STATEMENT

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In Opposition to House Bill 1032 –
Prescription Drug Cost Transparency Legislation
January 6, 2021

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes House Bill 1032, which would require significant reporting mandates, will not help patients, could threaten access to needed prescription medications, and potentially chill the innovation of future treatments.

Discussions about cost and affordability of medicines are important. No patient should have to worry about whether they can afford 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 and changing the direction of health care as we know it. With more than 4,500 medicines in the pipeline (74% which have the potential to be first in class medicines and 42% of which could be personalized medicines), patients have greater hope than ever before. However, this transparency bill is likely to skew important discussions of policy issues in ways that are systematically biased against innovation and ignores the value of medicines to patients, the overall health care system, and the economy of North Dakota.

Proposals to mandate *additional* disclosure of proprietary information by biopharmaceutical companies would neither benefit patients nor decrease health care costs.

The biopharmaceutical industry is one of the most heavily regulated industries in the United States. Companies currently report extensive information on costs, sales, clinical trials, and total research and development (R&D) expenditures in 10-K filings. Proposals to mandate public disclosure of additional confidential and proprietary information by biopharmaceutical companies ignore the large amount of information already publicly reported on an annual basis by companies and are based on the faulty assumption that prescription drug spending is the major driver of increases in health care costs.

The reporting requirements for manufacturers do not reflect the total investment of industry 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. In fact, according to Tuft's Center for Study of Drug Development (CSDD), only 12% of medicines in the pipeline make it through the approval process by the federal Food and Drug Administration (FDA).[1] An 88% failure rate underscores how expensive and risky drug development is.

Drug costs are the *only* costs in the health care system that *decrease* over time due to market changes, such as brand to brand competition and patent expirations.

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. In fact, it is projected that from 2019-2023, there will be approximately $105 billion in savings due to competition from generic and biosimilar products as patents for brand

1 Tufts Center for the Study of Drug Development (CSDD), "Briefing: Cost of Developing a New Drug," Nov 2014.
2 QuintilesIMS Institute, "Medicines Use and Spending in the U.S." May 2017.

medicines expire.[2] In addition, nearly 90% of all medicines dispensed in the U.S. are generic and cost pennies on the dollar.[3] Generics offer a cheaper alternative for patients when their health care provider deems a generic appropriate. However, one component of health spending that is not decreasing, is health insurance. Instead, it is seeing significant increases. Between 2007 – 2017, deductibles for patients have tripled and co-insurance has doubled. The Kaiser Family Foundation has routinely shown patient costs are increasing faster than insurers' costs. Morevover, health insurance and health plan administration costs are rising at more than twice the rate of drug spending.

According to new research from the Berkeley Research Group (BRG), rebates, discounts, and fees paid by manufacturers, are on the increase, while the share received by manufacturers has decreased over time.[4] In fact, nearly half (46%) of total spending on brand medicines went to the supply chain and other entities in 2018. This is a 13%-point increase from 2013, when other stakeholders retained 33% of brand medicine spending. This data reaffirms that we need to look at the entire supply chain in order to solve patient affordability challenges. Misaligned incentives must be fixed in the supply chain, including the broken rebate system, to ensure patients benefit at the pharmacy counter from the significant discounts and rebates.

In addition, brand and generic biopharmaceutical companies, unlike other sectors of health care, generated $41 million in rebates to the State of North Dakota and federal government in 2018. This is 55% of the total Medicaid spending on prescription drugs in the state.[5]

If the intent of House Bill 1032 is to improve access and affordability to needed medicines, the language of the bill is misguided.

The legislation does nothing to address how much consumers ultimately pay for a medicine, an amount determined by insurers, *not* biopharmaceutical companies. This legislation should do something to help patients afford their prescription medicines, such as passing on the rebates directly to the patients at the point of sale at the pharmacy counter. Instead, these rebates are going to the plans and other supply chain stakeholders. Recent data shows that insurers are increasingly requiring patients to pay exorbitant out-of-pocket (OOP) costs to access the medicines they need, far more than other health care services covered by an enrollee's health plan. A recent IQVIA study that looked at OOP patient spending for brand name medicines from 2015 – 2019 and showed that patient's spend on deductibles and co-insurance accounted for more than 2/3 of total OOP spend for brand medicines in five out of seven therapy areas examined. For two therapy areas (oncology and multiple sclerosis), it accounted for more than 90%.[6] This occurrence is contrary to the purpose of insurance—to spread the costs of health care utilization, so that patients can access needed care, including medicines.

Today, a patient pays only about 3% for OOP hospital costs, but 13% or more for their medicines.[7] 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% of all prescriptions filled in the U.S. Express Scripts alone covers about 90 million Americans.[8]

The biopharmaceutical industry supports over 800 jobs in North Dakota, with a generous annual average compensation

3 IQVIA Institute Drug Channels Institute
4 Berkeley Research Group (BRG). Revisiting the Pharmaceutical Supply Chain: 2013-2018. http://www.thinkbrg.com/newsroom-publications-revisit-pharma-supply-chain.html
5 The Facts About Medicaid in North Dakota. http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2019/ND-One-Pager_19.pdf.
6 Spending and Affordability in the U.S., Aug. 4, 2020. http://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us
7 Avalere Health analysis of the US Department of Health and Human Services, Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey, 2015. http://meps.ahrq.gov/mepsweb. Accessed February 2018 (analysis includes individuals with any source of health care coverage, public or private; this includes individuals who had health coverage without coverage for prescription drugs, which can be expected to account for less than 2% of those with health coverage).
8 http://lab.express-scripts.com/lab/drug-trend-report
9 Biopharmaceutical Section Impact on North Dakota's Economy. http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_GB_StateFactSheet/PhRMA_GB_StateFactsheet_2019_North-Dakota.pdf.

of $80,097 per year, as compared to the average job salary in North Dakota of $56,226. That translates into $10 million in both state and federal taxes annually, as well as a total annual economic output of $207 million for the state. The industry is committed to working with lawmakers, patients, doctors, and other health care stakeholders to pursue policies that promote manufacturing, R&D, and innovation, while ensuring consumers have access to needed medicines.

Prescription medicines have transformed the trajectory of many debilitating diseases and conditions, including COVID-19, HIV/AIDS, cancer, and heart disease, resulting in decreased death rates, improved health outcomes, and better quality of life for patients. Better use of medicines could eliminate up to $213 billion in U.S. health care costs annually, which represents 8% of the nation's health care spending.[10] Therefore, instead of focusing on reporting of information that does nothing to help the patient, perhaps the conversation should focus on better use of medicines, which yields significant health gains by avoiding the need for other, more costly, medical services.

House Bill 1032 is not the way to accomplish improved access and affordability, therefore, PhRMA respectfully urges North Dakota lawmakers to oppose this bill.

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.

10 Su W, Lockwood C; IHS Markit. Comparing health outcome differences due to drug access: a model in non-small cell lung cancer. http://cdn.ihs.com/www/prot/pdf/0119/IHSM_NSCLC%20HTA%20model%20white%20paper_18Jan2019r.pdf. Published December 13, 2018.