STATEMENT

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Opposition Statement to Minnesota House File 1246
Advance Price Notification and Transparency
March 10, 2020

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes HF 1246, legislation that would, among other things, require prescription drug manufacturers to provide 60-day advance notification of certain price increase as well as significant reporting. HF 1246 will not help patients and could threaten access to needed prescription medications and the innovation of future treatments.

Discussions about the cost and affordability of medicines are important. Patients should not need to worry about affording the health care they need. However, the notion that spending on medicines is the primary driver of health care cost growth is false - and ignores cost savings that medicines provide to the health care system overall. Medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs. New medicines are making crucial contributions to medical advances, changing the direction of healthcare as we know it. This bill is likely to skew discussions of policy issues in ways that are systematically biased against innovation.

The net prices for all medicines grew just 0.3 percent in 2018, less than the rate of inflation, according to IQVIA. Other categories of services account for far larger increases in premiums and heath costs, yet this bill focuses on requiring prescription drug manufacture reporting, and does so based on a price metric, wholesale acquisition cost (WAC), that does not reflect what purchasers actually pay, thus overstating costs for medicines.

Proposals to mandate disclosure of proprietary information by biopharmaceutical companies would neither benefit patients nor decrease healthcare costs.

The biopharmaceutical industry is one of the most heavily regulated industries in the United States. Companies already report extensive information on costs, sales, clinical trials, and total research and development (R&D) expenditures. Neither HHS nor FDA are permitted to disclose this type of information, even if requested.

Proposals to mandate public disclosure of proprietary information by biopharmaceutical companies would create unprecedented, burdensome requirements that could disrupt effective market competition and increase health care costs. These damaging proposals ignore the large amount of information already publicly reported by companies and are based on the faulty assumption that prescription drug spending is the major driver of increases in healthcare costs.

Calculating drug development costs by product would not be reflective of total investment because of the long-term nature of research and development. Manufacturers pursue research efforts that include many failures and iterations on the path to development of a single approved drug. Accounting for all the research activities that informed the development of a single product would be overly burdensome and challenging given research costs are often spread across long periods of time, a wide range of therapeutic areas, and include a range of precompetitive and other research that would be difficult if not impossible to attribute to a single product. Additionally, much of the information that could be required to be disclosed is considered protected, confidential corporate information, is protected by federal and state law, and includes substantial competitive information. Mandating disclosure of proprietary trade secrets would damage competition and increase costs.

Further, the legislation does not account for the value provided by innovative therapies. It is important to remember that these advances help control health care spending. Greater patient access to prescription medicines means fewer doctor visits and hospital stays and a decrease in costly medical procedures, all of which translate into lower health care costs overall. For example, in 2014, a new drug came to the market that provided a cure for more than 90% of patients with hepatitis-C, eliminating a lifetime of hospitalizations, debilitating symptoms, and treatments with harsh side effects and replacing it with a complete cure in just 12 weeks. Since 2014, several new treatment/cures have come to the market, further driving down the price of the medicine. Clearly, innovation and progress in the pharmaceutical industry means better outcomes and quality of life for patients and their families as well as reduced healthcare costs to patients and the system.

The advance notice provisions could be harmful to the market and to future innovation.

HF 1246 would require manufacturers to provide advance notification of WAC price increases. Providing notice of WAC increases or prices does not account for rebates, discounts, and other price concessions on these drugs and thus does not accurately reflect the true cost to an insurer. According to the IQVIA Institute, in 2017, brand prescription medicine invoice prices (~WAC prices) increased by 6.9 percent, but their net prices only increased by 1.9 percent once rebates and discounts paid to insurers by biopharmaceutical manufacturers were included in the calculation. Patient premiums are only impacted by the net price because that is the amount that insurers actually pay. Thus, the vast majority of the increases, balanced against the significant manufacturer discounts, when taken together, will not have any impact on a plan's overall costs.

Advance notification of WAC price increases creates financial incentives for secondary distributors to enter the pharmaceutical supply chain thus creating a "gray" market. Gray market distribution networks consist of several different companies – some doing business as pharmacies and some as distributors – that buy and resell medicines to each other before one of them finally sells the drugs to a hospital or other health care facility. As the medicines are sold from one secondary distributor to another, the possibility of counterfeit medicines augmenting the supply of legitimate medicines increases, thereby threatening patient safety. In the past, this type of purchasing has caused great difficulty for hospitals. During medicine shortages, hospitals are sometimes unable to buy medicines from their normal trading partners, usually one of the three large national "primary" distributors, AmerisourceBergen, Cardinal Health, or McKesson.

At the same time, hospitals are deluged by sales solicitations from gray market companies offering to sell the shortage medicines for prices that are often hundreds of times higher than the prices they normally pay.

Notification of a 16% WAC price increase on any drug during a more than two-year period does not reflect a true understanding of the current practice of drug pricing and rebating in the country. Such notification could result in voluminous reporting on price increases that will in no way assist in making thoughtful changes to formulary design or budgeting decisions.

In practice, the process is staggered. Pharmaceutical manufacturers make independent pricing decisions, so the timing of WAC price increases varies. And, to complicate matters, a given company may not take a price increase on all of their drugs on the same day. Thus, there could literally be a price change for some product by some company on well over 100 days in a given year.

Finally, advance notification of price increases does not help shed light on cost savings that plans receive when a branded drug becomes available as a generic during a plan year, often providing significant cost savings to the plan. In other words, an increase in one or a limited number of drugs does not necessarily mean a plan will have a net increase in overall prescription costs. A vast increase in one drug's price can be offset by the introduction of generic drugs in the market.

Drug costs are the only costs in the health care system that diminish over time.

It is important to note that medicines are the *only* part of the health care system where costs decrease over time. When brand name medicines face brand competition, or when they lose their patent protection and generic drugs become available, prices drop, often significantly. Today, nearly 90% of all medicines dispensed in the United States are generic and cost pennies on the dollar. One component of health insurance, however, is seeing significant increases. Health insurance and plan administration costs are rising at more than twice the rate of drug spending.

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.

If the intent of HF 1246 is to improve access and affordability to needed medicines, the language of the bill is misguided.

The intent of the legislation is misguided. If the intent is to help patients better understand drugs

[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.

costs, this bill will in no way serve that educational purpose. The legislation does nothing to address how much consumers ultimately pay for a medicine; an amount determined by insurers not biopharmaceutical companies. Recent data shows that insurers are increasingly requiring patients to pay exorbitant out-of-pocket costs to access the medicines they need, far more than other health care services covered by an enrollee's health plan. This is contrary to the purpose of insurance—to spread the costs of health care utilization so that patients can access affordable needed care, including medicines.

Today, a patient pays only about 5% for out-of-pocket hospital costs but 20% or more for their medicines. Additionally, insurers are increasing utilization management techniques to aggressively restrict a patient's use of medicine. Currently, three major pharmacy benefit managers (PBMs) negotiate steep discounts on prescription drugs for more than 70 percent of all prescriptions filled in the United States—Express Scripts alone covers 90 million Americans. Each time a PBM or other entity achieves a larger discount on a drug purchased in the commercial market than the federal minimum rebate of 23.1% of average manufacturer price (AMP), state Medicaid programs benefit immediately without having to do anything—because by federal law, states must receive the best price that any commercial entity receives for a drug. In addition, state Medicaid programs are insulated from prices that increase faster than inflation. Specifically, the Centers for Medicare and Medicaid Services charges an additional rebate called the "inflation penalty" any time the price percent of increase is greater than the percent increase of the Consumer Price Index-Urban (CPI-U). All of this happens automatically for the state.

The biopharmaceutical industry is committed to working with Minnesota lawmakers, patients, doctors, and other health care stakeholders to pursue policies that promote innovation and help ensure consumers have access to needed medicines. However, HF 1246 is not the way to accomplish this important goal and, therefore, PhRMA respectfully urges lawmakers to oppose this bill.

PhRMA opposes HF 1246 for the above stated reasons. Please vote "NO" on HF 1246.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing 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.