reimburse the pharmacy for drugs prescribed to the health plan members.



Second, PBMs negotiate discounts with drug manufacturers off of manufacturers' list prices for drugs, which take the form of rebates paid from the manufacturer to a PBM.⁵⁸ A PBM may pass some or all the rebates it receives from a drug manufacturer on to its health plan clients. PBMs claim that, as a result, the rebates they secure reduce the cost of drugs for health plans. Often, however, a PBM keeps the entirety of the rebates it receives for itself, and does not pass any of the amount along to its health plan clients. Rebates from drug manufacturers have become a critical source of revenue for PBMs.⁵⁹

In 2019, the Minnesota Legislature and Governor enacted a bill that requires PBMs to be licensed by the Minnesota Department of Commerce. Among many other things, this new licensure law requires PBMs to act in good faith on behalf of their health plan clients and to disclose conflicts of interest, and it contains numerous transparency-promoting mandates.⁶⁰

2.2.5 Pharmacies and Pharmacists.

Pharmacies are entities that prepare, dispense, and sell medications. They are generally licensed and regulated by state pharmacy boards in their respective states. In Minnesota, the Minnesota Board of Pharmacy regulates pharmacies, though it does not regulate the prices pharmacies charge or the reimbursement rates they are paid by health plans or health plans' PBMs.⁶¹

For most prescription drugs, patients pay either: (1) a copay or coinsurance, as determined by their health plan coverage; or (2) the pharmacy's usual and customary price, also sometimes known as its "cash price," if the patient has no insurance coverage. The cash price of a prescription drug is typically calculated by the pharmacy as the cost of the drug to the pharmacy, plus a small markup, plus a dispensing fee. One recent survey indicated that, at independent retail pharmacies, 91% of prescriptions are submitted to third-party payers for reimbursement, including Medicare, Medicaid, and private health plans. The remaining 9% of prescriptions are sold directly to patients at the pharmacy's cash price, and are not covered by insurance.⁶²

2.2.6 Authorized Prescribers.

Authorized prescribers⁶³ are licensed health care professionals who determine which medications are appropriate for a patient. Prescribers may have a variety of competing drugs to choose from to treat a particular patient's condition. At other times, they may have only a single available drug to do so. Determining which drug to prescribe is a clinical decision in which the prescriber must take into account a variety of factors, including the anticipated benefit to the patient, side effect profile of the drug, and availability in the market.

Prescribers do not have up-front visibility into a patient's health plan coverage for a given drug at the time the prescription is written. When a patient's medication is not covered by their insurance, sometimes the pharmacy will work with the prescriber to find an alternate medication, or try to obtain a "prior authorization" from the patient's health plan. Obtaining a prior authorization from the prescriber can delay the filling of the patient's prescription, as it generally requires that a prescriber submit clinical data to the health plan, or the health plan's PBM, to justify the need for a prescription drug that is not on the plan's formulary.

One factor that may influence physician prescribing practices is the physician's involvement with, or compensation from, drug manufacturers or distributors. A 2016 study that examined physician prescribing patterns found a "significant association between attending a single meal promoting a specific drug...and the prescribing of the promoted drug over therapeutic alternatives."⁶⁴ For this and other reasons, Minnesota law prohibits any manufacturer or wholesale drug distributor from providing health care practitioners with gifts valued at more than



\$50 in any calendar year.⁶⁵ But even under this law, manufacturers or distributors can pay for educational expenses and provide payments to physicians for “reasonable” expenses.⁶⁶ Accordingly, some have argued for stricter laws in an attempt to further decouple physician prescribing patterns from financial reimbursement or other similar incentives.

2.2.7 Health Plans, Insurers, and Managed Care Firms.

Generally, health plans, insurers, and other managed care firms (collectively “health plans”) are third parties that pay for patients’ care, including for prescription drugs. The money used to cover these costs, however, ultimately comes from the pooled resources of the patients themselves. As referenced above, health plans often outsource the work of managing the prescription drug benefit they provide to plan members to the PBM that the health plan has hired. Health plans’ members incur more or fewer out-of-pocket expenses for the drug they are prescribed—in the form of a deductible, copayment, or coinsurance payment—based on how the drug is classified on the formulary of the health plan or its PBM. Uninsured patients are left to pay the pharmacy’s cash price entirely out of pocket for the drugs they need.

2.2.8 Employers.

More than half of non-senior Americans—approximately 152 million people in total—receive health insurance through private health plans that are selected and offered to them by either their employer or a close family member’s employer.⁶⁷ Employees typically pay a contribution toward their individual or family coverage that is deducted through the payroll process, and their employers pay the remainder of the insurance premium as a form of compensation to the employee.⁶⁸ More than 99% of people with employer-provided health insurance can also receive prescription drug coverage as a part of their offered health plans.⁶⁹ Most commonly, the drug coverage offered contains cost sharing tiers, whereby patients pay different amounts out of pocket depending on the characteristics of the prescribed drug, including whether it is a generic, brand name, or specialty drug.

Both federal and state governments regulate employer-provided health insurance. Workers and their families enjoy important rights and protections under a variety of laws, including the federal Consolidated Omnibus Budget Reconciliation Act of 1985 (“COBRA”), Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and the Affordable Care Act (“ACA”) of 2010.

2.2.9 Government.

State and federal government play a number of important roles in the pharmaceutical industry supply chain. First, both the federal and state government are providers of prescription drugs benefits. Through Medicare, for example, the federal government provides insurance for all Americans 65 and older, as well as some younger Americans with disabilities. In addition, federal and state governments jointly fund Medicaid, which is called “Medical Assistance” in Minnesota. Medical Assistance provides low-cost prescription drug benefits to approximately 1.1 million lower-income Minnesotans. The Minnesota Department of Human Services also administers MinnesotaCare, which, in addition to covering doctor visits and hospital stays, provides prescription drug benefits for eligible residents whose income falls below certain specified limits. As employers, federal, state, and local governments may also offer health plan and prescription drug benefit options to their employees.

Second, the government is a direct purchaser of prescription drugs. For example, MMCAP INFUSE⁷⁰ is a multistate buying group that is open to governmental entities (in Minnesota and other states) that provide health care services, such as certain state agencies, school districts, and correctional facilities. MMCAP INFUSE is administered by the



Minnesota Department of Administration. It allows participating governmental entities to utilize their volume buying power to negotiate lower prices for the drugs they purchase. Government entities that wish to participate in the MMCAP INFUSE program must satisfy certain statutory and other criteria to do so.⁷¹ The federal government is also a major purchaser of prescription drugs, which it purchases on behalf of entities such as the Department of Veterans Affairs and the Department of Defense.

Third, the government is a provider of prescription drugs. For example, the Minnesota Department of Corrections administers prescribed drugs to adult and juvenile persons in the care of the department. The federal government also provides prescribed drugs to many people, including eligible veterans.

Finally, the government regulates both brand-name and generic prescription drugs. As explained in greater detail elsewhere in this report, the FDA regulates prescription drugs to ensure their safety and efficacy. The Minnesota Board of Pharmacy likewise regulates, among other things, pharmacists and pharmacies to ensure that prescription drugs are safely distributed to Minnesotans.

2.2.10 Patients.

Patients, of course, are the last link in the sales and distribution chain. Typically, patients either purchase drugs from retail pharmacies that were prescribed to them by an authorized prescriber, or are administered drugs by a health professional at a hospital, clinic, or other medical setting. Patients or their employers pay for all or a portion of the drugs they use through copays or coinsurance, deductibles, and premiums (for insured patients) or out of pocket (for uninsured patients). We are all patients because everyone at some point in their lives will need and use prescription drugs.

Although patients are the intended beneficiaries of the drug sales chain, all too often they are its victims. Most patients do not understand the opaque nature of or the many parties involved in the drug sales chain. Nor do most realize how the conduct of some of these parties, alone or in conjunction with others, result in ever-increasing drug prices that patients are ultimately forced to bear.

2.3 The Current Federal and State Legal Landscape Regarding Prescription Drugs.

While there are many federal and Minnesota laws that address prescription drugs in one manner or another, those that are particularly relevant to the Task Force's recommendations are (1) federal laws governing the process by which the FDA approves and regulates prescription drugs, (2) federal patent laws, as well as federal exclusivity laws that apply to prescription drugs that are distinct from patent laws, (3) the federal 340B drug pricing program, which results in perhaps the lowest prices for drugs sold in the United States, and finally (4) certain Minnesota laws regulating prescription drugs.

2.3.1 The FDA's Approval and Regulation of Prescription Drugs Generally.

a. Overview of the FDA's Regulatory Role.

Since the passage of the Food and Drugs Act in 1906, the FDA has been the primary regulator of prescription drugs in the United States. Under the original 1906 law, the FDA's authority was limited largely to ensuring that drugs had not been adulterated or misbranded. In 1938, the FDA's authority was significantly expanded with the passage of the Food, Drug, and Cosmetic Act. This law mandated pre-market approval for all new drugs, requiring



the manufacturer to prove the safety of the drug to the FDA before it could be legally sold in the United States. The law also required that drugs have labels with adequate directions and disclosures to ensure their safe use. In 1962, the Food, Drug, and Cosmetic Act was amended to require drug companies to also prove the efficacy (i.e., effectiveness) of new drugs, before they could be legally sold in the U.S.

In addition to its regulating of so-called “small-molecule drugs”—which is what many people traditionally think of when colloquially referring to prescription drugs—the FDA is also the primary regulator of biological products, or “biologics,” in the United States.⁷² Currently, the FDA has approved more than 20,000 drugs for marketing and sale in the United States.

b. FDA Approval Process for New Drugs.

Before a new small-molecule drug may be legally sold in the United States, the drug manufacturer must submit a New Drug Application (“NDA”) that provides the FDA with certain, specified information, including clinical testing results, to determine whether the drug is safe and effective, whether the benefits of the drug outweigh its risks, whether the drug’s proposed labeling is appropriate, and whether the methods and controls used to manufacture the drug are sufficient to preserve the drug’s strength, quality, and purity.⁷³

Biologics undergo a similar approval process before they may be sold in the United States. To obtain FDA approval, a biologic manufacturer must file a biologic license application demonstrating through laboratory and clinical studies that, among other things, the product satisfies safety, purity, and potency requirements.⁷⁴ While the federal Public Health Services Act generally governs the approval process for biologics, they are also subject to regulation as “drugs” under the Food, Drug, and Cosmetic Act.⁷⁵

c. FDA Approval Process for Small-Molecule Generic Drugs.

The FDA similarly approves and regulates generic small-molecule drugs, but generic drug manufacturers need only submit an abbreviated new drug application (“ANDA”).⁷⁶ With an ANDA, the generic drug manufacturer relies upon the FDA’s finding of safety and effectiveness for the original, brand name drug to essentially “fast track” the approval process for the generic drug.⁷⁷ To obtain FDA approval, a generic drug manufacturer must generally show that the drug contains the same active ingredients, dosage, and dosage delivery, and is bioequivalent to the original, brand-name drug.⁷⁸ In addition, the generic drug manufacturer must certify either (1) that the brand name drug’s patent has expired or is invalid, or (2) that the generic manufacturer’s sale of the drug will not infringe on any of the brand name drug’s patents.⁷⁹

d. FDA Approval Process for Generic “Biosimilar” and “Interchangeable” Biologics.

Due to the complexities inherent in a drug derived from living organisms, generic versions of biologic drugs are not approved in the same manner as generic small-molecule drugs. Because of complex issues surrounding approval of generic biologics, in 2009, Congress passed the Biologics Price Competition and Innovation Act to allow for the licensure of “biosimilar” drugs.

Biosimilar drugs are biologic products that are similar to a previously-licensed, branded biologic drug. The FDA allows for abbreviated licensure and approval of a biosimilar biologic product if the manufacturer can show, among other things, that the biosimilar drug is highly similar to the original biologic.⁸⁰ In addition, the biosimilar manufacturer must demonstrate that the manner of administration, dosage form, and the strength of the biosimilar is the same as those of the original biologic drug.⁸¹



“Interchangeable” biologic drugs are biosimilar drugs that, in addition to satisfying the just-discussed requirements, have also demonstrated that among other things, they can be expected to produce the same clinical results as the original biologic in any given patient.⁸² As of July 2019, the FDA had not approved an interchangeable biological product.⁸³

2.3.2 Federal Patent and Drug Exclusivity Laws.

a. Federal Patent Laws As Applied to Prescription Drugs.

It is important to note that drug manufacturers can obtain patents on many aspects of the drug, not just the creation of its molecular structure that makes it a “drug” in the first place. Pharmaceutical companies can obtain a patent for a drug’s substance/active ingredient/molecule, its use, its dosage or delivery system, manufacturing process, and for a combination product (i.e., combining two previously known drugs), among other things.⁸⁴ For example, a company may receive a patent on a newly-discovered drug molecule to treat a particular disease, and then, years later, obtain a new patent related to the same molecule, but in an “extended release” form of the drug. Or the manufacturer may receive a patent for a drug in pill form, then years later, patent a new system whereby the drug can be delivered by placing a dissolving strip on the patient’s tongue. A particular drug may thus be covered by scores of patents, many of which are unrelated to the drug’s active ingredient.

Patent laws allow drug manufacturers to largely control the market for their drugs. A patent is a property right that grants the holder 20 years to exclusively use, enjoy, and profit from their patented invention.⁸⁵ The Patent and Trademark Office is the federal agency that reviews patent applications and grants (or rejects) applications for a particular patent. The applicant for the patent must establish that the invention is novel, useful, and non-obvious.⁸⁶ Patent rights are privately enforced, meaning that a holder of a patent right must sue to stop any alleged infringement, and if they prevail, may seek any damages, including any lost profits. Congress also enacted specialized patent rules for pharmaceuticals in 1984. This law, commonly known as the “Hatch-Waxman Act,”⁸⁷ provides an extension of up to five years, in addition to the original patent term.⁸⁸ The act also provides for patent dispute procedures that apply only to pharmaceuticals.

The FDA publishes all approved brand name drugs in a publication known as the “Orange Book,” which includes a list of all of the patents that a drug manufacturer claims covers a particular drug.⁸⁹ A company seeking FDA approval for a generic drug must, as described above, file an Abbreviated New Drug Application (“ANDA”) in which the generic manufacturer certifies its drug does not infringe on any patents protecting the branded drug.⁹⁰ If the manufacturer of the branded drug disputes the “no infringement” certification, it has 45 days to file a patent-infringement lawsuit against the generic manufacturer. If a lawsuit is filed, the FDA generally cannot approve the application from the generic manufacturer for 30 months, so as to give the two drug manufacturers time to litigate the patent dispute.⁹¹

Special patent procedures also govern biologics and biosimilars. Biologic manufacturers do not have to provide patent information in their licensure applications to the FDA. Federal law does, however, provide a process through which the biologic drug manufacturer exchanges information (including applicable patent information) with the applicant for the biosimilar drug about their respective products,⁹² which is sometimes known as the “patent dance.” The exchange of information triggers deadlines for the parties to initiate any patent infringement litigation. Similar to the process for small-molecule drugs under the Hatch-Waxman Act, this information exchange process is designed to provide the parties with an opportunity to resolve patent disputes prior to the marketing of the biosimilar.⁹³



b. Federal Exclusivity Law as Applied to Prescription Drugs.

Wholly distinct from the patent rights discussed above, the FDA further grants periods of “exclusivity” in which drug manufacturers are protected from any competition, including generic or biosimilar/interchangeable competition, for a given time period. There are multiple types of exclusivity periods that can apply to prescription drugs, the most significant of which are:

“First Generic” Exclusivity. A particularly important exclusivity for pricing purposes is the FDA’s grant of 180 days of exclusivity to the “first applicant” seeking approval to market generic versions of small-molecule drugs,⁹⁴ and one year of exclusivity for the manufacturer of the first interchangeable version of a biological product.⁹⁵

“Orphan Drug” Exclusivity. If a small-molecule drug or biologic is designated and approved to treat diseases or conditions affecting fewer than 200,000 people in the United States, or the drug can treat more than 200,000 people but the manufacturer has no hope of recovering its costs, the FDA will not approve another application for the same drug for the same orphan disease or condition for seven years from the time of approval of the original drug.⁹⁶

“New Chemical” Exclusivity. Generally speaking, if a drug contains a new chemical,⁹⁷ the FDA will not approve for five years another drug that contains the same active molecule as in the new chemical entity.⁹⁸

In addition to these exclusivities, the FDA grants several other drug exclusivities, all of which may affect the price of prescription drugs.⁹⁹

2.3.3 The Federal 340B Drug Pricing Program.

The federal 340B Drug Pricing Discount Program (“340B Program”) was established in 1992 after the enactment of the Medicaid drug rebate program. The Health Resources and Services Administration (“HRSA”), an agency within the U.S. Department of Health and Human Services, administers the 340B Program. The purpose of the 340B Program is to enable “covered entities to stretch scarce federal resources as far as possible” to reach “more eligible patients and provid[e] more comprehensive services.”¹⁰⁰ The 340B Program requires participating drug manufacturers to sell outpatient drugs to eligible facilities and programs, referred to as “covered entities,” at significantly reduced prices in order to have their drugs covered by Medicaid.¹⁰¹

Covered entities include sixteen eligible purchasing groups, such as qualifying hospitals, specialized clinics, federally qualified health centers (“FQHCs”), and entities referred to as “FQHC Look-Alikes.”¹⁰² In Minnesota, there are more than 2,000 covered entities participating in the 340B Program, with over half being “disproportionate share hospitals” who receive payments from the Centers for Medicaid and Medicare Services to cover the costs of providing care to uninsured patients.¹⁰³ Hospitals such as Hennepin County Medical Center, part of Hennepin Healthcare, and Abbott Northwestern Hospital, part of Allina Health, participate under this covered entity type.¹⁰⁴ Examples within other types of covered entities in Minnesota include Mayo Clinic’s Hemophilia Treatment Centers in Rochester, and Min No Aya Win Human Services on the Fond du Lac Reservation in Cloquet.¹⁰⁵ These covered entities can dispense 340B drugs to eligible patients in a variety of ways, including in-office administration, dispensing through an in-house pharmacy, or by contracting with a retail pharmacy to dispense 340B drugs to the patients.



Covered entities may only administer and dispense the 340B drugs to eligible patients, who are defined as individuals who have an established relationship with the covered entity and receive health care services from a practitioner employed or contracted with the covered entity. An individual is not an eligible patient if the only service received from the covered entity is the dispensing or administration of a drug.¹⁰⁶

The discount on drugs through the 340B Program is significant because the program requires that manufacturers sell drugs at a price no higher than the net price paid by Medicaid. Further, drug manufacturers may offer even lower prices without triggering a new Medicaid “best price.”

Some covered entities pass the lower prices they receive through the 340B Program along to eligible patients. In a 2018 study published by the U.S. Government Accountability Office, 30 of the 55 covered entities surveyed reported providing low-income, uninsured patients discounts on 340B drugs, with 23 covered entities reportedly passing on the full 340B discount on to these low-income patients.¹⁰⁷

Covered entities that do not pass along direct cost savings on 340B drugs to low-income patients may still provide benefits to them through other mechanisms. There are no regulations, however, that require covered entities to pass the savings they receive on the drugs they purchase through the 340B Program on to patients in any particular manner. Accordingly, this has led some to question whether covered entities use the 340B Program as merely another revenue stream, particularly if a health care provider participating in the 340B Program provides little uncompensated care.

Participation in the 340B Program is voluntary for covered entities. In Minnesota, not all eligible entities have enrolled in the program. Entities may not be aware they are eligible, for example, as FQHC Look-Alikes. In the absence of clear policies and rules for the 340B Program, the requirement to keep auditable records, and the risk of HRSA and manufacturer audits, some eligible entities may choose not to enroll in the 340B Program rather than risk operating in a non-compliant manner. This means some eligible Minnesota entities, and potentially their eligible Minnesota patients, are missing out on significant drug savings by failing to participate in the 340B Program.

2.3.4 Selected Minnesota Laws Regarding Prescription Drugs.

The FDA is the primary regulator of most aspects of drug manufacturing, distribution, and sales practices in the United States. While far less extensive than the federal regulatory framework, Minnesota law also addresses the distribution, sale, and use of prescription drugs in certain instances. For example, the Minnesota Board of Pharmacy regulates, among other things, pharmacies and pharmacists in Minnesota.¹⁰⁸ In addition, the Board of Pharmacy helps ensure the quality of all drugs sold in the state¹⁰⁹ and licenses drug manufacturers operating in Minnesota.¹¹⁰ Moreover, state law prohibits the manufacture, sale, or delivery of adulterated or misbranded drugs.¹¹¹

Minnesota has also enacted legislation that helps lower prescription drug costs by encouraging the use of generic drugs. Under Minnesota law, pharmacists may generally substitute generic versions of small-molecule drugs without the doctor’s intervention.¹¹² Similarly, pharmacists in Minnesota may substitute any interchangeable biologic for the original branded biologic without the prescribing doctor’s intervention.¹¹³ Moreover, in the last legislative session, the Legislature enacted legislation regulating the conduct of PBMs in Minnesota, which will be administered by the Minnesota Department of Commerce.¹¹⁴



2.4 Examples of Problematic Drug Pricing Practices.

Examples of exorbitant prices being charged for drugs—or significant price increases on new drugs and even drugs long off patent—are troublingly common. Below are four selected case studies that illustrate the problems the recommendations in this report are intended to address.

Case Study #1—EpiPen

Epinephrine, or adrenaline, is used to treat severe allergic reactions known as anaphylaxis. Synthetic epinephrine was first manufactured in 1909. In the 1980s, auto-injector technology was paired with epinephrine, and became available to civilians as the EpiPen. The FDA describes epinephrine auto-injectors as “combination products” because they include both a drug, epinephrine, and the administration device, the auto-injector. The development of generic alternatives for combination products includes recreating both the device and the drug, which is more challenging than developing a generic alternative for a drug alone. As such, EpiPen dominated the market for epinephrine auto-injectors as of 2014, with over 90% market share.¹¹⁵

In 2007, Mylan Laboratories (“Mylan”) bought the rights to sell EpiPen, although it had not developed either the auto-injector or the drug it contains. At the time, each pen cost patients about \$57. In 2011, Mylan announced that it would begin selling EpiPen products exclusively in packs of two. By 2016, after repeated price increases, Mylan was selling EpiPen 2-packs for over \$700, a price increase of more than 500%. Mylan’s profits jumped from \$874 million in 2007—before it acquired EpiPen—to almost \$4.8 billion in 2017. During this period, the pay of Mylan’s CEO rose from nearly \$2.5 million in 2007 to \$97 million in 2016, an increase of more than 3,800%.

At the same time it was raising the price for a drug it neither developed nor manufactured, Mylan repeatedly misclassified the drug as generic, thereby allowing it to pay smaller rebates to the federal government for EpiPen’s use in programs such as Medicaid. In 2017, Mylan paid \$465 million in a settlement with the U.S. Department of Justice over its misclassification of the product as a generic drug.¹¹⁶ This amount represented less than half of its revenue from its sales of EpiPen for just the year of 2015.

Mylan garnered national attention in 2016 for its large price increases on EpiPen. It drew bi-partisan criticism from Congress, as well as from parents who relied on the everyday presence of an EpiPen to keep their children safe. Many patients reacted to the price hike by holding on to their expired EpiPens, attempting to measure out a correct dose of epinephrine in a syringe themselves, or simply living without the security the EpiPen offered until they could afford a new one. Other patients, including parents whose children required EpiPen availability at both school and at home, admitted to splitting their EpiPen 2-pack to save money, despite knowing that two doses may be needed in an emergency situation.

Mylan responded to this criticism by introducing a generic version of the EpiPen in December 2016, which it sold for roughly \$300 for the 2-pack, or roughly triple what its own name-brand pens were selling for in 2007. By comparison, EpiPen 2-packs were available to consumers in Canada for less than \$200, and in the United Kingdom for less than \$80.

Despite the public outrage, Mylan did not significantly reduce EpiPen’s prices. When interviewed about its reluctance to change, former executives commented that the company’s lack of action was in line with Mylan’s history of learning to thrive by absorbing and then ignoring public dismay.¹¹⁷ Mylan and its EpiPen product have thus become “a case study in the limits of what consumer and employee activism, as well as government oversight” in the current regulatory climate can achieve.¹¹⁸



Case Study #2—Lorazepam and Clorazepate¹¹⁹

Lorazepam is a benzodiazepine commonly used as a sedative and to treat anxiety, tension, and insomnia. It was first marketed for sale in the United States in 1977. Clorazepate is also a benzodiazepine and is used to treat anxiety, hypertension and in adjunct therapy for opiate and other types of withdrawal. It was first marketed for sale in the United States in 1972.

As discussed above, drug manufacturers purchase the active ingredients found in the finished-form of their drugs from API suppliers. Often there are only a handful of API suppliers that make a particular active ingredient needed to manufacture a drug. This limited competition among API suppliers is referred to as an “oligopoly” in antitrust jargon. As of the mid-1990s, there were only two API suppliers for the active ingredients needed to make lorazepam and clorazepate.

In 1998, the Minnesota Attorney General’s Office and dozens of other state attorneys general, in conjunction with the Federal Trade Commission, sued Mylan Laboratories—which, in addition to EpiPens, manufactures generic lorazepam and clorazepate—for successfully seeking to monopolize the APIs needed to make these two drugs. Mylan did so, the lawsuit alleged, by negotiating the exclusive rights to purchase the relevant active pharmaceutical ingredients for these drugs from the only two API suppliers of the ingredients. These exclusive contracts were to last for ten years, thereby denying Mylan’s rivals’ access to the APIs required to manufacture competing versions of generic lorazepam and clorazepate.

Following these negotiations, Mylan increased the price it charged for lorazepam by amounts ranging from 1,900% to 2,600% (for example, it increased the price for a 500 count bottle of lorazepam from \$7.30 to \$191.00). It similarly increased the price of clorazepate by amounts ranging from 1,900% to 3,200% (for example, it increased the price for a 500 count bottle of clorazepate from \$11.36 to \$377.00).

Case Study #3—Insulin

About 330,000 people, or nearly 8% of Minnesota residents, have diabetes.¹²⁰ Diabetes and pre-diabetes related costs in Minnesota total about \$4.4 billion per year.¹²¹ Insulin was first discovered in 1922. To ensure it would be available to the public, the scientists who created the original method for insulin treatments sold the patent for \$1 to the University of Toronto. Despite the original patent expiring long ago, the price of insulin has skyrocketed since the 1990s. The price for some insulin products has increased more than 1,100% over the last two decades,¹²² and diabetics’ insulin costs doubled between 2012 and 2016 alone, now averaging about \$5,705 a year.¹²³ This has led to some diabetics rationing their insulin because they cannot afford the medication, sometimes with tragic results.¹²⁴

A large driver of these price increases is the prevailing rebate practices between insulin manufacturers and PBMs. Manufacturers raise their insulin prices so they can offer PBMs larger rebates off of these prices. In return, PBMs provide more favorable payment terms to a particular manufacturer’s insulin—instead of a competitor’s insulin—when it is later dispensed to a diabetic at a pharmacy. Put more simply, manufacturer-PBM rebate practices are driving up insulin prices because manufacturers now compete to offer the largest rebates, not the lowest priced insulin. Manufacturers increasing their prices, in turn, allows them to offer larger rebates to PBMs while still holding their post-rebate, net price—and hence their profits—steady.¹²⁵



Case Study #4—Valeant Pharmaceuticals, now known as Bausch Health Companies.

Valeant Pharmaceuticals International (“Valeant”) is a multinational healthcare company based in Canada that sells, among other things, brand name, branded generic, and generic prescription drugs. In 2008, under the leadership of a new CEO, J. Michael Pearson, Valeant began rapidly and aggressively acquiring existing drug manufacturers. After doing so, it typically slashed these companies’ research activities and fired much of their staff. Through this business strategy, Valeant acquired decades-old, off-patent drugs, many of which had little, if any, competition. After acquiring the drugs, Valeant sharply increased their prices, and hence its profits.

In 2010, for example, Valeant acquired the drugs Cuprimine and Syprine as part of its acquisition of the specialty drug company, Aton Pharma. For decades, Cuprimine and Syprine had been used to treat Wilson’s disease, a potentially deadly disease characterized by the body’s inability to process copper. From the time Valeant purchased these drugs to the summer of 2015, it cumulatively increased the price of Cuprimine by 5,786% and Syprine by 3,161%.¹²⁶

Similarly, in 2015 Valeant acquired Salix Pharmaceuticals and increased the price of its diabetes medication, Glumetza, by 800%.¹²⁷ That same year, Valeant purchased the rights to two life-critical cardiac drugs, Isuprel and Nitropress, and increased their prices overnight by 525% and 212%, respectively.¹²⁸ During a 2015 investigation of Valeant by the House Committee on Oversight and Government Reform,¹²⁹ the Committee obtained documents indicating that Valeant purchased Isuprel and Nitropress for the sole purpose of later increasing these drugs’ prices and thus Valeant’s revenues. These documents also demonstrated that Valeant “identified goals for revenues first, and then set drug prices to reach those goals.”¹³⁰ All told, Valeant raised the price of more than 20 of its other drugs by at least 200% between 2014 and 2015.¹³¹

In the fall of 2015, Valeant’s business practices began to receive significant congressional and regulatory scrutiny, causing its stock price to plunge. In the summer of 2018, Valeant changed its name to Bausch Health Companies in an attempt to distance itself from the controversies resulting from its dramatic drug price increases and the ensuing investigations of its business practices.

2.5 How High Drug Prices and Price Increases Affect Minnesotans.

High pharmaceutical drug prices affect different groups of Minnesota patients and entities in different manners, sometimes due to differing insurance coverage and sometimes for other reasons.

2.5.1 Impact on Insured & Underinsured Minnesotans.

Approximately 152 million Americans receive health insurance coverage through their employers,¹³² including many Minnesotans. But even among people who have employer-sponsored insurance, many are considered “underinsured” because they still incur significant out-of-pocket costs to pay for prescription drugs and other medical care not paid for by their health plan.¹³³ As of 2018, about a quarter of all persons with health insurance were considered “underinsured.”¹³⁴ High and increasing drug prices impact insured and/or underinsured persons in a number of ways.



First, as health plans' spending on drug costs increases, it—in combination with the increased cost of other medical care—puts upward pressure on premiums. Employers, in turn, are asking their employees to shoulder an ever larger share of health plan premiums. As of 2017, Minnesota families with health insurance paid on average \$4,998 per year in out-of-pocket costs towards their health insurance premiums.¹³⁵

Second, employers and individuals are increasingly turning to high-deductible health plans as a way to reduce the premiums they must pay for the plan. Those covered by high deductible health plans have to pay the cost of the drugs they need out of pocket until their deductible is met each year. IRS regulations define a high deductible health plan as any plan with a deductible of at least \$1,350 for an individual or \$2,700 for a family.¹³⁶ In practice, however, such deductibles can be far higher for individuals or families. For example, one Minnesota employer offers plans with deductibles of up to \$3,150 for single coverage and \$6,300 for family coverage.¹³⁷ As of 2018, almost 46% of Americans are covered by a high deductible health plan.¹³⁸ This results in insurance coverage paying less and less of the cost of the medications these patients need because they never reach their deductible.

Third, some health plans require members to make a “co-insurance” payment when purchasing a drug that the plan covers. Co-insurance payments are typically a percentage of the price of the drug being purchased (e.g., 20%), as opposed to a “copayment,” which is typically a flat fee regardless of the cost of the drug (e.g., \$50). As the price of drugs increase, the burden of Minnesotans' covered by health plans that impose co-insurance payments likewise increases.

Fourth, health plans are sometimes limiting or even excluding certain drugs from being covered by insurance at all. This often is done through periodic adjustments to the list of drugs included on a health plan's formulary, or through pre-certification practices like prior authorization or step therapy. If a medication is not covered by the health plan, generally patients must pay the entire cost out of pocket, notwithstanding that they are insured.

2.5.2 Impact on Uninsured Minnesotans.

In 2018, 13.3% of non-elderly Americans did not have health insurance.¹³⁹ The impact that high and increasing drug prices have on those without insurance is not a mystery—they are often crippling because such persons pay for the entirety of the drugs that they buy. As a result, more than half of people who were uninsured at some point in 2018 were forced to forgo medical care despite a need for it, such as not filling prescriptions, skipping recommended testing or treatment, not seeing a doctor despite experiencing a health issue, or not receiving needed specialist care.¹⁴⁰

2.5.3 Impact on Minnesota Seniors.

High drug prices are especially problematic for seniors, who tend to use a higher amount of prescription medications than non-seniors and who may live on a fixed or modest annual income, such as Social Security or a pension. According to a recent Kaiser Family Foundation (“KFF”) poll, 89% of seniors report taking at least one prescription medication, and more than half take four or more drugs.¹⁴¹ The median yearly income of seniors on Medicare is just \$26,000, with a quarter of beneficiaries reporting incomes of less than \$15,000.¹⁴² Not surprisingly, 76% of seniors think the cost of prescription drugs is unreasonable, and nearly a quarter who take at least one drug report difficulty affording their medications.¹⁴³

In this same poll, nearly three quarters of seniors reported that they receive prescription drug coverage through Medicare Part D.¹⁴⁴ Medicare Part D can be expensive for those who find themselves in a coverage gap called the “donut hole,” which, for 2019, is triggered when an enrollee incurs \$3,820 in drug expenses. Once in the donut hole, enrollees pay up to 25% of the costs for brand-name drugs and 37% of the costs for generics.¹⁴⁵ Once the enrollee



has paid \$5,100 in drug costs out of pocket, he or she then qualifies for what is called “catastrophic coverage,” bringing their expense down to no more than 5% of the cost of each drug.¹⁴⁶

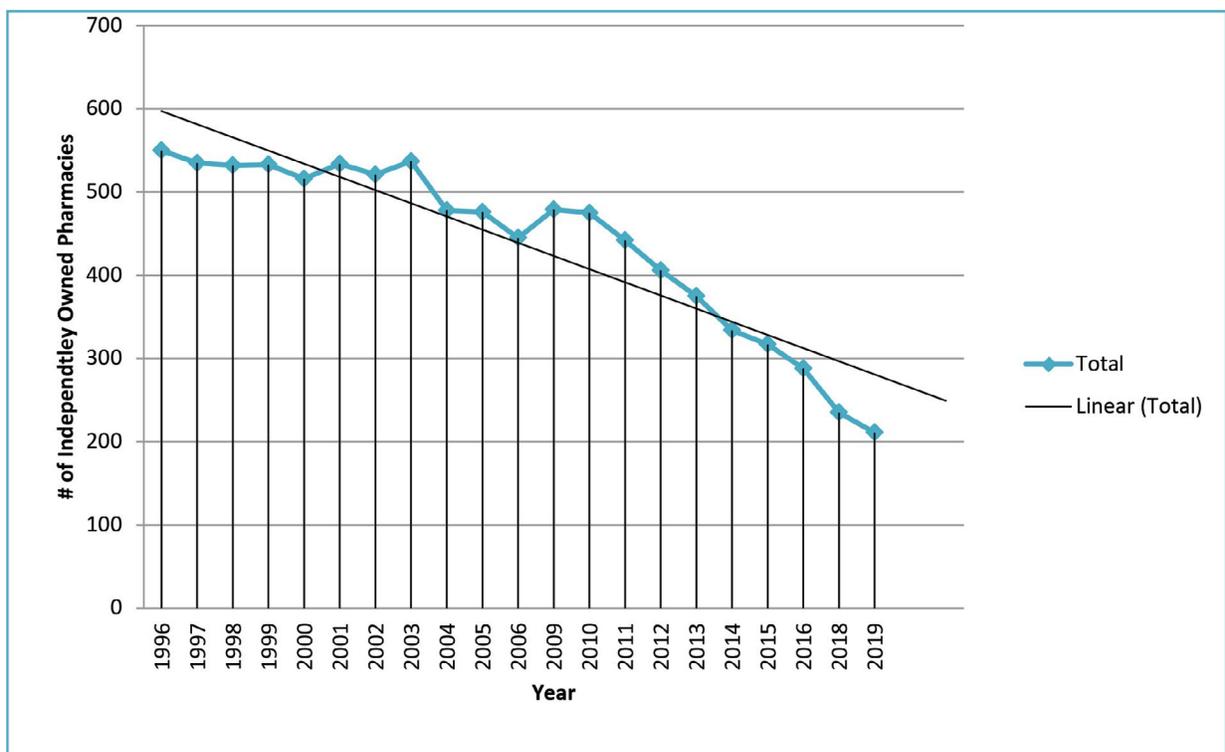
Seniors in the donut hole tend to pay far more for prescription medications. For example, in 2016, seniors with drug spending below the donut hole had an average out-of-pocket expense of \$268. Seniors with drug spending significant enough to enter the donut hole had an average out-of-pocket expense of \$1,175, while seniors with drug spending in the catastrophic range averaged \$3,196. These statistics did not include seniors that received low-income subsidies.¹⁴⁷

The KFF poll indicated that despite the fact that nearly all respondents had some form of drug coverage, as many as 21% of the seniors reported not taking medications as prescribed due to high drug costs.¹⁴⁸ These seniors reported not filling a prescription, taking over the counter medicines instead of those prescribed by their doctors, and cutting pills in half or skipping doses.¹⁴⁹ Compounding the problem, more than half failed to report this behavior to their doctors.¹⁵⁰ The troubling result is that 22% of the seniors who failed to take medication as prescribed reported that their health worsened as a result.¹⁵¹

2.5.4 Impact on Independent Minnesota Pharmacies.

Independent pharmacies in Minnesota and elsewhere are a vital source of care for patients. The number of independent pharmacies in the United States continues to decline each year. In 2011, there were approximately 23,100 independent pharmacies; by 2017, that number dipped to less than 22,000. The number of independent pharmacies in Minnesota has experienced an even steeper decline, from about 550 in 1996 to just over 200 today:¹⁵²

Independently-Owned Pharmacies in Minnesota, 1996 – 2019



Approximately 75% of independent pharmacies serve populations areas of 50,000 or fewer. It is thus critically important to take into account the impact of high drug prices on such pharmacies when attempting to address the issue, and to ensure that residents who live in greater Minnesota continue to have access to the prescription drugs they need.

Independent pharmacies face several difficulties that large pharmacy chains do not. One of them is often onerous and opaque “direct and indirect remuneration” (“DIR”) fees.¹⁵³ Some PBMs charge independent pharmacies—who often accept a significant number of Medicare and Medicaid patients and have small profit margins—DIR fees months after a drug has been dispensed to a patient. By levying DIR fees on pharmacies PBMs effectively reduce the amount the PBM pays a pharmacy for the drugs it dispenses to patients, saving the PBM money and also obscuring the true amount a pharmacy is paid by a PBM.

Another challenge for independent pharmacies is that PBMs sometimes direct or “steer” patients to brick-and-mortar or mail-order pharmacies that they own.¹⁵⁴ They do this through pharmacy network restrictions, offering lower out-of-pocket costs to patients who patronize their own pharmacy, or limiting other pharmacies’ ability to dispense 90-day supplies of prescription medications, which are often preferable to patients. For example, CVS operates as both a network of pharmacies and also as a PBM (CVS Caremark and SilverScript). In doing so, CVS’s PBM steers patients to its own pharmacy managed networks, thereby reducing the number of pharmacies available to CVS patients in exchange for supposed pharmacy savings.

In short, as a former president of the National Community Pharmacists Association explained, “When prices go up, payers—be they health plans or employers or PBMs on behalf of their clients—want a cut and where do they turn to cut first? The easiest target is our [pharmacy] reimbursement.”¹⁵⁵

2.5.5 Impact on Minnesotans of Color.

High prescription drug costs present unique challenges for people of color. One such hurdle is the higher un-insurance rates among people of color. According to a 2017 Kaiser Family Foundation survey, while 4% of Minnesota’s nonelderly white population lacks insurance coverage, 7% of African Americans, 18% of Hispanics, and 22% of Native Americans lack insurance coverage.¹⁵⁶

In addition, some providers believe in and act on some racist myths that can lead to limited access to and affordability of prescription medications for people of color. For example, a 2016 survey of white medical students revealed that half of them held at least one false belief about physiological differences between black patients and white ones, such as the idea that black people have less sensitive nerve endings or thicker skin than white people.¹⁵⁷ Not surprisingly, African Americans and Hispanics are more likely than whites to receive lower doses of pain medication or none at all, despite higher pain scores.¹⁵⁸ This disparate treatment of pain persists even in hospice settings.¹⁵⁹ Some providers’ hesitation or refusal to prescribe pain-reducing medications for people of color despite the fact that white people are more likely than African Americans and Latino/as to misuse these types of drugs.¹⁶⁰

Misuse of race in pharmacogenomics—a field of research that studies how a person’s genes affect how he or she responds to medications—can also lead to increased medication costs for people of color.¹⁶¹ The history and development of a drug called “BiDil” illustrates this point.¹⁶² BiDil is a combination of two preexisting generic drugs that have long been used to treat heart failure, regardless of the race of the patient. Despite a lack of scientific evidence that race has any relationship to BiDil’s effectiveness, a company called NitroMed was able to obtain race-specific FDA approval for the drug. NitroMed relied on a trial that enrolled only African Americans and then



used the results to argue the drug provided specific benefits to them. By marketing BiDil as a race-specific drug, NitroMed was able to extend its patent on BiDil, and thus its control over the profits by 13 years. The ability to obtain race-specific patents exists despite the lack of evidence that race is a relevant biological variable in assessing the safety or efficacy of drugs. As one author put it, “[p]ooling people in race silos is akin to zoologists grouping raccoons, tigers and okapis on the basis that they are all stripey.”¹⁶³



3. Significant Causes And Contributors Resulting In High Prescription Drug Prices.

There are legions of causes, perverse economic incentives, and other factors that contribute to the high and ever-increasing cost of prescription drugs in the United States. Discussion of every such factor is beyond the scope of the Task Force's report, so the discussion in this section focuses on seven of the most significant causes of high drug prices:

- 3.1 misuse and abuse of federal patent and drug exclusivity laws;
- 3.2 patients' inability to access more affordable sources of medications through safe, vetted
- 3.3 importation channels;
- 3.4 anticompetitive conduct that occurs in the drug industry;
- 3.5 deceptive and other unlawful marketing practices used in the drug industry;
- 3.6 the opacity of, and conflicts of interest present in, PBMs' business models;
- 3.7 perverse economic incentives that result in more expensive branded drugs being used even when generics are available; and
- 3.8 the lack of transparency into pricing and other practices in the pharmaceutical drug industry.

3.1 The Misuse and Abuse of Patent, Exclusivity, and Related Laws to Insulate Drug Manufacturers From Competition Significantly Contributes to High Prescription Drug Costs.

3.1.1 Misuse and Abuse of Patent Laws.

As discussed above, a single drug may be covered by dozens of patents. This is sometimes called a "patent thicket." Relatedly, some drug makers will file successive patents on a drug with the same active chemical ingredient, a practice sometimes referred to as "evergreening" or "patent layering."¹⁶⁴ For example, AbbVie filed 247 patent applications for Humira, which is used to treat arthritis and is the top-selling drug in the world. A total of 132 of those patents were issued, resulting in 39 years of patent protection.

Often, the patents making up a patent thicket or the successive patents that constitute evergreening cover only minor innovations or improvements, and may offer little to no therapeutic benefit to patients taking that particular drug. Still, such abuse of patent laws allows a manufacturer of a brand name drug to effectively extend the artificial monopoly provided by patent protections on the branded drug, thereby delaying entry into the market of a competing



generic version of the same drug. The price on the brand-name drug protected by a patent thicket or evergreening stays high because there is no competition. This hurts patients and others who pay for the drug because the first generic on the market can lead to a price drop of 20%. When multiple generics are competing, prices can go down by 80% to 85%.¹⁶⁵

3.1.2 Misuse and Abuse of Drug Exclusivity Laws.

Proponents of FDA exclusivities argue that they provide incentives for drug manufacturers to create new drugs. As with patents, however, these exclusivities can be manipulated to artificially protect drug manufactures from competition, leading to significantly higher drug prices.

Perhaps the most widely abused FDA exclusivity is the “orphan drug” exclusivity. In 1983, Congress passed the Orphan Drug Act with the goal of encouraging drug manufacturers to develop drugs to treat rare diseases and conditions, such as ALS and Huntington’s disease.¹⁶⁶ The act as originally designed allowed drug manufactures to have seven years of exclusivity—in addition to tax credits and FDA fee reductions—to recoup investments on research and development for new drugs likely to have reduced sales due to small patient populations. This granting of an artificial monopoly, however, has given drug makers a virtually unfettered ability to raise drug prices during the exclusivity period. By 2014, the average annual price for an orphan drug was \$111,820, versus \$23,331 for a mainstream, non-orphan drug.¹⁶⁷ By 2017, the world’s 10 most expensive drugs were all orphan drugs.

The orphan drug exclusivity grant has also morphed into a vehicle for drug manufacturers to insulate themselves from competition for even well-established drugs that treat large patient populations. By 2015, seven of the top ten best-selling drugs in the United States had also won designation as orphan drugs. Drug companies can achieve this designation for even widely used drugs by the so-called “salami slicing” of a drug’s approved treatment indication into ever narrower indications for disease subtypes until they can qualify for orphan drug status.¹⁶⁸ For example, Humira, the best-selling drug in the world—with \$19.9 billion in worldwide sales in 2018 alone—was originally approved by the FDA in 2002 to treat rheumatoid arthritis.¹⁶⁹ Three years after the drug’s initial approval the manufacturer of Humira, AbbVie, sought orphan drug status for the drug to treat juvenile rheumatoid arthritis. The FDA approved this use in 2008. Since that approval, AbbVie has obtained approval for Humira to treat four more rare diseases, and one approved use of Humira for an eye disease extends the drug’s exclusivity for that disease until 2023. While orphan disease uses of Humira likely constitute less than 25% of the drug’s total sales,¹⁷⁰ even just 10% of total sales amounts to more than \$1 billion in sales per year.¹⁷¹

Brand name drug makers also abuse orphan drug exclusivity in other ways. For example, in the late 1990’s, Roche’s brand-name drug Rituxan was initially approved to treat only a rare type of non-Hodgkin’s lymphoma that affected approximately 14,000 patients per year.¹⁷² After receiving orphan drug exclusivity, however, Roche obtained approval to use Rituxan to treat a variety of much more common conditions, including rheumatoid arthritis. By 2017, Rituxan had \$7.9 billion in worldwide sales. Such tactics can allow brand name drug companies to claim seven years of FDA marketing exclusivity, reduced FDA application fees, and tax subsidies intended to foster the creation of true orphan drugs, all while reaping the benefits of sales to much larger patient populations than Congress intended when it established orphan-drug exclusivity.

Neither is the abuse of exclusivity laws confined to orphan drug exclusivity. For example, in order to sell a prescription drug “over the counter” or in a different dosage form, the drug manufacturer must file a supplemental NDA seeking FDA approval.¹⁷³ However, because FDA approval of a supplemental NDA grants three years of additional exclusivity for the new indication, drug manufacturers often delay filing a supplemental NDA until



existing patent and exclusivity protections have almost expired, thus insulating the drug from generic competition on the new approved indication.¹⁷⁴ Moreover, because the FDA grants three years of exclusivity for certain clinical investigations deemed “essential” to the approval of an NDA or supplemental NDA of a drug,¹⁷⁵ to obtain additional exclusivity drug manufacturers will often delay studies or conduct internal clinical investigations near the end of existing exclusivities, thus delaying drug innovation and increasing drug prices.

Additionally, when generic competition becomes inevitable, brand name drug manufacturers may release their own “authorized generic” version as the first generic version of the brand name drug. This allows the brand name drug manufacturer to obtain 180 days of exclusivity protection from true generic drug competition, thus further delaying the price reductions that generic drug competition brings.¹⁷⁶ For example, when PDL Biopharma discovered that a competitor was planning to develop a generic version of Tekturna, a blood pressure medication, PDL developed its own authorized generic version of the drug. PDL’s CEO admitted that the authorized generic version of Tekturna “was timed to secure us the benefit of being first to market” for a generic version of the drug.¹⁷⁷

3.1.3 Misuse and Abuse of Citizen Petitions and REMS Protocols.

Citizen Petitions. Under federal law, any “interested person” may file a petition with the FDA requesting that the FDA take action, including on a pending application for approval of a generic or biosimilar drug.¹⁷⁸ These are commonly referred to as “citizen petitions.” While citizen petitions provide an important conduit for the exercise of the First Amendment right to petition the government, they can be subject to abuse in the form of branded drug manufacturers frivolously questioning the safety and efficacy of proposed generic drugs.¹⁷⁹ The former Chief Counsel for the FDA has stated that these meritless citizen petitions “appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application, but rather to delay approval by compelling the [FDA]” to review late-presented arguments.¹⁸⁰ By doing so, citizen petitions can delay the entry of generic drugs into the market, allowing branded drug manufacturers to enjoy monopolistic pricing power for longer than they would otherwise be entitled.

REMS Protocols. To obtain FDA approval for a generic drug, the generic manufacturer will have to conduct certain dissolution and bioequivalence tests on the branded drug (known as the “Reference List Drug” or “RLD”) with which it will compete. To do that, the generic manufacturer must obtain thousands of samples of the drug. For most drugs, the generic manufacturer can simply buy the drug from a wholesaler. Some drugs, however, are subject to a Risk Evaluation and Mitigation Strategy (“REMS”) protocol. A REMS protocol often consists of a series of requirements and processes imposed by the FDA to ensure the safety of the drug at issue, such as certification of prescribers or pre-prescription liver testing of patients, and can even include restrictions on distribution of the drug. If a generic manufacturer wants to compete with a branded drug that is subject to a REMS protocol, the generic manufacturer must establish an identical program.¹⁸¹

Some branded manufacturers will misuse REMS protocol to deny a generic manufacturer access to the drug. To prevent this anticompetitive practice, the FDA has developed a program by which a generic manufacturer can obtain a letter from the FDA stating that the FDA will not consider providing access to the drug a violation of the REMS protocol. But this, in turn, has resulted in some branded drug manufacturers actually patenting the REMS protocol itself, which may subject the generic manufacturer to a patent infringement lawsuit when it attempts to implement its own, equivalent REMS protocol regarding its competing generic drug.¹⁸²



3.2 Patients' Inability to Access More Affordable Sources of Medications Through Safe, Vetted Importation Programs Contributes to High Prescription Drug Costs.

Although the opaque nature of the United States' healthcare system makes it difficult to compare prescription drug prices in the United States with those of other countries, it is clear that the United States spends far more money per capita on prescription drugs than any other high-income country and this gap in spending is continuing to grow. One analysis found, for example, that Crestor, a medication used to lower high cholesterol and triglyceride levels, costs \$86.40 per month in the United States and only after discounts are applied. Compare that to Canada, where Crestor costs \$32.10 per month; Japan, where it costs \$28.80 per month; and France, where it costs \$19.80 per month.¹⁸³ Similarly, Humira, a biologic drug used to treat rheumatoid arthritis, costs \$2,504.50 per month after discounts in the United States, compared to \$1,164.32 in Canada, \$980.34 in Japan, and \$981.79 in France.¹⁸⁴ The disparity in drug prices between the United States and other countries is not unique to these two medications: it exists across a wide variety of brand-name, generic, and biologic prescription drugs.

In light of the disparities in drug prices between the United States, Canada, and other developed countries, many have proposed importing lower-priced drugs from elsewhere, with Canada being the most discussed option. The majority of Americans support importation as a potential solution to access cheaper prescription drugs. A 2019 survey found that 80% of Americans support allowing the purchase of prescription drugs imported from Canada.¹⁸⁵

Federal law, however, generally prohibits the importation of non-FDA-approved medications into the U.S., including FDA-approved drugs produced outside the U.S. that have not been evaluated through the FDA process.¹⁸⁶ The federal Food, Drug, and Cosmetic Act ("FDCA") establishes two exceptions to this rule. First, one part of the law gives the Secretary of the Department of Health and Human Services ("HHS") authority to promulgate regulations to establish an importation program from Canada if the Secretary finds the program would pose no additional risk to the public and would significantly reduce the cost of drugs to U.S. patients. Second, the FDA may allow temporary importation when a drug is in shortage. Additionally, the FDA has allowed individuals to bring into the U.S. a small amount of an unapproved drug for personal use "where effective treatment is not available in the United States, it is for the treatment of a serious medical condition, and there is no commercialization of the drug to U.S. residents."¹⁸⁷

Several states, including Vermont, Colorado, and Florida, recently passed drug importation legislation that authorizes them to seek federal approval to import prescription drugs from Canada. To date, no state has sought and gained federal approval. Previous attempts by states to allow the importation of prescription drugs from foreign countries have failed because HHS opposed them due to safety concerns.

On July 31, 2019, the HHS and the FDA announced the "Safe Importation Action Plan," which describes two potential pathways for establishing an importation program. The first would involve establishing new regulations that would allow "States, wholesalers, or pharmacists [to] submit plans for demonstration projects for HHS to review outlining how they would import Health-Canada approved drugs."¹⁸⁸ The second pathway would allow manufacturers of FDA-approved drugs to import to the U.S. the versions of the drugs that they sell in foreign countries and then re-sell these imported drugs at lower prices here, if they establish that the foreign version is the same as the U.S. version.

While all of these importation plans are in the early stages, those focused on importing drugs from Canada have raised concerns over the possible effect on Canada's pharmaceutical drug supply and potential price increases on pharmaceutical drugs for Canadians. Canada has only approximately 38 million residents compared to the 330 million people that live in the United States. This raises questions about Canada's ability to be an adequate source



of supply for any drugs sought to be imported on a nationwide basis. Thus, any large-scale importation plan could face roadblocks in Canada, and suggests that any importation of lower-priced drugs will have to be sourced from other nations in addition to Canada.

3.3 Anticompetitive Conduct in the Drug Industry Significantly Contributes to High Prescription Drug Costs.

Anticompetitive conduct is pervasive in the drug industry. Some types of anticompetitive conduct that have been particularly prominent in the industry over the last two decades and that have contributed to high drug prices are: (1) drug “product hopping,” which effectively coerces patients to use high-priced, brand-name drugs subject to patent protection, (2) “pay for delay” arrangements that drug manufacturers use to delay competition from cheaper, generic drugs, (3) per se anticompetitive conduct by drug manufacturers that continues despite it being clearly unlawful, and (4) significant industry consolidation among drug manufacturers.

3.3.1 Drug “Product Hopping” Prevents Patients’ from Switching to Cheaper Generic Drugs, Resulting in Their Continued Use of Higher-Priced Branded Drugs.

As discussed above, when a manufacturer creates a new drug they are granted artificial monopoly power over the drug for a period of time through federal patent or drug exclusivity laws (or both). Because of this grant of a monopoly, it is more profitable to sell the drug during the time period the manufacturer’s patent or exclusivity rights protect it from competition. When the monopoly period ends and generic versions of the drug can more easily enter the market, prices—and profits—often fall significantly. This provides a strong incentive for branded drug manufacturers to try to extend the period the drug is covered by patent or exclusivity rights. One method of doing so is called drug “product hopping.”

In a product hop, a branded drug manufacturer, typically shortly before its patent or exclusivity rights expire, makes minor changes to some aspect of a drug besides its substance/active ingredient/molecule. After doing so, the manufacturer secures additional patent or exclusivity rights to the “new” version of the drug, and ceases selling the prior version. Generally, the minor alterations made to the drug are not intended to change its effects, but to maintain the manufacturer’s monopoly pricing power.

Accordingly, in a product hop case, a manufacturer is not making a new or superior product; the manufacturer is instead exploiting patent or exclusivity laws to extend its monopoly power and keep other, cheaper generic equivalent drugs from entering the market. While product hopping has been held to likely violate antitrust laws,¹⁸⁹ it is still a common practice in the drug industry.

One recent example of this practice regards the drug Suboxone, made by Indivior, Inc. Suboxone is a very profitable drug used to treat opioid withdrawal. More than 40 state attorneys general, including Minnesota, filed a lawsuit against Indivior in 2016 alleging unlawful product hopping.¹⁹⁰ The lawsuit claims that, as Indivior’s period of exclusivity on the tablet-form Suboxone was coming to an end, it created a therapeutically identical film-strip version of Suboxone, which it patented. Indivior then shifted the market to the newly patented, film-strip version of the product by falsely claiming that it was safer than the tablet form, delaying the entry of generic versions of Suboxone tablets to market.¹⁹¹



3.3.2 Drug Manufacturers Routinely Enter Into “Pay for Delay” Arrangements that Delay the Introduction of Cheaper, Generic Drugs.

Similar to product-hopping, “pay for delay” arrangements between drug manufacturers are a way to delay competition from lower-priced generic drugs. Pay for delay agreements begin when a generic manufacturer files an Abbreviated New Drug Application with the FDA to manufacture a generic version of a branded drug. Once this occurs, the branded manufacturer has 45 days to dispute, by filing a lawsuit, the generic manufacturer’s certification to the FDA that producing the generic version of the drug will not infringe on the branded manufacturer’s patent rights.

In litigation, a defendant typically pays a plaintiff to settle a lawsuit. In a patent case, this means that a generic manufacturer (i.e., the defendant) would pay the branded manufacturer (i.e., the plaintiff) to settle the lawsuit. But in a pay for delay arrangement, the exact opposite occurs—the branded manufacturer, whose patents are allegedly being infringed, actually pays the generic manufacturer, who is allegedly doing the infringing. In exchange for this payment, the generic drug manufacturer agrees to delay introducing its generic version of the drug into the market until a certain amount of time has passed. These counterintuitive payment arrangements are also sometimes called “reverse payment settlements.”

Regardless of what they are called, the essence of these arrangements is that a branded drug manufacturer pays a rival generic manufacturer not to compete with it by delaying introduction of the rival’s generic drug into the U.S. market, leaving the branded drug as the only one available. In some cases, while generic drugs have competed with branded drugs in other countries around the world, pay-for-delay arrangements have resulted in the absence of such competition—and the reduced prices it would bring—in the United States.¹⁹²

3.3.3 Even Per Se Unlawfully Anticompetitive Practices, Such as Price Fixing, Remain a Problem in the Drug Industry.

Due to a variety of factors, conduct that is patently unlawful is still troublingly common in the drug industry. Price fixing is just one example of such conduct. It has long been “per se” unlawful for two rivals to fix the price of the competing products that they each sell.¹⁹³ Nevertheless, drug manufacturers have been repeatedly accused¹⁹⁴ of fixing drug prices, including in an ongoing price-fixing lawsuit brought by Minnesota and 48 other state attorneys general in federal court in Pennsylvania.¹⁹⁵ The lawsuit alleges that for many years, generic manufacturers have participated in a per se anticompetitive scheme whereby each one agreed that it would only sell to certain customers and avoid price competition to maintain what they believed was their “fair share” of the market for the drugs at issue. Later, these manufacturers altered their alleged scheme to implement simultaneous price increases for their competing generic drugs, with some of these increases exceeding 1,000%. Typically, “[f]or drugs that attract a large number of generic manufacturers, the average generic price falls to 20% or less of the price of the branded drug.”¹⁹⁶ Because of the alleged price-fixing agreement among competing generic manufacturers, however, the normal effects of competition did not occur. As a result, these generic manufacturers significantly increased their profits at the expense of patients being able to buy cheaper prescription drugs.

3.3.4 Consolidation has Significantly Reduced the Number of Competitors in the Drug Industry.

Finally, as in many industries, mergers and acquisitions between pharmaceutical companies can affect the price and quality of their products. Large mergers have been the norm in the drug industry over the last twenty years, with one of the more recent being a \$74 billion deal between Bristol-Myers Squibb and Celgene, two of the largest American drug companies. Other significant mergers and acquisitions among drug manufacturers since the 1990s include the following:



- Amgen’s acquisition of Otezla in 2019 (\$13.4 billion);
- Takeda Pharmaceutical’s acquisition of Shire in 2018 (\$62 billion);
- Johnson & Johnson’s acquisition of Actelion in 2017 (\$30 billion);
- Abbott Laboratories’ acquisition of St. Jude Medical in 2016 (\$25 billion);
- Shire’s acquisition of Baxalta in 2016 (\$32 billion);
- Bayer’s acquisition of Monsanto in 2016 (\$66 billion);
- Actavis’ acquisition of Allergan in 2014 (\$66 billion);
- Glaxo Wellcome’s merger with SmithKline Beecham in 2000 (\$64.3 billion);
- Pharmacia & Upjohn’s merger with Monsanto in 1999 (\$26.5 billion); and
- Pfizer’s acquisition of Warner-Lambert in 1999 (\$90.27 billion).

As the pharmaceutical industry grows more and more consolidated, these mergers cause increasing concern. Consolidation among drug manufacturers presents several problems from a competition standpoint. Fewer major players means less competition and potentially higher prices. It can also discourage research and development for new drugs, as large companies may find it more profitable to simply buy companies that own new drugs, instead of investing in developing new drugs.

Mergers in other parts of the drug industry, such as the recent merger between CVS (representing America’s largest retail pharmacy chain, plus a PBM) and Aetna (the third-largest health insurer in the United States), can also cause prices to rise by constraining competition. Because of the complex supply chains and payment schemes for prescription drugs, as discussed above, antitrust enforcers must monitor excessive consolidation in many different parts of the industry.

3.4 Deceptive and Other Unlawful Marketing Practices in the Drug Industry Significantly Contribute to High Prescription Drug Costs.

Drug manufacturers for decades primarily marketed their pharmaceuticals directly to health care providers. But “direct-to-consumer” advertising of prescription drugs by manufacturers—that is, marketing a drug directly to patients, such as in an advertisement on TV—exploded after the FDA loosened restrictions on this practice in 1997. From 1997 through 2016, direct-to-consumer advertising has been the fastest growing form of marketing for prescription drugs, with spending on these type of ads increasing “from \$1.3 billion (79,000 ads) in 1997 to \$6 billion (4.6 million ads, including 663,000 TV commercials)” in 2016.¹⁹⁷ The United States is one of only two countries in the world—the other being New Zealand, which has a population of only four million people—that permits direct-to-consumer advertising of prescription drugs.¹⁹⁸

Studies have found that direct-to-consumer advertising leads to increased patient requests for high-cost, brand-name drugs—despite the availability of cheaper generic substitutes—as well as greater costs resulting from increased visits with health care providers. For example, the House Commerce Committee found in 2008 that “[e]very \$1 spent on direct-to-consumer advertising results in up to a \$6 increase in sales. One study demonstrated that every \$1,000 spent on direct-to-consumer advertisements resulted in 24 new prescriptions.”¹⁹⁹

This has led to concerns that direct-to-consumer advertising may be placing added pressure on physicians to prescribe expensive, branded drugs that are heavily advertised to, and subsequently requested by, patients. As a result, the American Medical Association in 2015 called for a ban on direct-to-consumer advertising, explaining that “a growing proliferation of ads is driving demand for expensive treatments despite the clinical effectiveness of less costly alternatives,” and continuing that “direct-to-consumer advertising also inflates demand for new and more expensive drugs, even when these drugs may not be appropriate.”²⁰⁰



Such advertisements further frequently tout the discount coupons and patient assistance programs that can help a patient afford the advertised drugs.²⁰¹ As discussed further below,²⁰² “these strategies have been criticized for encouraging use of expensive drugs despite lower-cost options, undermining insurance design, diminishing competitive pressure to lower prices, and ultimately shifting higher costs back to payers.”²⁰³

Despite the significant increase in direct-to-consumer advertising, the FDA has issued a decreasing number of violation letters to manufacturers since 1997 (156 violation letters) through 2016 (11 violation letters).²⁰⁴ This may be due to the FDA being “overwhelmed by the massive increase in promotional submissions” by manufacturers.²⁰⁵ It seems unlikely that the FDA’s absence of regulatory action is attributable to a lack of problematic advertising practices by manufacturers. Indeed, since 2007, the U.S. Department of Justice and state attorneys general entered into approximately 103 settlements with manufacturers over their allegedly unlawful marketing practices, resulting in more than \$10.5 billion in financial penalties being imposed.²⁰⁶ Most commonly, these unlawful practices included manufacturers advertising their prescription drugs for off-label purposes.²⁰⁷ The Minnesota Attorney General’s Office itself has sued and obtained millions of dollars from drug manufacturers for engaging in allegedly unlawful advertising practices.²⁰⁸

In May 2019, the Centers for Medicare and Medicaid Services (“CMS”) published a final rule requiring direct-to-consumer advertisements of any prescription drugs available through Medicare or Medicaid to include the list price of that drug in the ad.²⁰⁹ The purpose of the rule was to ensure patients understood the cost of advertised drugs. In June 2019, however, three drug manufacturers (Merck, Eli Lilly, and Amgen) sued CMS over the proposed rule, arguing that it did not have the authority to issue it and that the rule violated their First Amendment rights.²¹⁰ Hours before it was to take effect, a federal judge blocked the implementation of the rule in response to this lawsuit. CMS’s appeal of this ruling is still pending.

3.5 The Opacity of, and Conflicts of Interest Present in, PBMs’ Business Models Significantly Contributes to High Prescription Drug Costs.

As explained above, pharmacy benefit managers occupy a critical position in the drug sales chain.²¹¹ Multiple practices of PBMs are problematic because they either directly cause drug prices to increase, prohibit other people from taking action to reduce the cost of drugs, or obscure critical information that would allow others to take such action.

PBM Rebate Practices.²¹² A significant source of revenue for PBMs is rebates that drug manufacturers pay to PBMs for each unit of a drug sold through the pharmacy networks that PBMs create and maintain for their health plan clients. The prevailing PBM rebate practices incentivize higher drug prices in a number of ways.

Because rebates that manufacturers pay PBMs are taken off of the manufacturer’s list price of a drug, a manufacturer can offer larger rebates to PBMs—while still holding its post-rebate, net price steady—by increasing a drug’s list price. This practice is akin to a department store increasing the price of a clothing line so it can offer shoppers “bigger” discounts as part of a sale. This prevailing PBM rebate structure incentivizes manufacturers to increase the price of the drugs they sell so PBMs can more easily demand, and manufacturers can more easily pay, larger rebates without affecting manufacturers’ bottom line.

These same rebate practices also incentivize PBMs to sell more expensive medicine through their pharmacy networks, as opposed to switching to cheaper generics. An example illustrates this issue best: A drug manufacturer makes branded “Drug X,” which has a list price of \$50 and for which the manufacturer pays a rebate of \$20 to a PBM for each unit of the drug that is sold. A different drug manufacturer makes a generic version of Drug X. The



list price of this generic is \$30, but a PBM will only receive a \$10 rebate for each unit that is sold. Because the PBM receives a larger rebate for continuing to sell the branded version of Drug X (\$20) than it would by selling the competing generic drug (\$10), the PBM continues to keep branded Drug X on its formulary despite the price being significantly more than that of the generic version of the drug. This decision by the PBM drives up the cost of Drug X for both patients and health plans.

PBMs Lack of Transparency.²¹³ PBMs also impede the transparency that those who pay for drugs—typically health plans and patients—have into how those drugs are priced, distributed, and utilized. This makes it difficult for health plans and patients to attempt to control how much they spend on drugs or engage in efforts to hold down drug costs. The lack of transparency results largely from the contracts that PBMs enter into with retail pharmacies and health plans, which act as a “chokepoint” by restricting information these parties are entitled to learn about how the PBM does business. PBM contracts tend to be very one sided and frequently include, among many other problematic provisions:

- Substantial restrictions on health plans accessing data, including even claims data regarding reimbursement rates and any difference between what a PBM reimburses a pharmacy and what the health plan pays the PBM;
- Limiting audit rights and approval of audit firms;
- A lack of transparency into the contractual relationship between PBMs and the retail pharmacies;
- Failure to disclose the financial incentives that drug manufacturers provide to PBMs to drive demand for the manufacturer’s drugs; and
- Purposefully vague or nonexistent definitional terms governing, for example, classification and reimbursement for branded versus generic drugs.

These and many other practices by PBMs that reduce transparency make it difficult for others in the drug supply chain to take concrete steps to reduce the costs of drugs and the amount of money they spend on drugs.

PBM Conflicts of Interest. Some PBMs also operate their own “specialty” and/or mail order pharmacies that directly compete with the retail and other pharmacies with which the PBM also does business. These circumstances present obvious conflict-of-interest concerns: for example, a PBM could engage in business practices that steer purchasers and payers to buy a drug from a pharmacy the PBM owns, even if the price of the drug is cheaper at a competing pharmacy.

3.6 Perverse Economic Incentives that Result in High-Cost Drugs Being Used Even When Generic Alternatives Are Available Significantly Contribute to High Prescription Drug Costs.

Financial inducements offered by drug manufacturers and others to prescribers and patients alike often result in the use of high-cost branded drugs, even though cheaper generic versions of the same drug are available. Such perverse economic incentives are sometimes attractive to patients because they reduce their direct out-of-pocket costs but their decision to use a higher priced, branded drug drives insurance premiums higher because health plans must pay for the remainder. Three particular types of drug industry practices that create perverse economic incentives and contribute to higher drug prices are (1) patient discount coupons, (2) patient assistance programs, and (3) prescriber financial payments.



3.6.1 Drug Manufacturers' "Patient Discount Coupons."

Many health plans use "tiered pricing" for prescription drugs, which charge plan members smaller copays for generic drugs and higher copays for branded drugs.²¹⁴ This tiered pricing is meant to incentivize patients to use cheaper generic medications. To nullify this financial incentive for using generic drugs, branded drug manufacturers now offer copay or other drug discount "coupons" to patients through advertisements, physicians, online, or as debit-type cards.²¹⁵

The coupons are generally redeemed when the patient purchases the branded drug at the pharmacy, and reduce or eliminate patients' out-of-pocket copay costs. Typically, to assess their eligibility for the coupon, patients are required to provide their personal information to the manufacturer, including their contact information, age, income, and insurance status. These coupons are also usually time-limited, meaning that patients with chronic conditions who use branded drugs will eventually be required to pay full price for the drug once their coupon discount period expires. In 2010, drug discount coupons were used for approximately 100 million dispensed prescriptions.²¹⁶ Since then their prevalence has only grown. A more recent study has found that patients with insurance used drug discount coupons for one out of every five branded drug prescriptions they filled in 2016.²¹⁷ For some branded drugs, coupon use was as high as two-thirds of all filled prescriptions.²¹⁸

Drug manufacturers argue that such coupons defray the out-of-pocket costs patients pay for branded prescription drugs. In reality, however, discount coupons are used by branded drug manufacturers to bolster the sales of their more expensive drugs; dissuade patients from using more cost-effective generic drugs, as a strategy to avoid reducing the high prices they charge for these drugs; and to build patient loyalty to the branded version of the drug.

For example, manufacturers build the cost of discount coupons into their budget and pricing strategies and use analytics—including leveraging the personally identifying data they gather from patients who apply for their coupons—to target their coupon offers to maximize brand loyalty and bolster the market for the branded prescription drug being discounted.²¹⁹ One study estimated that manufacturers receive returns on investment in such coupon programs of approximately 4 to 1, and as much as 6 to 1, in the form of increased use of the branded prescription drug by patients.²²⁰

By increasing the sales of their higher priced branded drugs through these coupon campaigns, manufacturers also prevent patients from switching to cheaper, generic versions of the drug. For example, a 2013 study found that 62% of all manufacturer coupons were for brand-name prescription drugs competing against a cheaper generic.²²¹ Another study found discount coupons "increase branded sales by 60+ percent, entirely by reducing the sales of bioequivalent generics."²²²

Manufacturers further use discount coupons "as part of a marketing strategy to keep prices for brand-name drugs higher than they otherwise would be after a lower-cost generic substitute comes to market."²²³ Accordingly, California²²⁴ and Massachusetts²²⁵ have banned the use of drug discount coupons for branded drugs where a generic version of the drug is available. Moreover, Medicare, Medicaid, and military and veterans federal health plans prohibit the use of discount coupons because they have been deemed unlawful inducements under the federal anti-kickback statute.²²⁶

In sum, the result of drug manufacturers' discount coupon programs is to raise overall health care costs by steering patients away from cheaper generic medications and inducing them to buy higher cost branded drugs. While a discount coupon may reduce the amount a patient pays out of pocket for a branded drug in the near term, the coupon does not reduce the price a health plan is charged for that branded drug. Patients often do not realize that third-party payers are still charged the higher price for the branded drug even when a generic version of the drug



is available, thereby increasing costs and driving up premiums that the very same patient who used the discount coupon must pay in the long term.²²⁷ In this way, manufacturer “coupons” raise healthcare costs overall. Indeed, one study estimated that discount coupons for just 23 branded drugs (that competed against a generic substitute drug) resulted in an extra \$700 million to \$2.7 billion in drug spending over five years for these 23 drugs alone.²²⁸ Patients often don’t realize that this is the overall impact of using copay coupons.

3.6.2 Drug Manufacturer “Patient Assistance Programs.”

Similar to drug discount coupons, drug manufacturers have also created “Patient Assistance Programs” for income-eligible patients to acquire drugs at no or reduced costs. These programs usually either directly distribute branded drugs to patients at reduced cost, or defray copays, deductible expenses, or other out-of-pocket expenses associated with using a branded drug. Like drug discount coupons, these programs are also controversial.

First, many Patient Assistance Programs (“PAPs”) are funded by branded drug manufacturers. Some manufactures have attempted to conceal their relationship to the PAP, however, by discreetly establishing or supporting a nonprofit, tax-exempt charity to ostensibly run the program. For example, a number of drug manufacturers have been investigated by the Department of Justice regarding their relationship with PAPs run by purportedly independent, charitable organizations.²²⁹

Second, manufacturer-sponsored PAPs “are almost always restricted to expensive, patented, brand-name products.”²³⁰ Just like drug discount coupons, this results in PAPs incentivizing patients to use expensive branded drugs and steers them away from using cheaper, generic versions of the same medications.²³¹ Indeed, some healthcare consultants have touted PAPs as “improving consumer loyalty to brand-name drugs, and increasing [branded] drug utilization and sales.”²³² For example, one firm has called manufacturer-backed PAPs a “key strategy for improving patient uptake” of branded drugs.²³³ Thus, PAPs, just like discount coupons, contribute to increased healthcare costs for all patients “in the form of higher insurance premiums, deductibles and copayments.”²³⁴

3.6.3 Prescriber Financial Inducements for Prescribing Particular Drugs.

Manufacturers spend billions each year to market their pharmaceuticals directly to medical providers.²³⁵ Based on one study, their return-on-investment for such marketing is “2 to 1 overall and 10 to 1 for new branded drugs.”²³⁶ Researchers have found that in 2016, manufacturers “paid physicians and teaching hospitals \$978.96 million for non-research activities, including \$381.13 million to serve as faculty or speakers presenting [manufacturer]-developed materials during lunch or dinner talks. Other payments were for consulting (\$210.05 million), food and beverages (\$164.21 million), travel and lodging (\$96.9 million), and honoraria (\$14.64 million).”²³⁷

Manufacturers often provide such payments to opinion leaders who serve as consultants and speakers that champion the manufacturer’s expensive branded drug to other prescribers. Studies have found that these types of payments and gifts to physicians “appear to stimulate physicians to prescribe the promoted drug; even small gifts promote increased prescribing, although larger gifts are associated with larger effects.”²³⁸ For this reason, Minnesota bans manufacturers from providing gifts to healthcare practitioners, though this prohibition still allows manufacturers to pay practitioners certain education-related expenses for speaking at a conference, for example, as well as for certain consulting expenses.²³⁹

Notwithstanding such laws, some manufacturers still attempt to increase demand for their branded drugs by making improper payments to prescribers. For example, in May 2018 the Minnesota Attorney General’s Office sued opioid manufacturer Insys Therapeutics, Inc., for allegedly engaging in an illegal marketing scheme designed to



induce Minnesota health care providers to prescribe their branded opioid products.²⁴⁰ As one part of its scheme, Insys allegedly created a sham speaker program to justify its payments to opioid prescribers.²⁴¹ Insys paid these prescribers money disguised as bona fide honoraria for participation in “educational events.”²⁴² Instead, the events were shams that often did not even occur and the payments were bribes—i.e., illegal kickbacks—intended to induce prescribers to write prescriptions for Insys’s branded opioid product, or reward them for already doing so.²⁴³ Insys targeted its ostensible speaker program in Minnesota to two physicians, allegedly paying them more than \$43,000 in sham “speaker fees.”²⁴⁴ In exchange, these two Minnesota physicians allegedly wrote over 90% of the prescriptions in the state for Insys’s opioid product, Subsys, generating over \$4 million in sales.²⁴⁵ Numerous Insys employees, including high-level executives, have been criminally charged and convicted for their participation in this type of illegal scheme.²⁴⁶ A bankruptcy court recently confirmed the liquidation of Insys, resolving the enforcement actions brought by the Minnesota Attorney General’s Office and the Minnesota Board of Pharmacy.²⁴⁷

3.7 The Lack of Transparency Regarding How Drugs Are Priced and Paid For Significantly Contributes to High Prescription Drug Costs.

The prescription drug market is uniquely opaque at virtually all levels. As reflected in the diagram in Section 2.2, the sales chain is complex and involves many different companies that manufacture, distribute, or pay for drugs in some manner. Information gaps exist at each level of the sales chain. As a result of the different negotiations between different parties in the sales chain, there is generally not a “single” price for a drug. Instead, the manufacturer’s list price²⁴⁸ serves as a starting point or “benchmark” for different prices paid by different payers. Health plans, patients, and other payers do not have access to information reflecting what each entity pays in relation to this list price, rendering it exceedingly difficult to understand the prices paid for prescription drugs at all level of the sales chain.

Manufacturers set list prices for drugs sold. How a manufacturer determines the list price is not transparent. In practice, list prices are sometimes inflated in anticipation of negotiations over rebates paid to PBMs, as discussed previously, and other pricing concessions, such as discounts and coupons, as also discussed above. Manufacturer rebates paid to PBMs generally vary by drug and PBM. There is no transparency into the size of the rebates manufacturers pay to PBMs, as this information is labeled proprietary. This obscures the true price manufacturers receive for the drugs they sell. The share of the rebates that a PBM passes on to its health plan client, if any, is also often unknown, exacerbating the lack of transparency at this separate level of the sales chain.

A lack of transparency in pricing also exists for the other entities involved in the prescription drug distribution system. The drug manufacturer typically sells drug products to a wholesaler, at a price often referred to as the average manufacturer’s price or wholesale acquisition cost. Wholesalers then distribute drugs to pharmacies and providers. Wholesalers generally charge pharmacies a percentage off of a reference price or list price. From the pharmacy, medication goes to a consumer. A consumer with insurance pays an amount determined by the insurer. Pharmacies are often reimbursed by insurers and PBMs based on a percentage off of the reference or list price. Thus, cost sharing with consumers is often a function of the list price. Consumers without insurance are charged a cash price. In each of these transactions, the purchaser often has little or no information about the actual prices others in the distribution chain are paying, obscuring visibility into the entire process.



Regarding reimbursements and pharmacies, little is publicly known about how health plans or PBMs reimburse pharmacies for drugs dispensed to a health plan's patients. The PBM or health plan generally determines both what a patient's copay will be and the reimbursement paid to the pharmacy for dispensing a drug. For generic drugs, the reimbursement is referred to as the maximum allowable cost ("MAC"), a proprietary formula determined by the PBM.

This lack of transparency at all levels of the distribution chain hinders the prescription drug market from functioning according to normal market principles, as buyers need sufficient information about prices to foster competition among rival sellers. But, in the market for prescription drugs, for the reasons described above, patients, health plans, and other payers often lack even basic pricing information necessary to make informed choices about their health care.²⁴⁹

Transparency could benefit multiple entities in the drug sales chain, in addition to patients, by making it difficult for manufacturers or others to charge higher prices to some purchasers versus others, or provide different discounts or rebates.²⁵⁰ For example, one study considered whether knowledge of prices affected business-to-business markets in the hospital supply purchasing context.²⁵¹ The study noted that there was variation across hospitals paying for the same brand of medical devices. The study determined that when hospitals gained access to information on peer hospitals' purchasing, they saw savings on the same brands.

Increasing transparency could result in more accountability for manufacturers and allow regulators and the public to more readily recognize abusive or unconscionable practices such as price-gouging. While the lack of transparency allows manufacturers more opportunities to overprice drugs, transparency may disincentivize such practices. More information about the gap between a list price and net price could inform future policy to curb drug spending. Accordingly, transparency is needed to begin to address drug-pricing practices.



4. Selected Past and Current Legislative, Regulatory, and Law Enforcement Strategies That Have Attempted to Address High Prescription Drug Prices.

Numerous strategies have been contemplated, attempted, or implemented over the years that have sought to combat high drug prices, at both the state and federal level. Given the current cost of many prescription drugs and how quickly they continue to increase in price, it is clear these efforts have yet to accomplish their intended goal. Yet it is still important to be aware of and understand the major legislative, regulatory, and law enforcement strategies that have been tried previously, to learn from them, and to consider whether drug prices would be even higher had they never been attempted or implemented in the first place.

4.1 Selected Past and Current Federal and State Legislative and Regulatory Strategies to Address High Drug Prices.

Past federal and state efforts to curb excessive drug prices have long sought to identify targets for regulation, with varying success. Through August 2019, state legislatures have introduced 880 bills addressing laws regarding drugs, of which 130 were signed into law.²⁵² Legislatures and regulators, in particular, have focused on attempting to increase transparency in drug pricing, build economies of scale, create punitive disincentives for abusive practices, and directly legislate pricing and rebates.

4.1.1 Pricing Transparency Strategies.

Because the various actors in the drug industry—from manufacturers to PBMs to retail pharmacies—all affect drug pricing through opaque mechanisms, states have struggled to effectively monitor abusive pricing practices. Transparency-focused strategies take aim at this secrecy with the twin goals of (a) allowing governments to better regulate pharmaceuticals, and (b) allowing patients to make more informed decisions about their drug purchases based on price, thereby enhancing price competition among therapeutically equivalent drugs.

In June 2016, Vermont became the first state in the nation to require that the manufacturers of 15 costly state-purchased drugs justify price hikes, or be subject to a civil penalty of up to \$10,000 per violation.²⁵³ Numerous other states have since followed suit.²⁵⁴ Most of these laws, such as Oregon's, require manufacturers to provide the state with specified information designed to allow regulators to determine the reasonableness of a price increase, including the total sales revenue for the drug for the previous calendar year and the ten highest prices paid for the drug in any country outside the United States.²⁵⁵ Fewer state laws require public disclosure of specific drug pricing, though some do. For example, Florida has passed a law requiring that retail prices for certain frequently-prescribed medications be published monthly on a public website,²⁵⁶ and Nevada has passed a statute requiring manufacturers to publicly disclose price increases for certain drugs.²⁵⁷

The drug industry has vigorously opposed states' efforts to require additional transparency. As an example, while Vermont's state senate has 30 members, the pharmaceutical industry has had at least 35 registered lobbyists in Vermont.²⁵⁸ Transparency legislation has been introduced, but defeated, in states across the country, including Minnesota,²⁵⁹ New Jersey,²⁶⁰ North Carolina,²⁶¹ and Virginia.²⁶² Even after enactment, transparency legislation has been challenged through litigation brought by the drug industry.²⁶³ As of yet, however, the transparency aspects of states' legislative efforts have largely been upheld in court.



The federal government has also made efforts to introduce price transparency into the prescription drug market. In May 2018, for example, the United States Department of Health and Human Services (“HHS”) introduced the “American Patients First” blueprint to bring down drug prices.²⁶⁴ As a first step in that blueprint, HHS required drug companies to disclose the list price for prescription drugs in TV ads,²⁶⁵ but, following a legal challenge by three drug manufacturers, a federal district court ruled that HHS had exceeded its statutory authority in adopting this requirement.²⁶⁶ Other federal agencies have attempted to combat drug transparency problems. On May 16, 2019, for example, the Centers for Medicare and Medicaid Services announced changes to Medicare Part D and Medicare Advantage that would facilitate physicians in those programs discussing with their patients the out-of-pocket cost of drugs any time a prescription is written.²⁶⁷

The effect of transparency efforts on drug prices has yet to be determined. For example, Vermont’s 2016 initiative resulted in a 2017 report²⁶⁸ that generated criticism about the lack of specificity available to the public in the report and a lack of understanding as to how the report would translate into lower drug prices. Responding to this criticism, the Vermont legislature passed a second, broader bill in 2018.²⁶⁹

4.1.2 Strategies to Increase Purchasing Power.

Cooperative purchasing, or the pooling of buying power to negotiate lower prices, is a popular tool in states’ arsenals to combat rising drug prices. Two general models have emerged: (1) middlemen that leverage large membership bases to obtain upfront discounts from drug manufacturers, and (2) group purchasing organizations (“GPOs”) that purchase drugs in sufficient quantities to lower the acquisition cost.

In the 1980s, Minnesota became a national leader in the first effort, founding MMCAP INFUSE, a multistate collaborative bargaining arrangement whose membership now consists of public entities in all 50 states.²⁷⁰ Members include public health facilities, correctional facilities, education institutions, mental health facilities, and public safety/first responders, which collectively make up over 90% of the membership. The Minnesota Department of Administration began operating MMCAP INFUSE with the goal of leveraging group purchasing power to procure prescription drugs at the best price possible. MMCAP INFUSE is voluntary, free to participating entities, and funded through administrative fees collected from vendors. MMCAP INFUSE’s expertise is self-administered drugs, as opposed to physician-administered drugs. As such, MMCAP INFUSE’s member entities generally have a pharmacy operation to dispense purchased pharmaceuticals. Purchases exceed \$1 billion annually.

Following Minnesota’s lead, other cooperative purchasing arrangements have emerged in Washington and Oregon. Multiple private consortia requiring state and federal approval have also emerged for various states’ Medicaid markets.²⁷¹ Yet other states, including Massachusetts and Washington, have established intrastate purchasing arrangements.

The purchasing power of these pooled-resource arrangements allows participants to enjoy significantly lower prices than the general public.²⁷² While some arrangements do not extend membership to the general public,²⁷³ some emerging programs have fewer restrictions. Washington’s program, for example, is open to all Washington residents.

Leveraging buying power through GPOs is a time-proven method of obtaining lower drug prices, but it should be noted that the reduction is significant mostly when compared to the prices advertised to the general public, as opposed to the undisclosed prices paid by industry participants. All 50 states, and several cities, currently participate in some form of intra- or interstate GPO. Such GPOs provide a framework for states to work together and coordinate efforts to lower drug prices.



4.1.3 Disincentivizing Abusive Practices.

Drug prices can be improperly inflated by bad industry actors that use a variety of abusive practices, including misuse of patents, coordinated price-gouging, and outright kickbacks. There are numerous administrative, civil, and criminal laws designed to reduce and punish fraud. This report summarizes only a small subset of the tools available to federal and state governments.

While patents and drug approvals are administered by federal agencies—the U.S. Patent and Trademark Office and the FDA, respectively—enforcement of relevant laws that can be used to address unlawful drug industry practices falls to both federal and state governments. Many states, for instance, have enacted consumer protection laws, which, as in Minnesota, restrict drug manufacturers from mislabeling or falsely marketing drugs to improve sales and reduce competition.²⁷⁴ Additionally, 29 states have passed some form of a False Claims Act,²⁷⁵ which, in conjunction with state contracts, often functions to prevent drug companies from billing the government after materially violating a state or federal law. The False Claims Act, and some consumer protection acts, have mechanisms for private parties to bring lawsuits against bad actors in the pharmaceutical market, thereby broadening the reach of these laws.

While 34 states have enacted some form of price-gouging laws that apply in cases of emergency, regulating arbitrary increases in drug prices has proven difficult. Many state drug pricing transparency laws contain reporting requirements triggered by spikes in drug pricing; however, of the 17 states to consider regulating unconscionable price increases of pharmaceuticals, only Maryland has enacted specific drug price-gouging legislation.²⁷⁶ That legislation, which permitted Maryland to regulate drug prices based on sales from manufacturers to third parties, was struck down as unconstitutional in 2018.²⁷⁷

4.1.4 Direct Pricing Legislation.

Historically, legislation directly regulating the cost of drugs has been limited to those drugs eligible for reimbursement in a federal or state health care program. Medicaid, for instance, requires that a provider of drugs accept Medicaid's reimbursement for a drug at a "best price" rate, which is determined by finding the lowest price available from the manufacturer.²⁷⁸ Medicaid further authorizes the government to solicit and accept rebates from manufacturers to meet those "best prices."²⁷⁹

Maine has also successfully leveraged its "best price" Medicaid purchasing power to induce pharmaceutical manufacturers to provide lower drug prices to Maine consumers. With its program, Maine Rx, the state essentially filled the role of a PBM to Maine residents, and sought rebates from manufacturers that were at least equal to the rebate calculated under a federal program. For those manufacturers that did not enter into the agreement with Maine Rx, the state would publicly post the name of the manufacturer and require that all of its manufactured drugs obtain prior authorization before being reimbursed by Medicaid. Significantly, Maine's program regulated only sales of pharmaceuticals in Maine. The drug industry sued Maine over this initiative, but the United States Supreme Court upheld the program in 2003.²⁸⁰

In 2019, several states, including Maine and Maryland, passed new legislation forming a "Prescription Drug Affordability Board" that seeks to regulate pricing through annual spending targets for prescription drugs in state programs, utilizing new transparency legislation, the power to alter the state's formulary, and direct rebate negotiations.²⁸¹



Other state efforts to directly regulate drug prices have not fared well. As discussed above, Maryland's law was invalidated. Colorado, Florida, Maine, and Vermont have also passed laws that would permit international importation of drugs and their respective lower prices, but such efforts have been met with skepticism because federal approval is required.²⁸²

4.2 Selected Past and Current Law Enforcement Strategies to Address High Drug Prices.

In addition to the legislative efforts to address high drug prices, state and federal law enforcement agencies have also brought numerous law enforcement actions against companies to stop problematic practices that contribute to increased drug prices. Between 1991 and 2017, federal and state agencies have reached a total of 412 settlements, totaling \$38.6 billion dollars, with drug manufacturers.²⁸³ Nonetheless, the \$38.6 billion in penalties represents “only 5% of the \$711 billion in net profits made by the 11 largest global drug companies during just 10 of those 27 years (2003-2012).”²⁸⁴ Further, individual enforcement actions that typically only concern one or a handful of drugs, are a comparatively inefficient way to address this issue, given that the FDA has approved more than 20,000 prescription drugs for sale.

Sometimes the most consequential outcome of law enforcement actions that target problematic drug industry practices is that such litigation prompts policymakers to address the type of conduct at issue in the lawsuit more broadly, generally through legislative or rulemaking efforts. Examples of such actions are discussed at various points throughout this report. One example worth further discussion here, however, is the successful law enforcement campaign to change industry practices regarding how government programs pay for prescription drug coverage, which shifted the payment benchmark used by these programs from the average wholesale price (“AWP”) to the average sales price (“ASP”).²⁸⁵

Under government health programs, AWP served as the pricing benchmark for government reimbursement to health care providers. AWP was supposed to reflect the average price of the drug received by manufacturers. In practice, however, drug manufacturers falsely inflated and set artificially high AWP for their drugs. Such false AWP were “often considerably higher than the actual amount providers pay for drugs because the AWP do not reflect the many discounts drug companies offer providers as an incentive to purchase their products.”²⁸⁶

This AWP-inflation scheme created incentives that could increase drug costs. For example, providers could benefit by prescribing drugs with high “spreads” (the difference between the AWP and actual price providers pay) and drug companies could benefit by offering providers higher spreads through inflated AWP. Despite widespread knowledge and discussion of the problem in the 1990s, Congress did not act to change the pricing system.

At the same time, state and federal prosecutors took up the issue, leading to landmark settlements with Bayer Pharmaceuticals and TAP Pharmaceuticals in 2001. Both settlements were based on the False Claims Act and allegations that the companies reported AWP that were significantly higher than the average sales price offered to providers and further marketed that spread to providers. TAP Pharmaceuticals agreed to pay \$875 million and begin reporting a new pricing benchmark, the average sales price (“ASP”), tied to the actual market price of the drug. Bayer similarly agreed to report the ASP for its drugs. Both companies also agreed to enhanced internal compliance mechanisms and enhanced federal oversight.

These settlements led the way for other litigation by state attorneys general and private groups. They also prompted Congress to adopt the ASP standard, borrowed directly from the definition found in the settlements, for reimbursement rates in the Medicare Part D program.



5. Recommendations of the Minnesota Attorney General's Advisory Task Force on Lowering Pharmaceutical Drug Prices.

In an effort to lower the price of pharmaceutical drugs, the Task Force makes 14 recommendations, all of which contains additional, specific action steps. Each of the Task Force's recommendations stem from presentations or discussion at a working group or task force meeting, or individual suggestions by a Task Force member based on these presentations and discussions. The Task Force's recommendations are to:

- 5.1 create a Prescription Drug Accountability Commission to address drug pricing and related practices in Minnesota;
- 5.2 import through a prime vendor four critical access drugs (insulin, EpiPen, Truvada, and naloxone) on a trial basis, and if successful, expand this importation program
- 5.3 enact legislation prohibiting drug price-gouging;
- 5.4 strengthen Minnesota's consumer fraud laws as they relate to deceptive and misleading practices utilized in the pharmaceutical drug industry;
- 5.5 enact a state anti-kickback law that applies to both government programs and the private sector, including prohibiting copay coupons or equivalent programs when a generic version of the branded drug at issue is available;
- 5.6 amend Minnesota's antitrust laws to prohibit specific, anticompetitive practices long present in the drug industry, such as pay-for-delay settlements and product hopping;
- 5.7 advocate for reform of federal patent and drug exclusivity laws that are being misused and abused to block competition from rival generic drugs;
- 5.8 optimize and expand Minnesota's use of the 340B Drug Pricing Program to make the program's pricing discounts available to more Minnesota patients;
- 5.9 quantify how much all Minnesota government entities spend on prescription drugs, to enable these entities to better pool and utilize their bulk purchasing power to obtain additional pricing concessions from drug manufacturers;
- 5.10 optimize and better utilize Minnesota's bulk purchasing power through MMCAP INFUSE, including by expanding the pricing discounts this buying program receives to all Minnesotans;
- 5.11 more robustly regulate PBMs' business and pricing practices and increase transparency into the rebates they receive, through building on the legislative success of 2019;
- 5.12 enact measures to further increase transparency into how drugs are priced and reimbursed throughout the sales chain;
- 5.13 ensure patient access to pharmacists for effective medication use; and
- 5.14 support additional research into prescription drug pricing and drug benefits.



5.1 Create a “Prescription Drug Accountability Commission” to Oversee Drug-Industry Pricing Practices in Minnesota

Recommendation.

The Task Force recommends that Minnesota establish a Prescription Drug Accountability Commission. The objective of this Prescription Drug Accountability Commission (“Commission”) should be to create a review process to assure that prescription drug and biological drugs are priced reasonably, and that those entities involved in establishing drug prices may be held accountable for their decisions. Although accountability measures can take various forms, the Task Force recommends that the legislature authorize the Commission to investigate, review, and publish information on prescription drug prices, to take action to hold drug companies accountable for unreasonable or unlawful pricing practices, including by “capping” or setting maximum reimbursement prices for drugs under certain circumstances, and to make recommendations for additional legislative, regulatory, or other action necessary to address high drug prices.

Action Steps.

5.1.1 Perform a “drug affordability review” of high drug prices or significant drug price increases that impose an excess cost on Minnesota patients and the state’s healthcare system. Criteria to consider that would trigger a drug affordability review include:

For brand name drug and biological products:

- If the list price for one-month (or normal course of therapy) supply exceeds \$____;
- If the list price changes more than __% at a single point in time; or
- If the list price changes more than __% over a one-year period.

For generic drug and biological products:

- If the list price for one-month (or normal course of therapy) supply exceeds \$____;
- If the list price changes more than __% at a single point in time; or
- If the list price changes more than __% over a one-year period.

For specialty drug and biological products:

- If the list price for one-month (or normal course of therapy) supply exceeds \$____;
- If the list price changes more than __% at a single point in time; or
- If the list price changes more than __% over a one-year period.

For all drug and biological products, if one of the following apply:

- The drug product is in a “protected class” under Medicare Part D;
- Minnesota statutes or rules require coverage of the drug or drug products;
- The drug has a list price that is more than 10% above the evidence-based value assessment price established by the Institute for Clinical and Economic Review;
- The Minnesota Attorney General has designated the drug product pricing as “price-gouging”;
- The FDA or the American Society of Health System Pharmacists has designated the drug product as a “drug shortage”;
- The patent for the drug product’s active ingredient has expired, and the drug product is still protected by one or more other patents or exclusivities;



- g. The drug product is subject to patents or exclusivities on a combination, a change in dosage strength or form, an isomeric configuration, or another “ever greening” strategy after the drug product’s initial active ingredient patent and exclusivities have expired;
- h. The drug product has a Risk Evaluation and Mitigation Strategies (“REMS”) process in place and the REMS process is being used to delay generic entry; and
- i. A biological product has had more than seven years of market exclusivity due to patents, exclusivities, or other reasons.

The Commission should also have the authority to establish other criteria that would trigger an affordability review.

5.1.2 The Commission should require manufacturers to notify it of price changes that meet the criteria above, and the Commission could also commence its own review based on publicly available information.

If the Commission cannot obtain sufficient information from these sources, the Commission should be authorized to compel drug manufacturers, PBMs, and others to provide the necessary data regarding their pricing practices.

5.1.3 If the Commission determines that an affordability review of a drug is warranted, the Commission may require drug companies whose products meet the above criteria to submit price-justification information.

The Commission could then consider whether appropriate utilization of the product under review has led or would lead to excess costs for Minnesota patients or Minnesota’s health care system. The Commission should also review new drugs entering the market to determine price-justification information. The Commission should allow public input into each affordability review it conducts.

5.1.4 To better promote accountability and affordability, the Commission should be authorized to take appropriate actions if it determines that the price of a drug under review has led or would lead to excess costs for Minnesota patients or Minnesota’s health care system.

Among other things, the Commission should be authorized to “cap” or establish a maximum level of reimbursement that would be billed and paid among those in the supply chain; to identify a rebate for drugs covered by public payers in Minnesota; and to determine methods for public payers to meet spending targets. If after the affordability review, the Commission determines that a drug’s price or price increase is unreasonable or otherwise unlawful, it should refer the matter to the Minnesota Attorney General’s Office for potential prosecution, in addition to other action the Commission is authorized to take on its own accord.

5.1.5 In crafting this legislation, the legislature should review and draw from Task Force Co-Chair Senator Jensen’s Senate File 353 (91st Leg. 2019-20) bill, model legislation introduced by the National Academy for State Health Policy (“NASHP”),²⁸⁷ and similar drug pricing legislation introduced in other states such as Illinois, Maryland, Maine, Massachusetts, Missouri, New Jersey, and Oregon.²⁸⁸

The Oregon and Texas legislation, in particular, provide examples of legislation that enables state agencies to undertake pricing reviews. SF353, the NASHP model legislation, and Maryland’s legislation also provide examples of reimbursement capping, while bills in Maine and Massachusetts address public payers.



Responsible Persons/Entities.

Legislature would enact laws establishing the Prescription Drug Accountability Commission and defining its role. Subsequently, the Governor's Office and other stakeholders would appoint members to the Commission. The Minnesota Attorney General's Office would review and bring enforcement actions referred to it by the Commission under the law, as appropriate, including to enforce any action by the Commission to "cap" or set maximum reimbursement rates.

5.2 Import Critical-Access Drugs Into the State on a Trial Basis.

Recommendation.

The Task Force recommends that Minnesota develop a new channel to import and distribute of four critical access drugs—insulin, EpiPen, Truvada, and naloxone—through a prime vendor on a trial basis. These drugs should be imported for use in Minnesota at affordable prices that are consistent with the global market rates for these four pharmaceuticals. As Minnesota learns from its experience importing these critical access drugs, it can refine the importation process and eventually expand the importation program, if feasible. This importation process would not involve direct purchase or acquisition of prescription drugs by Minnesota patients through the internet or similar avenues.

Action Steps.

- 5.2.1 Pursuant to the recently-established federal Safe Importation Action Plan²⁸⁹ and 21 U.S.C. § 384, Minnesota should approach HHS and the FDA to develop and receive approval of policies, processes, and procedures for the importation and distribution of insulin, EpiPen, Truvada, and naloxone in the state through a prime vendor.**
- 5.2.2 Minnesota should then issue a request for proposal soliciting bids from the prime vendor that will identify safe and feasible sources for each of these critical access drugs and negotiate the price of the drug with appropriately licensed manufacturers and/or distributors.**

Concurrently, Minnesota should design and establish appropriate roles within the state for the entities involved in the importation process, such as establishing a regulator, financier, and/or distributor to work with the prime vendor selected to import these critical access drugs and ensure their availability at Minnesota pharmacies and other health care providers.
- 5.2.3 Within 24 months of implementing this importation channel for insulin, EpiPen, Truvada, and naloxone, Minnesota should evaluate and assess the effectiveness of this process. If it is found effective, it should be expanded to include additional drugs.**
- 5.2.4 The Legislature should pass any legislation needed to facilitate and support the importation of high-quality drug products at negotiated and affordable prices for distribution in Minnesota through this process.**



Responsible Persons/Entities.

The Governor's Office should select members of the Minnesota Department of Health and the Minnesota Department of Human Services to be included as part of an interagency working group to develop, in consultation with the relevant federal agencies, a satisfactory importation plan for insulin, EpiPen, Truvada, and naloxone. In addition, one or more representatives of the Minnesota Attorney General's Office should serve on the working group. The Legislature should enact appropriate legislation to facilitate and fund this initiative.

5.3 Enact Legislation Defining and Prohibiting Price-gouging Related to Prescription Drugs.

Recommendation.

As described throughout this report, some prescription drug manufacturers engage in a number of pricing practices that have resulted in skyrocketing costs for certain drugs, with prices sometimes increasing by 300-500% or more. The purpose of an anti-price gouging statute is to prevent and deter drug manufacturers from engaging in price-gouging practices for essential prescription drugs that are made available in Minnesota.

Action Steps.

5.3.1 **An anti-price gouging statute should prohibit drug manufacturers from charging or causing to be charged an unconscionable price—that is, a price that cannot be reasonably justified—for essential prescription drugs that are sold in Minnesota.**

Representative Lesch, a member of the Task Force, authored and introduced such a bill—House File 4 (91st Leg. 2019-20)—last legislative session. The statute should further provide for a notice mechanism to the Attorney General, such as the mechanism provided for in House File 4,²⁹⁰ for any unconscionable prescription drug price increases. Additionally, any such bill should be carefully crafted and reviewed so as to be able to survive any constitutional challenge from the drug industry.

Responsible Entities/Persons.

The legislature would enact an anti-price gouging statute of the nature described above. Once enacted, the Minnesota Attorney General's Office would enforce this statute by, among other things, reviewing reported price increases and bringing enforcement actions referred to it, as appropriate, to deter and remediate price-gouging practices within the state.



5.4 Strengthen Deceptive Trade Practices and Advertising Laws Related to Drug Pricing Information.

Recommendation.

Minnesota's consumer fraud and deceptive trade practices laws²⁹¹ generally prohibit fraudulent, deceptive, and misleading conduct, including with respect to prescription drugs. These laws, however, do not contain an "unfair" or "unconscionability" prong, as do equivalent laws in many other states,²⁹² prohibiting unfair or unconscionable conduct. These laws also do not address specific deceptive and misleading practices found in the drug industry. The Task Force recommends that the legislature reform and strengthen Minnesota's consumer protection laws in both of these manners.

Action Steps.

- 5.4.1 "Unfair" and "unconscionability" prongs should be added to Minnesota consumer-protection laws to allow the Attorney General's Office to take legal action against unconscionable pricing and other unfair business practices, including unconscionable drug-pricing practices.**
- 5.4.2 Review, define, and update the statutory text of Minnesota's consumer protection statutes by specifically addressing deceptive and misleading practices that relate to prescription drugs and their pricing, including by:**
- specifically prohibiting deceptive marketing practices that disclose only the copay amount for a drug without also disclosing the list price of the drug for a standard course of therapy;
 - specifically prohibiting deceptive marketing practices that represent the price of a drug is "90% off," for example, after a copay coupon, patient assistance program, or similar program is taken into account, which do not reflect what third-party payers (e.g., health plans) actually pay for the drug;
 - specifically prohibit deceptively marketing drug benefit programs that disclose only the copay amount, the plan paid amount, and the patient out-of-pocket amount, versus the total price of the drug.
- 5.4.3 More closely monitor and engage in additional enforcement actions to prevent and deter deceptive and misleading pricing practices used in the drug industry, including by giving private litigants the authority to do so directly when they have been harmed by such practices.**

Responsible Persons/Entities.

Legislature would amend and strengthen Minnesota's consumer-protection laws in the manners described above. The Minnesota Attorney General's Office, as well as injured Minnesotans, would enforce these laws, once amended.



5.5 Enact a State Anti-Kickback Law, and Prohibit Copay Coupons and Similar Practices When a Generic Version of a Drug is Available.

Recommendation.

The Task Force recommends that the legislature pass a state anti-kickback bill into law. The objective of this law should be to empower Minnesota enforcers to take action against behavior that is already illegal on a federal level²⁹³ by giving local law enforcement agencies, including the Minnesota Attorney General's Office, an additional tool to curb problematic practices in the drug industry.²⁹⁴

Action Steps.

5.5.1 **This anti-kickback statute should encompass kickbacks in the private marketplace, not just with respect to drugs paid for by state health care programs.**

As currently written, the federal anti-kickback statute prohibits illegal remuneration only if money is expended by government health programs, such as Medicare and Medicaid. The Task Force recommends that private payers, including private citizens, be protected from kickback-type behavior to the same degree as is the government.

The Task Force also recommends Minnesota enact a statute prohibiting copay coupons and equivalent financial inducements regarding branded drugs when a generic equivalent to the branded drug exists, as it views such financial inducements to use a branded drug in these circumstances as a form of a kickback. As discussed above,²⁹⁵ while the copay coupon may result in a lower up-front cost to a patient, that patient's insurance premium may rise as a result of the increased costs to the health plan of paying for the more expensive branded drug, resulting in a higher overall cost to the patient.

5.5.2 **Even when a copay coupon is offered for a branded drug for which no generic exists, Minnesota law should require patients to be told if there is a time limit on the copay coupon when it is first offered to the patient, and manufacturers should be required to provide patients sufficient advanced warning if they will no longer be eligible or otherwise able to use the coupon in the future, among other disclosures.**

Responsible Entities/Persons.

Legislature would enact a state anti-kickback statute of the nature described above, as well as statute prohibiting copay coupons and equivalent financial inducements when an equivalent generic drug is available. The Minnesota Attorney General's Office would enforce these statutes, once enacted.



5.6 Strengthen Laws Targeting Anticompetitive Behavior in the Drug Industry.

Recommendation.

Because the market for drugs is so complex, opaque, and often does not function in a competitive manner for the reasons discussed throughout this report,²⁹⁶ competition-focused solutions will only go part of the way towards addressing high drug prices. Nevertheless, they are important. While the anticompetitive conduct described in this report is extremely problematic, it is not easy and often resource-intensive to address using Minnesota's current antitrust laws, which speak in terms of broad standards, not specific practices.²⁹⁷ Changing these laws to make certain anticompetitive conduct in the drug industry explicitly illegal would greatly aid enforcement. The Task Force thus recommends that specific provisions be added to Minnesota's antitrust law rendering certain anticompetitive practices that exist in the drug industry as "per se" unlawful, including pay-for-delay and product hopping arrangements.

Action Steps.

5.6.1 To deter pay-for-delay schemes, Minnesota should amend its antitrust laws by adopting a provision similar to one recently enacted by California, which renders these arrangements presumptively unlawful.²⁹⁸

Because the bill establishes the presumption that pay-for-delay agreements are anticompetitive, it shifts the burden to drug manufacturers to prove that these type of agreements foster competition and increase access to affordable drugs in the marketplace.

5.6.2 To deter product-hopping schemes, Minnesota should amend its antitrust laws to also render these schemes presumptively unlawful.

In drafting such statutory language, guidance can be drawn from New York *ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015), which discusses circumstances that render product-hopping arrangements anticompetitive.

5.6.3 Pay-for-delay schemes and product-hopping arrangements should be added to Minnesota Statutes section 325D.53, which currently lists several specific behaviors— unrelated to the drug industry—that are per se unlawful.

5.6.4 Federal and state regulators should increase enforcement resources dedicated to reviewing mergers in the drug industry, and blocking those that are anticompetitive.

The question of how to slow corporate consolidation in the drug industry is broad and multifaceted. At the federal level, the U.S. Department of Justice and Federal Trade Commission review all large mergers. State attorneys general may also sue to prevent these mergers. Specific statutes governing drug-industry mergers may also be necessary.²⁹⁹

Responsible Persons/Entities. Legislature would enact the additional statutory subsections needed to address pay-for-delay arrangements and product hopping. The Minnesota Attorney General's Office would enforce these statutes, once enacted, as well as increase its enforcement activities with respect to policing drug-industry mergers.



5.7 Advocate for Reform of Certain Federal Patent and Exclusivity Laws Governing the Drug Industry.

Recommendation.

The Task Force recommends that Congress enact legislation to curb misuse and abuse of the patent and FDA drug exclusivity laws. Regarding patent laws, new legislation should be enacted to address patent thickets and “evergreening” of patents, such as modifying the current patent standards with respect to drugs to make it more difficult for minor changes that offer only trivial improvements to be the basis to secure new patent rights for a drug. The U.S. Patent and Trademark Office should also more closely scrutinize non-“new chemical” patents to prevent these type of practices, and more frequently refuse to grant a patent if the applicant simply makes an obvious improvement on an existing patent.

Action Steps.

5.7.1 Congress should reform federal patent laws by:

- a. Raising the standard for obtaining a patent on prescription drugs;
- b. Giving the FDA more authority to scrutinize which patents appear in the Orange Book;
- c. allowing for the removal of patents from the Orange Book that are later invalidated;
- d. requiring drug makers to elect a single period of market exclusivity—whether that be through a patent right, an FDA exclusivity, or other regulatory provision—so that multiple exclusivity periods could not be stacked;
- e. making it easier for generic drug makers to obtain samples of branded drugs needed for testing; and
- f. deeming REMS non-patentable.

5.7.2 Minnesota’s congressional delegation should propose and/or endorse these and other measures designed to eliminate drug companies’ misuse of patent laws.

5.7.3 Congress should also ensure that the U.S. Patent and Trademark Office has adequate resources to meaningfully review patents prior to the patent being granted.

5.7.4 Congress should continue to study means to combat drug manufacturers’ abuse of patent laws, including considering whether to create different standards for drug patents, deem certain subject matters non-patentable, or prevent stacking of patent terms, to ensure that patent laws promote innovation and patient health without increasing health care costs.

Regarding exclusivity laws, proposed legislation already exists that would combat misuse of FDA exclusivities. The “Improving Access to Affordable Prescription Drugs Act”³⁰⁰ would, among other things, allow the FDA to consider a generic drug manufacturer’s application to market a generic of a brand name drug that is covered by the “new chemical” exclusivity after three years instead of the current five, shorten the regulatory exclusivity of biologics from 12 years to 7 years, add additional requirements before branded-drug manufacturers could gain the three-year clinical investigation exclusivity, and would terminate all FDA exclusivities for a drug if the manufacturer engaged in certain wrongful acts, including misbranding, illegally marketing the drug, or entering into an anticompetitive settlement of a patent lawsuit.



- 5.7.5 **Congress should reform federal exclusivity laws by passing the Improving Access to Affordable Prescription Drugs Act.**
- 5.7.6 **Minnesota's federal congressional delegation should propose and/or endorse this act and other measures designed to eliminate drug companies' misuse of exclusivity laws.**
- 5.7.7 **Congress should continue to study means to combat drug manufacturers' abuse of FDA exclusivities, including considering whether to eliminate certain exclusivities, shortening exclusivity lengths, and adding additional requirements to ensure that exclusivities promote innovation and patient health without increasing health care costs.**

Responsible Persons/Entities.

Congress has the power to amend current patent and exclusivity laws. The entirety of Minnesota's federal Congressional delegation should introduce and/or sign on as co-authors to such legislation. The Minnesota Attorney General's Office should be a public champion for the reform of federal patent and exclusivity laws.

5.8 Optimize and Expand Use of the 340B Drug Pricing Program.

Recommendation.

Because of the significantly reduced prices that drug manufacturers are required to charge through the 340B Drug Pricing Program ("340B Program"), the Task Force recommends that Minnesota develop strategies and take actions to expand and optimize participation in —and use of— the 340B Program in the state, in government healthcare programs and the private market. This expansion and optimization of drugs procured through the 340B Program should include both self-administered drugs and physician-administered drugs.

Action Steps.

- 5.8.1 **A designated agency should perform and publish an inventory of all health care providers in the state to identify whether they are eligible for—and participating in—the 340B Program.**

This list could be used to identify any additional entities eligible for, but not enrolled in, the program and encourage them to join.

- 5.8.2 **Minnesota should develop and fund strategies to increase the participation of eligible entities in the 340B Program.**

Often times, eligible entities may choose not to enroll in the 340B Program due to the burden of maintaining records that document their compliance with all program requirements, or for other reasons.³⁰¹ This means some eligible entities are not receiving the benefit of being able to procure drugs at significantly reduced prices.



5.8.3 Minnesota should establish a technical assistance program to assist eligible entities with enrollment, implementation, and compliance with the 340B Program requirements.

The technical assistance program would encourage all eligible entities, even non-governmental entities, to effectively participate in and utilize the 340B Program. The technical assistance program would also clarify the eligibility criteria for participation in the program.

5.8.4 Regulatory changes should be enacted to require entities sharing in 340B Program drug pricing discounts to pass on a significant portion, if not all, of these savings directly to patients.

There are currently no regulations that require participating entities to pass the 340B Program savings on to patients in any particular manner.

5.8.5 As necessary and appropriate, legislation should be developed and enacted to facilitate and support the participation of Minnesota government and non-governmental entities in the 340B Program.

Responsible Persons/Entities.

As the primary regulator of health care providers in Minnesota, the Minnesota Department of Health should take the lead expanding and optimizing Minnesota's use of the 340B Program, with the support and assistance of the Governor's Office. To the extent any statutory changes are needed to facilitate additional entities participating in the 340B Program and ensure that drug savings obtained through the program are passed along to patients, this would be the responsibility of the legislature.

5.9 Create An Inventory of All Government Entities to Determine Whether They Purchase Drugs Directly or Indirectly, and Identify Their Annual Expenditures.

Recommendation.

The Task Force recommends that Minnesota survey, identify, and catalog what it spends on prescription drugs in the aggregate, including at the county and municipal level. The objective of this initiative is to better understand and quantify the total drug expenditures of Minnesota governmental entities, and to track these trends over time. To fully leverage its buying power—as discussed further in the next recommendation regarding MMCAP INFUSE—Minnesota needs to better collect and evaluate the current expenditures of state, county, and local entities on prescription drugs.

Actions Steps.

5.9.1 Create a survey in which the relevant Minnesota government entities identify their expenditures, both direct and indirect, on prescription drugs.

To ensure a complete picture of expenditures, this survey should seek drug spending data on self-administered drugs purchased from manufacturers, wholesalers, or pharmacies, as well as physician-administered drugs used in a medical setting. Entity profiles could be compared with nationwide community pharmacy purchasing information contained in National Average Drug Acquisition Cost profiles to ensure best pricing practices for purchasers.



- 5.9.2 **Minnesota should distribute this survey to all state, county, and municipal government entities on an annual basis.**
- 5.9.3 **Minnesota should utilize a centralized entity to collect and evaluate the survey responses on an annual basis and provide a report on the results to the participating government entities and the public, including an analysis of trends over time.**
- 5.9.4 **As necessary and appropriate, legislation should be developed and enacted to facilitate and support this survey process and ensure that all Minnesota government entities are able to provide the requested data.**

Responsible Persons/Entities.

The Governor’s Office is best positioned to coordinate the distribution, collection, and evaluation of survey responses from all relevant Minnesota government entities. The Governor’s Office should be assisted by both the Minnesota Department of Health and/or the Minnesota Department of Human Services, as they license many facilities that provide health care in the state, as well as other state agencies that oversee entities that purchase prescription drugs. The Legislature would enact any statutory changes needed to facilitate this survey process.

5.10 Optimize Use of MMCAP INFUSE Program and Further Expand It to Provide Similar Savings to Minnesota Patients.

Recommendation.

Pooled cooperative purchasing can be leveraged to extract lower prices from drug companies. Building on the recommendation to better quantify how much Minnesota spends on drugs, the Task Force recommends that Minnesota develop strategies and take action to expand and optimize participation by Minnesota government entities in the buying cooperative MMCAP INFUSE, the program that currently pools and leverage such buying power for the benefit of participating entities when purchasing drugs.³⁰² In addition, MMCAP INFUSE should be expanded to allow non-governmental Minnesota purchasers, i.e., private patients, to take advantage of the reduced pricing on prescription drugs the program achieves. In the alternative, a parallel program should be established to do so. An example of such a program is the Northwest Prescription Drug Consortium.³⁰³

Actions Steps.

- 5.10.1 **Accordingly, a survey should be conducted of all Minnesota government entities—state, county, and municipal—to identify whether they participate in the MMCAP INFUSE program, the level of their participation, and the reasons they do or do not participate in the program.**
MMCAP INFUSE’s expansion to serve additional Minnesota governmental entities requires that MMCAP INFUSE be aware of Minnesota governmental entities that are either not participating, or have only limited participation in the program.
- 5.10.2 **Based on this survey, strategies to increase the participation of Minnesota government and other entities in MMCAP INFUSE should be developed and implemented.**³⁰⁴



5.10.3 Regulatory and statutory changes should be implemented to facilitate and encourage the participation of Minnesota government and other entities in MMCAP INFUSE, including as follows:

- a. At present, many different statutes give many different government entities their own procurement power, which results in disaggregating buying power, instead of all purchasers buying drugs through MMCAP INFUSE. With respect to prescription drug purchases, the Legislature should amend the relevant procurement statutes to require Minnesota governmental agencies to consider MMCAP INFUSE's contracting first, before signing a procurement contract with a drug manufacturer or wholesaler directly, which is likely to be more expensive
- b. The Legislature should also consider consolidating statutes that give different government entities their own, separate procurement power, including with respect to drugs, into one statutory scheme;
- c. The Governor's Office should direct relevant state agencies to amend any procurement policies that inhibit participation in MMCAP INFUSE, as necessary, to ensure such policies and rules do not inhibit purchasing drugs through MMCAP INFUSE;

5.10.4 Expand MMCAP INFUSE and leverage its purchasing power to lower drug prices for Minnesota private patients.

MMCAP INFUSE's clientele is currently restricted by Minnesota statute to governmental entities and certain non-profit organizations.³⁰⁵ MMCAP INFUSE's current model erects barriers to the creation of a prescription drug card program that Minnesota residents can use at privately-run pharmacies. Although less desirable than expanding MMCAP INFUSE because it disaggregates purchasing power, creating a parallel buying program for the benefit of Minnesota private patients, or joining the Northwest Prescription Drug Consortium, should be considered as an alternative.

Responsible Persons/Entities.

Any changes to administrative regulations or policies that inhibit optimization of MMCAP INFUSE as currently structured would be changed by the relevant state agency, as overseen by the Governor's Office. The Minnesota Department of Administration, as the operator of MMCAP INFUSE, should inventory what other state, county, and local government entities are currently eligible to use the program, and foster additional use of MMCAP INFUSE by those entities that do not currently rely on it. The Department of Administration should also take the lead in expanding the program to private Minnesota residents, or establishing a parallel program for their use. The Legislature would pass statutory changes optimizing and/or expanding MMCAP INFUSE.



5.11 Minnesota Should Robustly Regulate PBMs and Their Business Practices, Building on the PBM Legislation Enacted in 2019.

Recommendation.

In 2019, Minnesota enacted legislation regulating PBMs. See 2019 Minn. Laws ch. 39 (to be codified at Minn. Stat. ch. 62W). While a good first step, the Task Force recommends that this law should be strengthened to better address problematic PBM business practices, including the opaqueness of their business model, and that the Minnesota Department of Commerce (“Commerce”), who will administer this law, robustly use its rulemaking and other authority granted by the law to ensure proper oversight of, and transparency into, the operations of PBMs in Minnesota.

Action Steps.

5.11.1 Section 62W.06 should be amended to require public disclosure of the pricing information referenced in this statute

Currently, disclosure is required only to a health-plan client on request, or to the Department of Commerce as part of a transparency report of which portions will be non-public.

5.11.2 Commerce should promptly implement the provisions of the PBM law, including engaging in robust rulemaking necessary to appropriately regulate PBMs;

5.11.3 Commerce should develop a financial indicator for PBMs that is the equivalent of the medical loss ratio for health plans. It should reflect the proportion of PBMs’ revenue that is used to provide drug benefits to health plan enrollees, versus the proportion used for administrative costs, profits, and other purposes.

5.11.4 Commerce should annually report, on a dedicated and easily-accessible website, on the following activities and practices of PBMs that operate in Minnesota:

- a. the number of PBMs licensed each year in Minnesota;
- b. the number and nature of any complaints it has received that a PBM has engaged in fraudulent activity or conduct that fails to comply with the requirements of Minn. Stat. § 62W;
- c. the number of PBMs that have been alleged to, or found to, not “exercise good faith and fairdealing in the performance of its contractual duties.” See Minn. Stat. § 62W.04.
- d. the network adequacy of all PBMs, and the methods used to determine network adequacy for each PBM;
- e. a quantitative summary of the provisions and requirements related to transparency of rebates, discounts, fees, and list prices of all licensed PBMs in a manner that allows comparability among PBMs operating in Minnesota (see Minn. Stat. § 62W.06);



- f. the pharmacy ownership status of pharmacies that contract with each PBM, see Minn. Stat. § 62W.07, and pharmacies in the network of each PBM, including but not limited to the number and percent of network pharmacies owned by the PBM, the ownership of any mail-order pharmacies, and specialty pharmacies used by the PBM;
- g. the number of Maximum Allowable Pricing lists used by each PBM for Minnesota health plans, (see Minn. Stat. § 62W.08); and
- h. any other provisions of chapter 62W that demonstrate the intended impact of the results and outcomes these statutes were meant to bring about, as well as any significant unintended consequences.

Responsible Persons/Entities.

The Minnesota Department of Commerce will be responsible for regulating PBMs, publicly reporting data on their practices, and administrative rulemaking, pursuant to chapter 62W. It would be the responsibility of the legislature to amend and strengthen Chapter 62W, including its transparency-promoting provisions.

5.12 Minnesota Should Encourage and Facilitate Price Transparency for Prescription Drugs.

Recommendation.

The Task Force believes additional pricing transparency is a necessary—but not a sufficient—measure required to address the high cost of prescription drugs. Accordingly, the Task Force recommends that Minnesota enact legislation to promote transparency into prescription drug prices. The objective of the legislation should be to establish a process to make transparent the actual, net price of critical and high visibility drugs in Minnesota. The information gathered through this process should be easily accessible to the public through a dedicated and easily-accessible website.

Action Steps.

5.12.1 Identify a list of critical and/or high-visibility drugs in Minnesota.

Such drugs may include: drugs advertised on television; drugs for which the pricing practices have been found to be price-gouging, as defined by the price-gouging statute the Task Force recommends be enacted; drugs in a “protected class” of drugs under Medicare Part D; drugs for which Minnesota statutes and rules require coverage; drugs above a certain price threshold for a course of therapy; drugs known to have copay coupons or that are subsidized through a patient assistance program when a generic equivalent is available; and drugs which are highlighted in the public media. The Legislature should also empower the entity compiling this list to establish other criteria for inclusion on the list, which should be published on a regular basis.



5.12.2 For the drugs that have been identified as critical and/or high-visibility drugs in Minnesota, develop a means to determine the current or recent actual, net price per course of therapy of the drugs, including through the ability to compel the production of this pricing information, if necessary.

Once this is accomplished, establish a process to publish the list of the drugs, and the prices of such drugs, online. The list should be updated at least quarterly.

5.12.3 The published information should also contain household economic information, including but not limited to the poverty level for an individual or a family, Social Security income, personal income, household income, and state and national gross domestic product.

Such information should assist the public in determining the affordability of drugs.³⁰⁶

5.12.4 As necessary and appropriate, legislation should be developed and enacted to facilitate and support this transparency-related initiative.

Responsible Persons/Entities.

The Legislature would enact any appropriate legislation. Once law, the Minnesota Department of Health would administer this process.

5.13 Assure Patient Access To Pharmacists' Services for Effective Medication Use.

Recommendation.

The Task Force recommends that Minnesota take additional steps to assure that all Minnesotans have access to a pharmacist in their local communities who can collaborate with other healthcare providers to facilitate safe, effective, efficient, and optimal medication use.

Action Steps.

5.13.1 Minnesota should promote policies aimed at preventing pharmacy closures in rural and other underserved areas.

The closing of independent and other pharmacies in greater Minnesota and other non-urban areas throughout the country has rightfully been met with concern. Such pharmacy closures contribute to nonadherence of prescription medications, among other negative effects on patient outcomes. The elderly, in particular, are at high risk as a result of such pharmacy closures, due to their high rates of prescription medication use, concerns over drug interactions, their greater likelihood of experiencing transportation problems, and often limited financial resources. One possibility to consider is whether a program similar to the one designed to support "critical access hospitals,"³⁰⁷ which generally serve rural areas, would be appropriate to support "critical access pharmacies."



5.13.2 Expand the use of Medication Therapy Management (“MTM”) to control drug costs.

MTM services provided by healthcare professionals, including pharmacists, to review and optimize therapy regimens for patients. They are especially effective for patients with chronic conditions, complex medication therapies, high drug costs, and those with multiple prescribers.³⁰⁸ The additional use of MTM to control drug costs should include optimizing use of this practice in Medicare, Medicaid/Medical Assistance, MinnesotaCare, and commercial health plans.

5.13.3 Encourage and promote collaborative practice agreements (“CPAs”) to foster better patient outcomes with prescription drugs.

Minnesota already permits CPAs,³⁰⁹ which define certain patient care functions that a pharmacist can autonomously provide, including optimization of drug therapies. Pharmacists are well-positioned to perform medication and wellness interventions that improve patient outcomes and these should be encouraged and promoted to foster better patient outcomes with respect to prescription drugs.

5.13.4 Encourage “academic detailing” to improve prescribing practices of targeted drugs.

“Academic detailing” is educational outreach to prescribers by other, independent health-care professionals who are unconnected to the drug industry. Offering physicians current research and evidence-based information provides them the opportunity to make informed clinical decisions regarding medication effectiveness, safety, and cost of therapy. The growth and success stemming from this process shows that physician prescribing can be changed without regulatory involvement.

5.13.5 Provide sufficient resources to ensure successful implementation of Minnesota’s recently-passed drug repository program³¹⁰ and to engage in a public awareness campaign to ensure that patients (and authorized subscribers) are aware of the benefits of the program.

This program provides that prescription drugs, in their original, sealed, unopened, tamper-evident packaging, may be saved by defined donor patients upon discontinued use of the medication or supply. These unused drugs or supplies become available for use by other eligible individuals, who may not otherwise be able to have access to the drug.

Responsible Persons/Entities.

The Minnesota Board of Pharmacy, as the primary regulator of the practice of pharmacy in the state, should take the lead in implementing the recommendations in this section. The Legislature should pass any funding or statutory changes needed.



5.14 Support More Research on Prescription Drug Prices & Drug Benefits.

Recommendation.

In 2017, Minnesotans spent nearly \$8.7 billion on prescription drugs in retail and medical settings.³¹¹ Despite this spending making up a significant share of the state's economy, Minnesota does not currently have a dedicated government agency or unit responsible for studying the trends and policies of the drug industry, including with respect to its pricing practices. The Task Force recommends that additional resources be devoted to such research.

Action Steps.

- 5.14.1 Minnesota should support additional research on inter-professional collaboration among healthcare providers who work in conjunction with one another to prescribe drugs to their patients and how this can be used to reduce drug costs.**
- 5.14.2 Minnesota should support additional research related to understanding how drug product discoveries and subsequent commercialization are funded, including how much funding provided to public entities—for example, public universities, government agencies, etc.—underlies the discovery, development, and commercialization of new prescription drugs.**
- 5.14.3 Minnesota should support additional research related to the use of pharmacogenomics in clinical practice, and how this method of personalized medicine may be used as a cost saving tool for individual patients and the state.**
- 5.14.4 Minnesota should support additional research related to broadly examining drug pricing, including the lack of transparency of prices, how drug costs impact Minnesotans, and exactly how much the state expends in prescription drug costs (most of which has been discussed in more depth in previous recommendations).**
Minnesota should also support additional research to track changes in drug-pricing policies implemented in the state and how these policies have affected drug spending.
- 5.14.5 Minnesota should support additional research related to the continued role of PBMs in the drug sales chain, including whether they should be subject to further regulation beyond what the Task Force had recommended above.**

Responsible Persons/Entities.

The Legislature should provide the Minnesota Department of Health with resources sufficient to initiate and conduct this research.



Conclusion and Next Steps



The Task Force considers this report as only a first step among many needed to lower skyrocketing pharmaceutical-drug prices. It will be up to lawmakers—and state and federal agencies with the administrative rulemaking authority—to implement some of the above recommendations. It will be up to the Minnesota Attorney General's Office and other law enforcers to re-double their efforts to police unlawful practices in the drug industry, under both existing law and any new legal tools implemented as a result of this report. It will be up to advocates to ensure the spotlight remains on the often life-or-death issue of lowering the exorbitant cost of prescription medications. The Task Force, with the assistance of the Minnesota Attorney General's Office, intends to be at the forefront of efforts to ensure the recommendations contained in this report are turned into policies that lower the cost of prescription medications for all Minnesotans.



Glossary of Terms

Acronym	Term
API supplier	active pharmaceutical ingredient manufacturer
ANDA	abbreviated new drug application
ASP	average sale price
AWP	average wholesale price
CDC	Centers for Disease Control
CMS	Centers for Medicare and Medicaid Services
CPA	collaborative practice agreements
CPI	consumer price index
DHS	Minnesota Department of Human Services
DIR fees	direct and indirect remuneration fees
FDA	Food & Drug Administration
FQHC	federally qualified health center
GPO	group purchasing organization
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
KFF	Kaiser Family Foundation
MAC	maximum allowable cost
MDH	Minnesota Department of Health
MTM	medication therapy management
NDA	new drug application
PAD	physician administered drug
PAP	patient assistance program
PBM	pharmacy benefit manager
REMS protocol	Risk Evaluation and Mitigation Strategy protocol
SAD	self-administered drug
WAC	wholesale acquisition cost



Committee Members

Co-Chair Nicole Smith-Holt.

Ms. Holt serves as a patient advocate on the Task Force. Ms. Holt tragically lost her 26-year-old son because he was unable to pay for the insulin he needed to treat his diabetes. She has since become a national leader in the fight to make insulin affordable for all diabetics.

Co-Chair Senator Scott Jensen, MD.

Senator Jensen is a legislative member of the Task Force. He is a practicing family physician who also represents Minnesota Senate District 47. Senator Jensen is the lead author of SF353 (91st Leg. 2019-20), the Prescription Drug Affordability Act. Senator Jensen was also the lead author of a recently-enacted law requiring the licensure of and regulating pharmacy benefit managers, better known as “PBMs.” See 2019 Minn. Laws ch. 39.

Elo Alston.

Mr. Alston serves as a patient advocate on the Task Force. He has been a type 1 diabetic for over 30 years. Mr. Alston has firsthand experience with the challenges faced by patients who require life-saving drugs, but lack medical insurance.

Jessica Braun, RN, APRN-CNP.

Ms. Braun is a medical practitioner representative on the Task Force. She is a family nurse practitioner with over 10 years of experience in a variety of health care settings including college health, acute care, chronic pain management, and family practice.

Nazie Eftekhari.

Ms. Eftekhari is a health insurance industry representative on the Task Force. She is the CEO and principal architect of HealthEZ, a Minneapolis-based company that provides services designed to simplify health-plan administration for employers, consumers, health care providers, and insurers.

Representative Rod Hamilton.

Representative Hamilton is a legislative member of the Task Force. He represents Minnesota House District 22B. Representative Hamilton has been a multiple sclerosis patient since 1994, giving him firsthand experience managing the rising costs of necessary prescription drugs. He is the co-author of multiple bills intended to make pharmaceutical-drug pricing more transparent.

Phu Huynh, PharmD, RPh.

Dr. Huynh is a small, independent pharmacy representative on the Task Force. He is a pharmacist and a pharmacy manager at NorthPoint Medical Clinic, where he has managed all operational aspects of this independent clinic and pharmacy for more than eight years. Through this experience, he has witnessed the impact on underserved patient populations of skyrocketing drug costs.



Christy Kuehn.

Ms. Kuehn serves as a patient advocate on the Task Force. Her husband suffers from type 1 diabetes and requires insulin, which costs their family more than \$2,200 a month. She has experience managing a family budget in the face of rising drug prices, which has led her husband to ration his insulin by taking half doses.

Shirlynn LaChapelle, RN, APN, SNP.

Ms. LaChapelle serves as a patient advocate on the Task Force. She has been working in healthcare as a Surgical Nurse Practitioner since 1976. Ms. LaChapelle has served as the president of the Minnesota Black Nurses Association, where she organized a number of outreach activities around the metro area to improve health outcomes in underserved communities. Ms. LaChapelle is the owner of Nursing is the Answer LLC, and is currently completing her Psychiatric Mental Health Nurse Practitioner Program.

Representative John Lesch.

Representative Lesch is a legislative member of the Task Force. He represents Minnesota House District 66B. He is chair of the House Judiciary Finance and Civil Law Division and the lead author of HF4 (2019-20), a bill to prohibit price-gouging on prescription drugs and rein in skyrocketing drug prices.

Senator Matt Little.

Senator Little is a legislative member of the Task Force. He represents Minnesota Senate District 58. Senator Little has introduced numerous bills aimed at increasing transparency and curbing high drug prices. He is also a co-author of SF472 (2019-20), The Alec Smith Emergency Insulin Act, which is named after Task Force Co-Chair Nicole Smith-Holt's son.

Rose Roach.

Ms. Roach serves as a patient advocate on the Task Force. She has served as the executive director of Minnesota Nurses Association since October 2014. Before joining Minnesota Nurses Association, Ms. Roach spent 25 years advocating for high-quality healthcare in Minnesota and California.

Stephen Schondelmeyer, PharmD, PhD.

Dr. Schondelmeyer serves as a pharmaceutical industry academic on the Task Force. He is a nationally-recognized expert in pharmaceuticals. He is a professor of pharmaceutical economics and an Endowed Chair in Pharmaceutical Management & Economics and Professor & Director of the PRIME Institute with the College of Pharmacy at the University of Minnesota, which focuses on pharmaceutical research related to management and economics.

Leonard Snellman, MD.

Dr. Snellman is a medical practitioner representative on the Task Force. He has been a pediatrician since 1985. He has served on the Pharmacy and Therapeutics Committee of HealthPartners since 1986, and is currently the chair of the Pharmacy and Therapeutics Committee for Children's Hospitals and Clinics of Minnesota, where he reviews new and existing medications and the role they play in the therapeutic regimen of patients.

Cody Wiberg, PharmD, RPh.

Dr. Wiberg is the executive director of the Minnesota Board of Pharmacy. Prior to joining the board he was the Pharmacy Program Manager for the Minnesota Department of Human Services. Dr. Wiberg is also a Clinical Assistant Professor for the University of Minnesota College of Pharmacy and an Affiliate Clinical Instructor and Course Director for the University of Florida Graduate School.



Endnotes

- 1 Although not official members of the Task Force, Representative Robert Bierman (House District 57A) and Representative Kristin Bahner (House District 34B) attended numerous Task Force meetings and were active participants in the Task Force’s work.
- 2 The members of Working Group #1 were Co-Chair Ms. Smith-Holt, Senator Little, Representative Hamilton, Dr. Wiberg, and Ms. LaChapelle.
- 3 See *generally* Bylaws of Advisory Task Force on Lowering Pharmaceutical Drug Prices (hereinafter “Bylaws”).
- 4 See Bylaws § 8.10.
- 5 See Bylaws § 8.11.
- 6 The Task Force in particular wants to recognize the assistance provided by the Minnesota Department of Health and the Minnesota Department of Administration. In addition to Commissioner Malcom’s testimony, representatives of each agency testified before the Task Force. Representatives from each department also participated in multiple working group meetings, and provided invaluable information to the Task Force.
- 7 For more information on the subjects discussed in this subsection, see generally Management Sciences for Health, *MDS-3: Managing Access to Medicines and Health Technologies* (3rd ed. 2012), www.msh.org/resources/mds-3-managing-access-to-medicines-and-health-technologies (last visited December 5, 2019) (“MDS-3”), and Henry Waxman et al., The Commonwealth Fund, *Getting to the Root of High Prescription Drug Prices* (July 2017), www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2017_jul_waxman_getting_to_root_high_rx_drug_prices_ib_v2.pdf (last visited December 5, 2019).
- 8 *MDS-3* at 9.3.
- 9 *MDS-3* at 9.3.
- 10 *MDS-3* at 9.3.
- 11 See Section IV.F (discussing subscriber marketing and financial inducements).
- 12 See Section III.A (discussing patent, exclusivity, and related laws and rules).
- 13 Examples of biologics include insulin, vaccines, and Humira—the top-selling drug in the world.
- 14 Dr. Stephen W. Schondelmeyer & Leigh Purvis, *AARP Rx Price Watch Report - Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update*, p. 1. (June 2019) (“June 2019 AARP Rx Price Watch Report”).
- 15 June 2019 *AARP Rx Price Watch Report* at 1.
- 16 June 2019 *AARP Rx Price Watch Report* at 1.
- 17 Minnesota Department of Health, *Issue Brief: Pharmaceutical Spending and Use in Minnesota: 2009-2013* at 2 (Nov. 2016), www.health.state.mn.us/data/apcd/docs/RxIssueBrief1Proof20161102.pdf (“MDH November 2016 *Issue Brief*”).
- 18 Centers for Medicare & Medicaid Services, *National Health Expenditures 2017 Highlights* at 1, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf (discussing national statistics); see also MDH November 2016 *Issue Brief* at 5 (discussing Minnesota statistics)..



- 19 MDH November 2016 *Issue Brief* at 2.
- 20 MDH November 2016 *Issue Brief* at 3.
- 21 Pharmacy claims generally refers to health insurance claims for prescription drugs that are “typically covered as part of a pharmacy benefit and may be obtained at retail and other pharmacy settings.” MDH November 2016 *Issue Brief* at 2.
- 22 MDH November 2016 *Issue Brief* at 2.
- 23 Stefan Gildemeister, Director Health Economics Program, Minnesota Department of Health, *Presentation to Advisory Taskforce on Lowering Pharmaceutical Drug Prices*, at slide 6 (July 23, 2019) (hereafter “7/23/19 Gildemeister Presentation”) (showing that in 2013 \$943 million was spent on these bundled medical claims for drugs in Minnesota, which was far more than any other therapeutic category).
- 24 MDH November 2016 *Issue Brief* at 5-6 (noting that this is a low estimate due to certain categories of data that were not captured as part of this study).
- 25 MDH November 2016 *Issue Brief* at 1-2.
- 26 MDH November 2016 *Issue Brief* at 2.
- 27 MDH November 2016 *Issue Brief* at 2.
- 28 MDH November 2016 *Issue Brief* at 3.
- 29 MDH November 2016 *Issue Brief* at 4 n.6.
- 30 Centers for Disease Control and Prevention (“CDC”), *Percentage of Adults Aged ≥18 Years Who Were Prescribed Medication in the Past 12 Months, by Sex and Age Group – National Health Interview Survey, 2017*. Morbidity and Mortality Weekly Report, Vol. 68 (No. 4) (February 1, 2019), www.cdc.gov/mmwr/volumes/68/wr/mm6804a6.htm?s_cid=mm6804a6_w (last visited October 25, 2019).
- 31 CDC, *Prescription drug use in the past 30 days, by sex, race and Hispanic origin, and age: United States, select years 1988-1994 through 2011-2014*. Table 79, United States, 2017, <https://www.cdc.gov/nchs/hus/contents2017.htm#079> (last visited October 25, 2019).
- 32 Minnesota Department of Health, *Background Statistics on Prescription Drugs Compiled by the Health Economics Program for the MN AG Task Force on Prescription Drugs* at 4. (October 1, 2019) (the report and statistics the Minnesota Department of Health compiled for the Task Force are on file with Ms. Sadaf Rahmani, the staff liaison from the Minnesota Attorney General’s Office to the Task Force) (hereafter “MDH Prescription Drugs Report”).
- 33 *MDH Prescription Drugs Report* at 4.
- 34 *MDH Prescription Drugs Report* at 4.
- 35 *MDH Prescription Drugs Report* at 4.
- 36 Dr. Stephen W. Schondelmeyer & Leigh Purvis, *AARP Rx Price Watch Report - Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update* at 5 (September 2018), www.aarp.org/content/dam/aarp/ppi/2018/09/trends-in-retail-prices-of-brand-name-prescription-drugs-year-end-update.pdf (last visited October 25, 2019).
- 37 *Id.* at 1.
- 38 Stephen W. Schondelmeyer & Leigh Purvis, *Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update*, AARP Public Policy Institute, (September 2019), www.aarp.org/content/dam/aarp/ppi/2019/09/trends-in-retail-prices-of-prescription-drugs-widely-used-by-older-americans.doi.10.26419-2Fppi.00073.003.pdf (last visited November 26, 2019).



- 39 Stephen W. Schondelmeyer & Leigh Purvis, *Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update*, AARP Public Policy Institute (June 2019), www.aarp.org/content/dam/aarp/ppi/2019/06/trends-in-retail-prices-of-specialty-prescription-drugs-year-end-update.doi.10.26419-2Fppi.00073.001.pdf (last visited November 26, 2019). The AARP Public Policy Institute analyzed 97 widely used specialty prescription drugs. Examples of the specialty drugs included in the analysis included Capecitabine (used to treat certain cancers), Avonex (used to treat multiple sclerosis), Truvada (used to treat and prevent HIV infection), and Humira (used to treat arthritis and other inflammatory conditions).
- 40 Lisa L. Gill, *How to Pay Less for Your Meds*, Consumer Reports (April 5, 2018), www.consumerreports.org/drug-prices/how-to-pay-less-for-your-meds/ (last visited October 22, 2019).
- 41 Thomas Goetz, *Health insurance aside, Americans still struggle to pay for their medications*, GoodRx (November 25, 2018), www.goodrx.com/blog/health-insurance-aside-americans-still-struggle-to-pay-for-their-medications/ (last visited October 22, 2019).
- 42 Dr. Lars Osterberg & Dr. Terrence Blaschke, *Adherence to medication*, *The New England Journal of Medicine*, 353:487-97 (August 4, 2005), www.nejm.org/doi/full/10.1056/NEJMra050100?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed (last visited November 25, 2019).
- 43 Ashley Kirzinger et al., *KFF Health Tracking Poll – February 2019: Prescription Drugs*, The Kaiser Family Foundation (March 1, 2019), www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/ (last visited November 25, 2019).
- 44 Kaiser Family Foundation, *Kaiser Health Tracking Poll: November 2016 (2016)*, <http://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-November-2016-Topline> (last visited November 25, 2019).
- 45 Bram Sable-Smith, *American travelers seek cheaper prescription drugs in Mexico and beyond*, National Public Radio (February 11, 2019), www.npr.org/sections/health-shots/2019/02/11/691467587/americans-look-for-cheaper-meds-in-mexico (last visited November 25, 2019).
- 46 Emily Rauhala, *As price of insulin soars, Americans caravan to Canada for lifesaving medicine*, *The Washington Post* (June 16, 2019), www.washingtonpost.com/world/the-americas/as-price-of-insulin-soars-americans-caravan-to-canada-for-lifesaving-medicine/2019/06/14/0a272fb6-8217-11e9-9a67-a687ca99fb3d_story.html?utm_term=.f1566f95c50d (last visited November 25, 2019).
- 47 See generally *MDH Prescription Drugs Report* and 7/23/19 Gildemeister Presentation.
- 48 For example, a person may be both an active pharmaceutical ingredient manufacturer and a drug manufacturer, or be both a health plan and operate a provider network
- 49 See Margaret A. Hamburg, M.D., *Remarks at the Annual Conference of the Food and Drug Law Institute*, 67 *Food & Drug L.J.* 123, 128 (2012) (“FDA-regulated products originate from approximately 300,000 foreign facilities spread across more than 150 countries. On the drug side, astoundingly, approximately 80% of the active pharmaceutical ingredients used in FDA-approved drugs sold in this country are manufactured outside of the United States, and 40 percent of finished drugs consumed here are manufactured elsewhere.”).
- 50 Generally, drug manufacturers’ pricing and other business practices as described in this paragraph, including their relationships with other entities in the drug sales chain, are described in depth in *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F.Supp.2d 20 (D. Mass. 2007), *aff’d* 582 F.3d 156 (1st Cir. 2009) (“*In re AWP Litigation*”).
- 51 21 U.S.C. § 360; see also 21 C.F.R. pt. 207.
- 52 Minn. Stat. § 151.252.
- 53 In industry jargon, the list price is known as the “wholesale acquisition cost (WAC),” which is in turn used to set the “average wholesale price (AWP)” of the drug. Manufacturers set WAC directly. AWP is generally set by adding a certain markup to WAC, usually about 20%. Thus, setting WAC also functionally sets AWP. See *In re AWP Litigation*, 491 F.Supp.2d 20 (D. Mass. 2007).
- 54 Generally, wholesale drug distributors business practices as described in this paragraph, including their relationships with other entities in the drug sales chain, are described in depth in *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), *aff’d* 582 F.3d 156 (1st Cir. 2009).



- 55 See Minn. Stat. § 151.47, subd. 1a(b) (requiring licensure to act as a wholesale distributor), Minn. R. 6800.1400 et seq. (describing licensing requirements and qualifications).
- 56 Generally, PBMs' rebate, pricing, and other business practices as described in this paragraph, including their relationships with other entities in the drug sales chain, are described in depth in *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), *aff'd* 582 F.3d 156 (1st Cir. 2009).
- 57 Even within the formularies, drugs are typically sorted into differing "tiers." Depending into which tier a PBM classifies a particular drug, a health plan's member will pay more or less out of pocket for the drug. Oregon Joint Interim Task Force on Fair Pricing of Prescription Drugs, *Report on Transparency Strategies for The Pharmaceutical Supply Chain*, 19 (November 2018), <https://olis.leg.state.or.us/liz/201711/Downloads/CommitteeMeetingDocument/152412> (last visited November 14, 2019) ("Oregon Drug Pricing Report").
- 58 Manufacturers will sometimes offer bundled discounts known as 'rebate walls,' wherein the manufacturer promises large rebates to PBMs, but only if the PBMs agree to cover a large number of drugs from the same manufacturer. Refusing to cover even one drug in the bundle could result in the entire rebate being taken away. See David Balto, *FTC Must Tackle Anticompetitive Drug Rebate Practices*, Law360 (May 17, 2019).
- 59 Manufacturers agree to pay PBMs rebates because a PBM can drive demand for a particular drug by agreeing to provide it preferential pricing or other treatment over a competing drug through use of the PBM's formulary.
- 60 See generally 2019 Minn. Laws ch. 39 (to be codified at Minn. Stat. ch. 62W).
- 61 See generally Minn. Stat. ch. 151 (establishing the Minnesota State Board of Pharmacy and charging it with licensing and regulating pharmacies and pharmacists in the state).
- 62 National Community Pharmacists Association, *NCPA 2017 Digest* at 21 (2017), www.ncpa.co/pdf/digest/2017/2017-digest-lr.pdf (last visited November 14, 2019).
- 63 Licensed health care professionals authorized to prescribe in Minnesota include: physicians, physician assistants nurse practitioners, dentists, optometrists, and podiatrists, as well as veterinarians (for animal use only).
- 64 Colette DeJong et al., *Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries*, *JAMA Internal Medicine* (August 2016), <https://jamanetwork.com/journals/jamainternalmedicinefullarticle/2528290> (last visited November 14, 2019).
- 65 Minn. Stat. § 151.461
- 66 Minn. Stat. § 151.461. There are other ways that practitioners are influenced to use specific drugs. For example, Centers for Medicare and Medicaid reimburses at a rate of 106% of the Average Sales Price of a drug, giving physicians an incentive to choose a more expensive drug over a cheaper one. See Centers for Medicare and Medicaid Services, Medicare Part B Drug Average Sales Price, www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html (last visited November 14, 2019).
- 67 The Kaiser Family Foundation, *The Uninsured: A Primer*, Supplemental Table #1 (December 2017), <http://files.kff.org/attachment/Supplemental-Tables-The-Uninsured-A-Primer-Key-Facts-about-Health-Insurance-and-the-Uninsured-Under-the-Affordable-Care-Act> (last visited November 25, 2019).
- 68 In 2018, the average worker contributed 18% of the premium for individual coverage and 29% for family coverage. The Kaiser Family Foundation, *Employer Health Benefits: 2018 Annual Survey*, 9 (2018), <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018> (last visited November 25, 2019).
- 69 *Id.* at 153
- 70 MMCAP INFUSE was previously known as the Minnesota Multistate Contracting Alliance for Pharmacy.
- 71 See, e.g., Minn. Stat. §§ 16C.105, 471.59, subd. 1(b).
- 72 Biologics are derived from living materials, whether they be human, animal, or microorganism in origin. They include any "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, . . . or analogous product, . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262, subd (i). The FDA also approves over the counter drugs.



- 73 See generally 21 U.S.C. § 355 (small molecule new drug application).
- 74 21 C.F.R. § 601.2, subd. (a).
- 75 42 U.S.C. § 262, subd. (j).
- 76 21 U.S.C. § 355, subd. (j).
- 77 See 21 U.S.C. § 355, subd. (j)(2)(A)(i).
- 78 21 U.S.C. § 355, subd. (j)(2)(A).
- 79 21 U.S.C. § 355, subd.(j)(2)(A)(vii). If the generic manufacturer claims that the patent is invalid or that the generic manufacturer's sale of the drug will not infringe on the drug, it must give notice to the owner of the patent and the holder of the approved brand name drug, which triggers a 45-day window to file a lawsuit for infringement of the patent. *Id.*, subd. (j)(5)(B)(iii). If no such infringement action is filed, the application may proceed. If an infringement action is filed, this may result in the FDA freezing the ADNA for up to thirty months. *Id.*
- 80 42 U.S.C. § 262, subd. (k).
- 81 42 U.S.C. § 262, subd. (k)(2)(A)(i)(II).
- 82 42 U.S.C. § 262, subd. (k)(4).
- 83 FDA, Center for Drug Evaluation and Research, *List of Licensed Biological Products* (July 23, 2019), www.fda.gov/media/89589/download (last visited November 25, 2019).
- 84 See 35 U.S.C. § 101
- 85 35 U.S.C. § 154(a)(2).
- 86 35 U.S.C. §§ 101, 102.
- 87 The law's official name is Drug Price Competition and Patent Term Restoration Act, Public Law 98-417 (1984) (codified at 21 U.S.C. §§ 301, 355, 360cc).
- 88 35 U.S.C. § 156.
- 89 21 U.S.C. § 355(b)(1).
- 90 21 U.S.C. § 355(j)(2)(vii).
- 91 21 U.S.C. § 355(j)(5)(B)(iii).
- 92 See 42 U.S.C. § 262(l)(2)(A),(B).
- 93 See *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1672 (2017).
- 94 21 U.S.C. § 355, subd. (j)(5)(B)(iv).
- 95 42 U.S.C. § 262, subd. (k)(6). This period of exclusivity can be extended in the event of a patent dispute involving the biological product.
- 96 21 C.F.R. § 316.31.
- 97 "New chemical" means "a drug that contains no active moiety that has been approved by FDA in any other [new drug application] under [21 U.S.C. § 355, subd (b)]." 21 C.F.R. § 314.108, subd (a).
- 98 21 C.F.R. § 314.108, subd. (b)(2). The FDA reduces the period of exclusivity to four years if the subsequent drug application contains a certification of patent invalidity or noninfringement. *Id.*
- 99 Other exclusivities that may apply to prescription drugs are: a biologic reference drug exclusivity, see 42 U.S.C. § 262, subd. (k)(7); a pediatric exclusivity, see 42 U.S.C. § 284m, 21 U.S.C. § 355a; an antimicrobial exclusivity, see 21 U.S.C. § 355f; and, essentially, an "other" exclusivity, see 21 C.F.R. § 314.108, subds. (4), (5).



- 100 United States Government Accountability Office, *Drug Discount Program – Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO Report No. 18-480 (June 2018), www.gao.gov/products/GAO-18-480 (last visited November 25, 2019).
- 101 HRSA, *340B Drug Pricing Program* (August 2019), www.hrsa.gov/opa/index.html (last visited October 29, 2019).
- 102 HRSA, *340B Eligibility* (May 2018), www.hrsa.gov/opa/eligibility-and-registration/index.html (last visited November 1, 2019). Specifically, covered entities include Federally Qualified Health Centers (“FQHC”), FQHC Look-Alikes, Native Hawaiian Health Centers, Tribal / Urban Indian Health Centers, Ryan White HIV/AIDS Program Grantees, children’s hospitals, critical access hospitals, disproportionate share hospitals, free standing cancer hospitals, rural referral centers, sole community hospitals, Black Lung Clinics, comprehensive hemophilia diagnostic treatment centers, Title X family planning clinics, sexually transmitted disease clinics, and tuberculosis clinics.
- 103 HRSA Table of Minnesota 340B Entities and Contract Pharmacies (October 1, 2019) (hereafter “Minnesota 340B Entities Table”) (this table was compiled for the Task Force, and is on file with Ms. Sadaf Rahmani, the staff liaison from the Minnesota Attorney General’s Office to the Task Force); see also 42 U.S.C. § 1395ww (establishing which hospitals are considered “disproportionate share hospitals”).
- 104 Minnesota 340B Entities Table.
- 105 Minnesota 340B Entities Table. The Minnesota Board of Pharmacy website also allows persons to search for 340B Program entities in Minnesota, which can be accessed at <https://mn.gov/boards/pharmacy/public/savingonprescriptiondrugs.jsp> (last visited November 27, 2019).
- 106 HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility*, 61 Fed. Reg., 55,158 (October 24, 1996), www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf (last visited November 25, 2019). Specifically, HRSA defines an individual as an eligible patient if (1) the covered entity has established a relationship with the individual and maintains the individual’s health records, (2) the individual receives health care services from who is employed or contracted with the covered entity, and (3) the individual receives health care services consistent with the services for which grant funding or federally-qualified health center look-alike status has been provided to the covered entity.
- 107 United States Government Accountability Office, *Drug Discount Program – Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO Report No. 18-480, at 35 (June 2018), www.gao.gov/assets/700/692697.pdf (last visited November 25, 2019).
- 108 Minn. Stat. § 151.06.
- 109 Minn. Stat. § 151.22.
- 110 Minn. Stat. § 151.252.
- 111 Minn. Stat. § 151.34.
- 112 Minn. Stat. § 151.21, subd. 3 (stating that pharmacists may substitute generic versions of drugs unless the prescribing physician has personally handwritten or indicated electronically, “dispense as written” or “D.A.W.”).
- 113 Minn. Stat. § 151.21, subd. 3. The FDA had yet to approve any biosimilar products as interchangeable as of July 2019, however, see FDA, Center for Drug Evaluation and Research, *List of Licensed Biological Products* (July 23, 2019), www.fda.gov/media/89589/download (last visited November 25, 2019), and biosimilar drugs that are not interchangeable must be specifically prescribed by doctors. Minn. Stat. § 151.21, subd. 3.
- 114 See 2019 Minn. Laws ch. 39 (to be codified at Minn. Stat. ch. 62W).
- 115 Tori Marsh, *2 Years After the EpiPen Price Hike, Here’s What’s Changed*, GoodRx (August 16, 2018), www.goodrx.com/blog/epipen-price-change-since-mylan-released-generic-epinephrine (last visited November 25, 2019).
- 116 The United States Department of Justice, *Press Release: Mylan Agrees to Pay \$465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebate* (August 17, 2017), www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates (last visited November 25, 2019).



- 117 Charles Duhigg, *Outcry Over EpiPen Prices Hasn't Made Them Lower*, The New York Times (June 4, 2017), www.nytimes.com/2017/06/04/business/angry-about-epipen-prices-executive-dont-care-much.html (last visited November 25, 2019).
- 118 *Id.*
- 119 In general, the information discussed in this paragraph is summarized from the allegations in the complaints in *Federal Trade Commission v. Mylan Laboratories, et al.*, Court File No. 98-cv-3114 (D.D.C.), and *State of Connecticut et al. v. Mylan Laboratories, et al.*, Court File No. 98-cv-3115 (D.D.C.). Some of these materials are also accessible on the Federal Trade Commission's website at www.ftc.gov/enforcement/cases-proceedings/9810146/mylan-laboratories-inc-cambrex-corporation-profarmaco-sri-gyma (last visited November 25, 2019).
- 120 Minnesota Department of Health, *Diabetes in Minnesota*, www.health.state.mn.us/diseases/diabetes/data/diabetesfacts.html (last visited November 25, 2019).
- 121 American Diabetes Association, *The Burden of Diabetes in Minnesota*, <http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/minnesota.pdf> (last visited November 25, 2019).
- 122 Carolyn Johnson, *Why treating diabetes keeps getting more expensive*, The Washington Post (October 31, 2016), www.washingtonpost.com/news/wonk/wp/2016/10/31/why-insulin-prices-have-kept-rising-for-95-years/ (last visited November 25, 2019).
- 123 Robin Respaut and Chad Terhune, *US insulin costs per patient nearly doubled from 2012 to 2016*, Reuters (January 22, 2019), www.reuters.com/article/us-usa-healthcare-diabetes-cost/u-s-insulin-costs-per-patient-nearly-doubled-from-2012-to-2016-study-idUSKCN1PG136 (last visited November 25, 2019).
- 124 Jeremy Olson, *Son's death pushes Minnesota mom into fight against high, rising drug prices*, The Minneapolis Star Tribune (May 11, 2018), www.startribune.com/son-s-death-pushes-mom-into-drug-price-spotlight/482344871/ (last visited November 25, 2019).
- 125 The Minnesota Attorney General's Office sued Sanofi Aventis, Eli Lilly, and Novo Nordisk over the alleged pricing practices described in this subsection in 2018, claiming they were deceptive, fraudulent, and unlawful. The lawsuit remains pending in federal court in New Jersey. See *State of Minnesota, by its Attorney General, Keith Ellison v. Sanofi Aventis et al.*, Case No. 18-cv-14999 (D.N.J.).
- 126 United States Senate, Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* (December 2016), www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf (last visited October 22, 2019).
- 127 Andrew Pollack and Sabrina Tavernise, *Valeant's drug price strategy enriches it, but infuriates patients and lawmakers*, The New York Times (October 4, 2015), www.nytimes.com/2015/10/05/business/valeants-drug-price-strategy-enriches-it-but-infuriates-patients-and-lawmakers.html (last visited October 22, 2019).
- 128 Andrew Pollack, *Drug goes from \$13.50 a tablet to \$750, overnight*, The New York Times (September 20, 2015), www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=1&pagewanted=all (last visited October 22, 2019).
- 129 United States House of Representatives, Committee on Oversight and Reform, *Oversight Committee Requests Info on Documents Withheld from Congress by Valeant Pharmaceuticals: Press Release* (March 10, 2016), <https://oversight.house.gov/news/press-releases/oversight-committee-requests-info-on-documents-withheld-from-congress-by-valeant> (last visited October 22, 2019).
- 130 United States House of Representatives, Committee on Oversight and Reform, *Memorandum - Documents Obtained by Committee from Valeant Pharmaceuticals* (February 2, 2016), <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Valeant%20Documents0.pdf> (last visited October 22, 2019).
- 131 *Id.* Moreover, in 2015, Valeant's alleged relationship with mail-order specialty pharmacy Philidor Rx Services was revealed, which was unknown even to its shareholders at the time. Greg Roumeliotis & Alexandria Sage, *Valeant under criminal investigation over Philidor ties: WSJ*, Reuters (August 10, 2016), www.reuters.com/article/us-valeant-investigation-idUSKCN10L2RG (last visited October 22, 2019). Valeant reportedly used Philidor "to mask its price increases and circumvent the traditional insurance reimbursement process, as well as the company's compliance with federal securities laws." United States House of Representatives, Committee on Oversight and Reform, *Oversight Committee Requests Info*



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- 132 The Kaiser Family Foundation, *The Uninsured: A Primer*, Supplemental Table #1 (December 2017), <http://files.kff.org/attachment/Supplemental-Tables-The-Uninsured-A-Primer-Key-Facts-about-Health-Insurance-and-the-Uninsured-Under-the-Affordable-Care-Act> (last visited November 14, 2019); see also Susan L Hayes, Sara R. Collins, and David C. Radley, *How Much U.S. Households with Employer Insurance Spend on Premiums and Out-of-Pocket Costs: A State-by-State Look*, The Commonwealth Fund (May 2019), www.commonwealthfund.org/publications/issue-briefs/2019/may/how-much-us-households-employer-insurance-spend-premiums-out-of-pocket (last visited November 14, 2019).
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- 137 Michelle Andrews, *Employers Are Scaling Back Their Dependence On High-Deductible Health Plans*, Kaiser Health News (October 29, 2019), <https://khn.org/news/employers-are-scaling-back-their-dependence-on-high-deductible-health-plans/> (last visited December 2, 2019).
- 138 Robin A. Cohen et al., *Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, 2018*, Centers for Disease Control - National Center for Health Statistics (May 2019), www.cdc.gov/nchs/data/nhis/earlyrelease/insur201905.pdf (last visited November 14, 2019).
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- 152 Minnesota Board of Pharmacy, Licensing and Registration Statistics (2019), <https://mn.gov/boards/pharmacy/resources/faqs/licensingandregistration.jsp> (last visited November 26, 2019).
- 153 Originally, DIR fees were created by the Center for Medicare and Medicaid Services (“CMS”) to reconcile drug manufacturer rebates after the sale, but are now frequently levied by PBMs on pharmacies. A DIR fee can consist of a number of different fees, including network participation fees, periodic reimbursement reconciliations, and fees assessed to pharmacies for claimed non-compliance with certain quality measures. PBMs are not required to disclose how the fees are calculated. National Community Pharmacists Association, *Frequently Asked Questions (FAQs) About Pharmacy “DIR” Fees* (October 8, 2018), www.ncpa.co/pdf/dir-faq.pdf (last visited November 27, 2019).
- 154 The recent passage of Minnesota Statutes section 62W.07 should help mitigate the impact of this PBM business practice on independent pharmacies in Minnesota.
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- 160 *Id.*
- 161 Harriet A. Washington, *Presentation to Working Group #1 of the Advisory Taskforce on Lowering Pharmaceutical Drug Prices* (July 18, 2019) (Ms. Washington is the author of the book “Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present.” A recording of Ms. Washington’s presentation is on file with Ms. Sadaf Rahmani, the staff liaison from the Minnesota Attorney General’s Office to the Task Force.).
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- 164 Congressional Research Service, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress* at 14 (April 4, 2019), <https://crsreports.congress.gov/product/pdf/R/R45666> (last visited November 22, 2019); see also John R. Thomas, *Visiting Scholar, Patent “Evergreening”: Issues in Innovation and Competition*, Congressional Research Service (November 13, 2009), www.ipmall.info/sites/default/files/hosted_resources/crs/R40917_091113.pdf (last visited November 22, 2019). A similar phenomenon is known as “product hopping,” which happens when a drug maker changes a drug that is about to go off-patent, and aggressively encourages users of the first drug to switch to the new version. This is discussed further below. See Section III.C.1.
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- 166 Orphan Drug Act, Public Law 97-414 (January 4, 1983).
- 167 EvaluatePharma, Orphan Drug Report, at 9 (3rd ed. 2015), <http://info.evaluategroup.com/rs/607-YGS-364/images/EPOD15.pdf> (last visited November 22, 2019).
- 168 National Public Radio, *Drugs For Rare Diseases Have Become Uncommonly Rich Monopolies* (January 17, 2017), www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies (last visited December 23, 2019). The Orphan Drug Act has also been criticized for allowing the re-classification of already-developed drugs or the development of “orphan drugs” that are actually marketed for off-label use. See, e.g., Sarah Jane Tribble, *FDA Moves to Rein In Drugmakers’ Abuse of Orphan Drug Law*, National Public Radio (September 13, 2017), <https://www.npr.org/sections/health-shots/2017/09/13/550700062/fda-moves-to-rein-in-drugmakers-abuse-of-orphan-drug-law> (last visited November 22, 2019).
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- 174 Rebecca S. Eisenberg, *Patents and Regulatory Exclusivity*, The University of Michigan Law School, Scholarship Repository, at 15 (2012), https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1126&context=book_chapters (last visited on November 22, 2019).
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- 178 21 C.F.R. §§ 10.25, 10.30.
- 179 Robin Feldman & Connie Wang, *A Citizen’s Pathway Gone Astray – Delaying Competition from Generic Drugs*, The New England Journal of Medicine (April 20, 2017), www.nejm.org/doi/10.1056/NEJMp1700202 (last visited on November 21, 2019).
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- 186 Amanda K. Sarata, Agata Dabrowska, *Prescription Drug Importation*, Congressional Research Service at 1 (December 21, 2018), <https://crsreports.congress.gov/product/pdf/IF/IF11056> (last visited November 14, 2019).
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- 188 U.S. Food & Drug Administration, *Safe importation action plan*, U.S. Department of Health and Human Services (2019), <https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf> (last visited November 14, 2019).
- 189 *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (holding that drug “product hopping” under the circumstances present there—withdrawing a twice-daily version of a drug and replacing it with a once-daily version of the same drug—was likely to be found to violate antitrust laws, and upholding a preliminary injunction against the practice); see also Federal Trade Commission, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott PLC et al.*, Case No. 15-2236, Brief of Amicus Curiae Federal Trade Commission Supporting Plaintiff-Appellant, ECF# 03112088104 (3rd Cir. Sept. 30, 2015), www.ftc.gov/policy/advocacy/amicus-briefs/2015/09/mylan-pharmaceuticals-inc-v-warner-chilcott-plc-et-al (last visited December 2, 2019).
- 190 *State of Wisconsin et al v. Indivior Inc., et al*, Case No. 16-cv-5073, First Amended Complaint (E.D. Pa.).
- 191 Apart from this ongoing civil litigation, the United States Department of Justice has also indicted Indivior criminally. See United States Department of Justice, *Press Release: Indivior, Inc. Indicted for Fraudulently Marketing Prescription Opioid* (April 9, 2019), www.justice.gov/opa/pr/indivior-inc-indicted-fraudulently-marketing-prescription-opioid (last visited November 27, 2019).
- 192 Sanofi, *Press Release: Sanofi Reaches Patent Settlement on Lantus® SoloSTAR®* (September 28, 2015), www.news.sanofi.us/2015-09-28-Sanofi-Reaches-Patent-Settlement-on-Lantus-SoloSTAR (last visited December 18, 2019) (“The agreement resolves a U.S. patent infringement lawsuit regarding Lilly’s pursuit of regulatory approval for a product that would compete with Lantus SoloSTAR. . . . In the U.S., Lilly will not sell its insulin glargine product before December 15, 2016.”).
- 193 See, e.g., *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 218 (1940) (“[F]or over forty years this Court has consistently and without deviation adhered to the principle that price-fixing agreements are unlawful . . . and that no showing of so-called competitive abuses or evils which those agreements were designed to eliminate or alleviate may be interposed as a defense.”). Other types of per se unlawful conduct under antitrust laws are market allocation schemes where competitors agree not to compete with one another in a particular geographic area or for a particular class of customers, group boycotts in which multiple competitors refuse to do business with another company unless that company stops doing business with other competitors, and certain types of tying arrangements in which unrelated products are sold together as a single unit, to force customers to buy both.
- 194 Antitrust lawsuits involving allegedly per se anticompetitive conduct often settle prior to a ruling on the merits by a court or a jury. As part of such settlements, drug manufacturers rarely are forced to admit the unlawfulness of their alleged conduct.
- 195 *State of Connecticut et al v. Actavis Holdco U.S. Inc., et al*, Case No. 17-cv-03768 (E.D. Pa. October 31, 2017).
- 196 *State v. Actavis Holdco Compl.* ¶ 7.
- 197 Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States: 1997-2016*, The Journal of the American Medical Association, Vol. 321, No. 1, at 80 (January 8, 2019), <https://jamanetwork.com/journals/jama/fullarticle/2720029> (last visited November 27, 2019) (hereafter “*Medical Marketing*”). According to one study, “[s]pending increases from 1997 through 2016 were greatest for drugs for diabetes/endocrine diseases (from \$22 million to \$725 million), dermatology conditions (\$67 million to \$605 million), pain/central nervous system disorders (\$56 million to \$542 million), arthritis (\$27



million to \$484 million), cardiac diseases (\$0 to \$379 million) and cancer (\$3 million to \$274 million), largely reflecting competition among expensive new biologics and cancer therapies.” *Id.* at 82; see also Joanne Kaufman, *Think You’re Seeing More Drug Ads on TV? You Are, and Here’s Why*, *The New York Times* (Dec. 24, 2017) (discussing another study that found TV ads for prescription drugs in 2017 increased to 771,368).

- 198 World Health Organization, *Bulletin of the World Health Organization: Direct-to-Consumer Advertising Under Fire*, Vol. 87, No. 8 (August 2009), www.who.int/bulletin/volumes/87/8/09-040809/en/ (last visited November 27, 2019).
- 199 United States House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Direct-to-Consumer Advertising: Marketing, Education, or Deception?* (May 8, 2008), www.govinfo.gov/content/pkg/CHRG-110hhrg54104/html/CHRG-110hhrg54104.htm (last visited November 27, 2019) (Hon. Bart Stupak opening statement).
- 200 American Medical Association, *Press Release: AMA Calls for Ban on DTC Ads of Prescription Drugs and Medical Devices* (November 17, 2015), www.ama-assn.org/press-center/press-releases/ama-calls-ban-dtc-ads-prescription-drugs-and-medical-devices (last visited November 27, 2019).
- 201 *Medical Marketing* at 88.
- 202 See Section III.F (discussing patient assistance programs, patient discount coupons, and other practices that create perverse economic incentives to purchase higher priced drugs).
- 203 *Medical Marketing* at 88.
- 204 *Id.* at 85.
- 205 *Id.* at 89.
- 206 *Id.* at 85.
- 207 *Id.*
- 208 See, e.g., *State v. Boehringer Ingelheim Pharmaceuticals, Inc.*, Court File No. 62-CV-17-7562 (2d Judicial Dist.) (deceptive marketing of Aggrenox, Atrovent, Combivent, and Micardis); *State v. Johnson & Johnson et al.*, Court File No. 62-CV-17-3263 (2d Judicial Dist.) (deceptive marketing of over the counter medications, including infants and children’s Tylenol liquid products as well as Tylenol, Benadryl, Roloids, Motrin, and Zyrtec); *State v. Bristol-Myers Squibb Co.*, Court File No. 62-CV-16-6869 (2d Judicial Dist.) (deceptive marketing of Abilify); *State v. Amgen, Inc.*, Court File No. 62-CV-15-5054 (2d Judicial Dist.) (deceptive marketing of Aranesp and Enbrel); *State v. GlaxoSmithKline LLC*, Court File No. 62-CV-14-3930 (2d Judicial Dist.) (deceptive marketing of Advair, Paxil, and Wellbutrin); *State v. Wyeth Pharmaceuticals, Inc.*, Court File No. 62-CV-14-5503 (2d Judicial Dist.) (deceptive marketing of Rapamune); *State v. Abbott Laboratories*, Court File No. 62-CV-12-4065 (2d Judicial Dist.) (deceptive marketing of Depakote); *State v. GlaxoSmithKline, LLC*, Court File No. 62-CV-12-8721 (2d Judicial Dist.) (deceptive marketing of Avandia); *State v. Janssen Pharmaceuticals, Inc., et al.*, Court File No. 62-CV-12-6880 (2d Judicial Dist.) (deceptive marketing of Risperdal); *State v. AstraZeneca Pharmaceuticals LP, et al.*, Court File No. 62-CV-11-1785 (2d Judicial Dist.) (deceptive marketing of Seroquel).
- 209 United States Department of Health and Human Services, *Regulation to Require Drug Pricing Transparency*, 84 Fed. Reg. 20,734-20,758 (May 10, 2019).
- 210 *Merck & Co., Inc., et al. v. U.S. Dep’t of Health & Human Servs., et al.*, Case File No. 19-cv-01738 (D.D.C. June 14, 2019).
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- 215 Congressional Research Service, *Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)* at 9 (June 15, 2017), <https://crsreports.congress.gov/product/pdf/R/R44264> (last visited November 27, 2019) (hereinafter “CRS *Discount Coupons and PAPs Report*”).
- 216 NEJM *No Such Thing as a Free Lunch*.
- 217 CRS *Discount Coupons and PAPs Report* at 1.
- 218 *Id.*
- 219 CRS *Discount Coupons and PAPs Report* at 8-9.
- 220 *Id.* at 8 n.32 (this study noted that, among other things, “a well-designed coupon program could add 30 days to 60 days of patient drug use during a year.”).
- 221 NEJM *No Such Thing as a Free Lunch*.
- 222 Leemore Dafny et al., *When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization*, *The National Bureau of Economic Research* (October 2016), www.hbs.edu/faculty/Publication%20Files/DafnyOdy_Schmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf (last visited November 27, 2019).
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- 224 2017 Cal. Stat. ch. 611 (codified at Cal. Health & Safety Code §§ 132000 *et seq.*), https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB265 (last visited November 27, 2019).
- 225 Mass. Gen. Laws ch. 175H § 3(b)(2); see also Thomas Sullivan, *Massachusetts & Drug Coupons: To Ban or Not to Ban, that is the Question*, *Policy & Medicine A Rockpointe Publication* (May 5, 2019), www.policymed.com/2019/05/massachusetts-drug-coupons-to-ban-or-not-to-ban-that-is-the-question.html (last visited November 27, 2019) (“The current law . . . prohibits manufacturers from offering discounts for any prescription drug that has an AB rated generic equivalent . . . or for any prescription drug that is a schedule II opioid”).
- 226 CRS *Discount Coupons and PAPs Report* at 12.
- 227 Recently, some health plans have attempted to combat the extra costs they pay as a result of discount coupons for branded drugs by implementing so-called “copay accumulators” policies. Under such policies, the health plan “doesn’t allow the value of a copay coupon to count against the [patients’] deductible or out-of-pocket maximum.” John S. Linehan, *State Legislatures Spring Ahead with Restrictions on Drug Copay Accumulators*, *Managed Care* (April 16, 2019), www.managedcaremag.com/voices/state-legislatures-spring-ahead-restrictions-drug-copayaccumulators (last visited November 27, 2019). Some have argued these programs are deceptive, and three states have enacted legislation restricting or banning such policies. *Id.*
- 228 Leemore Dafny et al., *When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization*, *American Economic Journal: Economic Policy* (May 2, 2017), www.aeaweb.org/articles?id=10.1257/pol.20150588 (last visited November 27, 2019).
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- 230 Norman V. Carrol, *Commentary – Pharmaceutical Patient Assistance Programs: Don’t Look a Gift Horse in the Mouth or There’s No Such Thing as a Free Lunch*, *Journal of Managed Care & Specialty Pharmacy*, Vol. 13, No. 7, at 615 (Sept. 2007), www.jmcp.org/doi/pdf/10.18553/jmcp.2007.13.7.614 (last visited November 27, 2019).



- 231 See *id.* (“physicians who treat medically indigent patients frequently face the choice of providing a ‘free’ PAP drug or an equally effective generic alternative.”)
- 232 CRS *Discount Coupons and PAPs* Report at 23.
- 233 CRS *Discount Coupons and PAPs* Report at 23-24 (quoting Jan Nielsen, Division President, of SonexusHealth).
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- 235 *Medical Marketing* at 84 (finding manufacturers consistently spend approximately \$5 billion annually on marketing directly to health providers).
- 236 *Id.*
- 237 *Id.*
- 238 *Id.* at 92; see also Freek Fickweiler, Ward Fickweiler, & Ewout Urbach, *Interactions Between Physicians and the Pharmaceutical Industry Generally and Sales Representatives Specifically and their Association with Physicians’ Attitudes and Prescribing Habits: A Systematic Review*, *BMJ OPEN* (2017) (“Physicians are susceptible to pharmaceutical industry and [physician-sales representative] interactions, which influences their clinical decision making leading to greater prescriptions of branded drugs over low-cost generic medicines and increasing healthcare costs.”)
- 239 Minn. Stat. § 151.461.
- 240 *State v. Insys Therapeutics, Inc.*, Case File No. 27-cv-18-9081 (4th Judicial Dist. Minn. 2018) (see generally Complaint).
- 241 *State v. Insys* Compl. ¶ 108.
- 242 *State v. Insys* Compl. ¶ 108.
- 243 *State v. Insys* Compl. ¶¶ 108, 110, 140-46.
- 244 *State v. Insys* Compl. ¶ 138.
- 245 *State v. Insys* Compl. ¶¶ 128, 133, 136; Aff. of Cerissa Stoltz in Support of the State’s Mot. For Temp. Inj., ¶ 4.
- 246 *State v. Insys.*, Minnesota Bd. of Pharmacy Committee on Prof’l Standards Am. Notice & Order for Prehearing Conf. & Hearing, ¶¶ 188-189.)
- 247 See *In re Insys Therapeutics, Inc. et al.*, Bankruptcy No. 19-11292, ECF# 1115 (Bankr. D. Del. 2020).
- 248 In industry jargon, the list price is known as the “wholesale acquisition cost (WAC),” which is in turn used to set the “average wholesale price (AWP)” of the drug. Manufacturers set WAC directly. AWP is generally set by adding a certain markup to WAC, usually about 20%. Thus, setting WAC also functionally sets AWP. See *In re AWP Litigation*, 491 F.Supp.2d 20 (D. Mass. 2007).
- 249 Moreover, some argue that patients often do not have choices so transparency is not sufficient to address problem drug pricing practices—they may not be able to switch drugs or forego using a drug, depending on what they have been prescribed, what alternative options exist, and what drug is covered by their health plan. See generally Alison Kodjak, *It Will Take More Than Transparency To Reduce Drug Prices, Economists Say*, National Public Radio (March 22, 2019), www.npr.org/sections/health-shots/2019/03/22/705469296/it-will-take-more-than-transparency-to-reduce-drug-prices-economists-say (last visited November 27, 2019).
- 250 Congressional Budget Office, *Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals* (June 5, 2008), www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf (last visited November 27, 2019); see also Kaitlyn N. Dana et al., *Drug Pricing Transparency: The New Retail Revolution*, Hospital Pharmacy (February 2017) www.ncbi.nlm.nih.gov/pmc/articles/PMC5345916/#i0018-5787-52-2-155-b3, (last visited November 27, 2019); America’s Health Insurance Plans, *Why Prescription Drug Price Transparency Matters* (June 2018), www.ahip.org/wp-content/uploads/2018/06/AHIP_IssueBrief_RxTransparency_62018FINAL.pdf, (last visited November 27, 2019).



- 251 Matthew Grennan & Ashley Swanson, *Transparency and Negotiated Prices: The Value of Information in Hospital-Supplier Bargaining*, National Bureau of Economic Research (February 2, 2018), www.nber.org/papers/w22039.pdf (last visited November 27, 2019).
- 252 National Conference of State Legislatures, *Prescription Drug Database: 2015-Present* (December 9, 2019), www.ncsl.org/research/health/prescription-drug-database.aspx (last visited December 12, 2019).
- 253 See 2016 Vermont Act No. 165 (S.216), <https://legislature.vermont.gov/bill/status/2016/S.216> (last visited December 12, 2019).
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- 255 See 2018 Oregon Laws ch. 7, <https://olis.leg.state.or.us/liz/2018R1/Downloads/MeasureDocument/HB4005> (last visited December 12, 2019).
- 256 Fla. Stat. § 408.062.
- 257 Nev. Rev. Stat. §§ 439B.600-695.
- 258 April McCullum, *Drug Costs Get Fresh Look in Montpelier*, Burlington Free Press (February 6, 2017), www.burlingtonfreepress.com/story/news/politics/government/2017/02/06/lawmakers-consider-updating-drug-cost-law/97465466/ (last visited December 12, 2019).
- 259 See, e.g., Minnesota House File 284 (91st Leg. 2019-20), www.revisor.mn.gov/bills/text.php?number=HF284&version=0&session_year=2019&session_number=0 (last visited November 27, 2019); Minnesota House File 288 (91st Leg. 2019-20), www.revisor.mn.gov/bills/text.php?number=HF288&version=0&session_year=2019&session_number=0 (last visited November 27, 2019); Minnesota House File 289 (91st Leg. 2019-20), www.revisor.mn.gov/bills/text.php?number=HF289&version=0&session_year=2019&session_number=0 (last visited November 27, 2019).
- 260 New Jersey Senate Bill 2389 (2019), <https://legiscan.com/NJ/bill/S2389/2018> (last visited November 27, 2019).
- 261 North Carolina House Bill 466 (2017-18), <https://legiscan.com/NC/bill/H466/2017> (last visited November 27, 2019).
- 262 Virginia House Bill No. 1436 (2018), <https://lis.virginia.gov/cgi-bin/legp604.exe?181+sum+HB1436> (last visited November 27, 2019).
- 263 See, e.g., *Pharmaceutical Research and Mfrs. of America et al. v. Sandoval et al.*, Case No. 2:17-cv-02315 (D.Nev. Sept. 1, 2017); see also *Pharmaceutical Research and Mfrs. of America v. David*, Case No. 2:17-CV-02573 (E.D.Cal. Sept. 28, 2018).
- 264 United States Department of Health and Human Services, *Press Release: CMS Drug Pricing Transparency Fact Sheet* (May 8, 2019), <https://www.hhs.gov/about/news/2019/05/08/cms-drug-pricing-transparency-fact-sheet.html> (last visited November 27, 2019).
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- 269 2018 Vermont Act No. 193 (S.92), <https://legislature.vermont.gov/bill/status/2018/S.92> (last visited November 27, 2019).



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- 271 For example, the National Medicaid Pooling Initiative. *See* National Conference of State Legislatures, *Pharmaceutical Bulk Purchasing* (May 29, 2019), www.ncsl.org/research/health/bulk-purchasing-of-prescriptiondrugs.aspx (last visited December 17, 2019).
- 272 According to MMCAP, members enjoy an average savings of approximately 23.7% below AWP for brand name drugs and 65% below AWP for generics. National Conference of State Legislatures, *Pharmaceutical Bulk Purchasing* (May 29, 2019), www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx (last visited December 17, 2019).
- 273 MMCAP, for instance, is restricted to governmental and certain nonprofit entities. National Conference of State Legislatures, *Pharmaceutical Bulk Purchasing* (May 29, 2019), www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx (last visited November 27, 2019).
- 274 *See, for example,* Minnesota's Prevention of Consumer Fraud Act at Minn. Stat. §§ 325F.68-70.
- 275 United States Department of Health and Human Services, Office of Inspector General, *State False Claims Act Reviews* (2019), <https://oig.hhs.gov/fraud/state-false-claims-act-reviews/> (last visited December 17, 2019). The federal False Claims Act is found at 31 U.S.C. § 3729.
- 276 *See* National Conference of State Legislatures, Prescription Drug Resource Center, *State Actions to Halt Price Gouging for Generic Drugs* (July 20, 2018), www.ncsl.org/Portals/1/Documents/Health/Generic_drug_antiprice_gouging_Maryland_31894.pdf (last visited December 17, 2019).
- 277 *Assoc. for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018), cert. denied, No. 18-546 (April 13, 2018).
- 278 42 C.F.R. § 447.505; *see also* Ramsey Baghdadi, *Health Policy Brief: Medicaid Best Price*, Health Affairs (August 10, 2017), www.healthaffairs.org/doi/10.1377/hpb20171008.000173/full/ (last visited December 17, 2019).
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- 282 *See, e.g.,* 5 Me. Rev. Stat. §§ 2401 *et seq.*; *see also* Selena Simmons-Duffin, *Florida Wants to Import Medicine from Canada. But How Would That Work?*, National Public Radio (June 18, 2019), www.npr.org/sections/healthshots/2019/06/18/733483431/florida-wants-to-import-medicine-from-canada-but-how-would-that-work (last visited December 17, 2019).
- 283 Sammy Almashat *et al.*, *Twenty-Seven Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2017*, Public Citizen, at 4 (March 14, 2018), www.citizen.org/article/twenty-seven-years-of-pharmaceutical-industry-criminal-and-civil-penalties-1991-through-2017/ (last visited November 27, 2019).
- 284 *Id.* at 6.
- 285 The discussion herein of this consequential AWP litigation, and the changes to the law it prompted, is based on an article by Paul Nolette, *Law Enforcement as Legal Mobilization: Reforming the Pharmaceutical Industry Through Government Litigation*, 40 Law & Social Inquiry 123 (Winter 2015).
- 286 *Id.* at 129-30.



- 287 See National Academy of State Health Policy, *Model Legislation: Affordability Review* (2019), <https://nashp.org/policy/prescription-drug-pricing/model-legislation/#toggle-id-3> (last visited December 2, 2019).
- 288 See National Academy of State Health Policy, *Comparison Chart of States' Affordability Review Board Bills* (March 19, 2019), <https://nashp.org/comparison-of-bills-creating-state-prescription-drug-affordability-reviewboards/> (last visited December 26, 2019).
- 289 See generally Food & Drug Administration, *Importation of Prescription Drugs*, 84 Fed. Reg. 70,796 (December 23, 2019), www.govinfo.gov/content/pkg/FR-2019-12-23/pdf/2019-27474.pdf (last visited on December 26, 2019).
- 290 Specifically, the bill provides that the Minnesota Board of Pharmacy, the Minnesota Department of Human Services, and private health plans must notify the Attorney General of any increase of 15% or more in the price of any essential prescription drugs sold in Minnesota.
- 291 See, e.g., Minn. Stat. § 325F.67, Minn. Stat. § 325F.69, and Minn. Stat. 325D.44.
- 292 See The National Consumer Law Center, *Consumer Protection in the States: A 50-State Evaluation of Unfair and Deceptive Practices Laws*, Map 2 (March 2018), www.nclc.org/images/pdf/udap/udap-report.pdf (last visited December 2, 2019) (noting that consumer protection statutes in 39 states include prohibitions against unfair or unconscionable conduct).
- 293 See 42 USC § 1320a-7b(b) (anti-kickback law); see also 42 USC § 1395nn (Stark law).
- 294 Currently, federal anti-kickback restrictions are effectively a stopgap measure until Minnesota enacts its own anti-kickback rules. See Minn. Stat. § 62J.23. This state statute, however, only vaguely references “restrictions” in federal law, and does not appear to explicitly adopt at least two important pieces of the federal anti-kickback statute: criminal liability and *per se* materiality in enforcement of the Minnesota False Claims Act.
- 295 See Section III.F.1 (discussing how copay coupons incentivize persons to use expensive, brand name drugs).
- 296 See, e.g., Sections II.A.1 (discussing how the drug industry is unique and often does not function like other markets), III.C (discussing various anticompetitive practices present in the drug industry).
- 297 See, e.g., Minn. Stat. 325D.51 (rendering unlawful “unreasonable” restraints on trade, without defining the term “unreasonable”).
- 298 California Assembly Bill No. 824 (2019), https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200AB824 (last visited December 11, 2019).
- 299 For example, in 2013, the FTC created a regulation specifically stating that transfers of patent rights to drugs are reviewable. 16 C.F.R. §§ 801.1(o) to (q), 801.2(g).
- 300 Improving Access to Affordable Prescription Drugs Act, S. 771 (115th Congress 2017-18).
- 301 NACHC 340B Manual for Health Centers (2d Ed. March 2018) at 6 (noting that the rules and expectations for 340B are “significantly less clear” than other federal programs and maintaining compliance “requires an on-going investment of significant resources and attention”)



- 302 See generally Section IV.A.2 (discussing strategies to increase purchasing power).
- 303 The Northwest Prescription Drug Consortium (“NPDC”) is a government-run organization similar to MMCAP INFUSE in that it offers participating private residents the opportunity to use a free prescription-drug card. NPDC reports that it is able to leverage its purchasing power to obtain an average discount of 80% on generic drugs, and 20% on brand name drugs. In 2018, those discounts were used by nearly 240,000 individuals who saved roughly \$10.8 million, when compared to usual and customary pricing. See generally Washington State Health Care Authority, *NW Prescription Drug Consortium & Washington Prescription Drug Program* (this slideshow is on file with Ms. Sadaf Rahmani, the staff liaison from the Minnesota Attorney General’s Office to the Task Force).
- 304 MMCAP INFUSE currently utilizes regional sales executives to connect with potential new clients and promote awareness at trade shows, for example. MMCAP INFUSE has had success with regional/local initiatives as an introduction or entryway into learning about MMCAP INFUSE services. For example, select emergency medical services and police departments are utilizing MMCAP INFUSE for Narcan purchases at discounted pricing. As these departments become aware of MMCAP INFUSE savings and services, the awareness and desire to expand usage of MMCAP INFUSE grows.
- 305 See Minn. Stat. § 471.59
- 306 Minnesota may look to legislation in Texas as an example of legislation that addresses ascertaining drug prices and publishing that information online. The Texas law requires drug manufacturers to submit a report stating the wholesale acquisition cost information for certain drugs; and to submit additional information if the wholesale acquisition cost increases by a certain amount. The agency must then publish general public drug price information on a website. See Texas HB 2536 (86th Legislature 2019-20), <https://legiscan.com/TX/text/HB2536/id/1932058> (last visited December 18, 2019); see also Dena Bunis, *Texas Governor Signs Prescription Price Transparency Bill*, AARP (June 17, 2019), www.aarp.org/politics-society/advocacy/info-2019/texas-prescription-drug-price-bill.html (last visited December 18, 2019).
- 307 See generally United States Department of Health and Human Services, Center for Medicare and Medicaid Services, *Critical Access Hospitals* (July 2019), www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CritAccessHospfctshst.pdf (last visited December 2, 2019).
- 308 For example, HealthPartners initiated a diabetes pilot program to determine MTM’s effectiveness, which revealed a projected cost savings of \$967,000 based on reduced hospital admissions and emergency room visits for their patient. See Dan Rehrauer, PharmD, Senior Manager, Medication Therapy Management Program and Community Pharmacy Partnerships, HealthPartners, *Presentation to Advisory Taskforce on Lowering Pharmaceutical Drug Prices* at slide 9 (September 25, 2019) (this presentation to the Task Force and the information contained therein are on file with Ms. Sadaf Rahmani, the staff liaison from the Minnesota Attorney General’s Office to the Task Force).
- 309 See Minn. Stat. § 151.01, subd. 27.
- 310 See Minn. Stat. § 151.555.
- 311 MDH Prescription Drugs Report at 1-2.







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