



**Minnesota House File 1183  
Drug Manufacturer and Wholesale Distributor Price Controls  
February 23, 2021**

**Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes House File 1183 (HF 1183), 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 nearly \$1 trillion in the search for new treatments and cures, including an estimated \$83 billion in 2019 alone.

Today, we are living in a new era of medicine. In 2019, 56 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.<sup>1</sup> 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 12% 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 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 1183 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 1183 incorrectly assumes that manufacturers determine what a patient pays at the pharmacy.**

This legislation singles out the biopharmaceutical industry and ignores the variety of stakeholders involved in determining what consumers ultimately pay for a medicine, including insurers, pharmacy benefit managers (PBMs), wholesalers, and the government. The important role that these entities play in determining drug 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

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<sup>1</sup> 2020 Profile Biopharmaceutical Research Industry, [http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Industry-Profile-2020\\_1.pdf](http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/Industry-Profile-2020_1.pdf).

ultimately pays—negotiate substantial rebates and discounts. PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately \$175 billion in 2019,<sup>2</sup> do not make their way to offsetting patient costs at the pharmacy counter.

According to research from the Berkeley Research Group (BRG), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year, while the share received by manufacturers has decreased over time. In 2018 manufacturers retained only 54% of brand medicine spending while members of the supply chain retained 46%.<sup>3</sup> 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 1.7% in 2019; and the Centers for Medicare & Medicaid Services reported that growth in retail prescription drug spending was only 2.5% in 2018.<sup>4</sup> 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.**

This proposal raises constitutional concerns under the Supremacy Clause because it would restrict the goal of federal patent law, which is to provide pharmaceutical patent holders with the economic value of exclusivity during the life of a patent. Congress determined that this economic reward provides appropriate incentive for invention and Minnesota is not free to diminish the value of that economic reward. Specifically, in the case of *BIO v. District of Columbia*, 496 F.3d 1362 (2007), the U.S. Court of Appeals for the Federal Circuit overturned a District of Columbia law imposing price controls on branded drugs, reasoning that the law at issue conflicted with the underlying objectives of the federal patent framework by undercutting a company’s ability to set prices for its patented products.

This legislation also raises other constitutional concerns, such as under the Dormant Commerce Clause. In *AAM v. Frosh*, 887 F.3d 664 (2018), the U.S. Court of Appeals for the Fourth Circuit overturned a law in Maryland on Dormant Commerce Clause grounds because it directly regulated the price of transactions that occurred outside of the state.

For the reasons described above, PhRMA urges legislators to reject HF 1183.

*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 directly employs over 7,600 individuals and the industry generates a total economic output of \$9.8 billion per year.<sup>5</sup> Additionally, the biopharmaceutical industry contributed approximately \$524 million in prescription drug rebates to the Minnesota Medicaid programs in 2018.<sup>6</sup>*

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<sup>2</sup> Fein, A. “The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers,” Drug Channels Institute. March 2020.

<sup>3</sup> BRG: Revisiting the Pharmaceutical Supply Chain 2013-2018. January 2020.

<sup>4</sup> IQVIA Institute, Medicine Spending and Affordability in the United States. August 2020. Centers for Medicare & Medicaid. “National Health Expenditure Data, Historical 2019.” December 2019.

<sup>5</sup> Biopharmaceutical Sector Impact on Minnesota’s Economy, [http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA\\_GB\\_StateFactSheet/PhRMA\\_GB\\_StateFactSheet\\_2019\\_Minnesota.pdf](http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_GB_StateFactSheet/PhRMA_GB_StateFactSheet_2019_Minnesota.pdf).

<sup>6</sup> The Facts About Medicaid in Minnesota, [http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2019/MN-One-Pager\\_19.pdf](http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2019/MN-One-Pager_19.pdf).