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:

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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.)

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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.)

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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 paractice 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.

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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.)

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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.)

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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.