



**Minnesota House File 4
Drug Manufacturer and Wholesale Distributor Price Controls
March 12, 2020**

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes House File 4 (HF4), which would impose price controls on the biopharmaceutical industry.

PhRMA represents the country's leading innovative biopharmaceutical research and biotechnology companies, which are devoted to discovering and developing new medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than \$900 billion in the search for new treatments and cures, including an estimated \$79.6 billion in 2018 alone.

Today, we are living in a new era of medicine. In 2019, fifty-six new medicines were approved, and currently there are 8,000 medicines in the pipeline. Seventy four percent of those medicines in development have the potential to be first in class treatments, representing a brand-new way to treat a condition. The industry is working tirelessly to bring new treatments to approval, but the process is risky, long and expensive, often taking more than 10-12 years and costing nearly \$2.6 billion to bring a drug to market according to Tufts University. In addition, only about twelve percent of drug candidates that make it into clinical testing actually receive FDA approval. Despite the risk, the effort is worth it when patients can access new treatments that can change their lives for the better.

Despite the incredible advances in innovative medicines, progress is useless if the patient cannot afford the treatment. That is why PhRMA is committed to addressing patient affordability challenges in several ways. It is more important than ever that public policies on the state and federal level support the industry's commitment to innovation, keeping in mind the challenges of research and development. Policies that harm or undermine this effort can mean a delay in bringing treatments to patients who desperately await relief and cures.

HF 4 attempts to address the issue of what a consumer pays for a prescription medicine by placing a price control on biopharmaceutical manufacturers. This legislation does not account for insurance benefit design issues that prevent discounts from flowing to patients and HF 4 assumes incorrectly that the price of a drug is determined solely by drug manufacturers.

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

the amount a patient ultimately pays—use their control over which medicines patients can access as leverage to negotiate substantial rebates and discounts. PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately \$166 billion in 2018,¹ do not make their way to offsetting patient costs at the pharmacy counter.

According to new research from the Berkeley Research Group (BRG), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year, while the share received by manufacturers has decreased over time. In 2018 manufacturers retained only 54% of brand medicine spending while members of the supply chain retained 46%.² Increased rebates and discounts have largely offset the modest increases in list prices noted and reflect the competitive market for brand medicines.

Growth in prescription drug spending is at a historic low, and prescription drug costs are expected to remain a relatively small and stable share of total health care costs into the future. According to the IQVIA Institute (formerly the IMS Institute), net spending on medicines grew only 0.3% in 2018; and the Centers for Medicare and Medicaid Services reported that growth in retail prescription drug spending was only 2.5% in 2018. At the same time, overall prescription drug prices declined by 1%. This, of course, does not necessarily reconcile with what patients are feeling at the pharmacy counter, which is why looking at the whole system is so important.

The bill raises constitutional concerns.

The Minnesota proposed language directly interferes with manufacturers' ability to price their products by allowing the Attorney General to enjoin them from raising prices, to impose a price ceiling, and to force disgorgement of profits from "unconscionably" priced drugs. The Federal Circuit struck down substantially similar D.C. legislation in the case of *BIO v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 1997), reasoning that the D.C. law at issue conflicted with the underlying objectives of the federal patent framework by undercutting a company's ability to set prices for its patented products.

The proposed language raises constitutional concerns because it would restrict the goal of federal patent law, which is to provide pharmaceutical patent holders with the economic value of exclusivity during the life of a patent. Congress determined that this economic reward provides appropriate incentive for invention and Minnesota is not free to diminish the value of that economic reward.

Additionally, in 2018, a similar price gouging law in Maryland was found to be unconstitutional under the dormant Commerce Clause of the U.S. Constitution and struck down. The Fourth Circuit decided 2-1 that law was unconstitutional because it directly regulates the price of transactions that occur outside of Maryland. *AAM v. Frosh*, 887 F.3d 664 (4th Cir. 2018).

For the reasons described above, PhRMA urges legislators to reject HF4.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research and biotechnology companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. In Minnesota, the biopharmaceutical industry employs over 7,500 individuals and the industry generates a total economic impact of \$10.5 billion per year. Additionally, the biopharmaceutical industry contributed approximately \$543 million in prescription drug rebates to the Minnesota Medicaid programs in 2017.

¹ Drug Channels Institute. "The Gross-to-Net Bubble Reached a Record \$166 Billion in 2018." April 2019

² BRG: Revisiting the Pharmaceutical Supply Chain 2013-2018. January 2020.