In Opposition to Nevada Senate Bill 265  
March 29, 2017

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) strongly opposes Nevada SB 265 because, among other concerns, it would negatively impact patients in Nevada and nationwide. While the bill as drafted purports to offer cost savings to consumers, in practice, it would most likely provide third parties such as insurers with a windfall instead. Further, SB 265 requires prescription drug manufacturers to report significant information related to drug pricing—that is proprietary and would be difficult, if not impossible, for a manufacturer to provide. SB 265 also requires prescription drug manufacturers to provide advance notification of certain price increases; such advance notification could have significant and harmful effects on the market and on future innovation. The bill will not help patients and, instead, could threaten access to needed prescription drugs and the innovation of future treatments.

Discussions about the cost and affordability of medicines are important. No patient should have to worry about whether he or she can afford needed health care services or items. However, the notion that spending on medicines constitutes the primary driver of health care cost growth is false - and it ignores the significant cost savings that medicines provide to the overall health care system. 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, thereby changing the nature and success of healthcare interventions as we know them. SB 265 myopically targets drug spending in ways that will likely have long-term, harmful effects on innovation and the development of new, life-saving therapies.

SB 265 would likely produce severe disruption and uncertainty in the marketplace for diabetes drugs, potentially jeopardizing patient access to critically important treatments and chilling innovation of future diabetes therapies.

Diabetes is among the top 10 causes of death in the United States, and, while it’s reassuring that death rates from diabetes are declining, the number of Americans diagnosed with diabetes has more than tripled since 1980, making the need for such innovative medicines greater. According to the CDC, in 2012 diabetes ranked 7th in the leading causes of death in Nevada.1

America’s biopharmaceutical researchers are persistent in their efforts to develop novel therapies to treat this complex and challenging disease and to improve the quality of life for patients. In 2016, there were 171 medicines in development for Type 1 and Type 2 diabetes and diabetes-related conditions, such as chronic kidney disease and diabetic neuropathy. SB 265 undermines efforts to develop such new, critical therapies.
As drafted, SB 265 does not meaningfully provide consumer cost savings given that insurers may collect these refunds and are not required to pass them on to consumers. Further inspection makes clear that the ultimate beneficiaries of this proposal are likely third parties such as insurers.

SB 265 also overlooks the key fact that manufacturers already pay substantial rebates to third parties and pharmacy benefit managers. A recent IMS report stated that the average rebate across all payers and supply chain entities is 38%.iii

In 2015, pharmaceutical manufacturers paid $181 million in brand and generic rebates (mandatory and supplemental) on Nevada’s Medicaid drug utilization alone. Nevada’s share of those rebates, mandatory and supplemental, was $65 million and the federal government received $116 million.vi These rebates are the product of a competitive marketplace that could vanish if the state eliminates incentives for negotiation, potentially resulting in greater costs to the state and the federal government. Researchers who previously examined price control measures in other countries have noted that they could lead to loss of other voluntary rebates.

Numerous studies document the correlation between decreased access to medicines and poor health outcomes. Price controls in other countries have resulted in fewer medicines and treatments for patients as compared to those in the United States and other developed countries. From 2008-2011, the United States saw 94 new molecular entities become available to patients, in contrast to just 88 in the United Kingdom and 63 in Canada.iv

**Proposals to mandate disclosure of significant 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. Yet, this information remains protected by confidentiality provisions – even when it is disclosed to HHS and the FDA. These confidentiality provisions help ensure manufacturers need not disclose proprietary and other sensitive information.

Proposals to mandate public disclosure of proprietary information by biopharmaceutical companies would create unprecedented, burdensome requirements that could disrupt market competition and, ultimately, increase health care costs. These damaging proposals also ignore the large amount of information already publicly reported by companies.

SB 265 would require the reporting of various data that is difficult, if not impossible, for manufacturers to provide. 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 of the research activities that informed the development of a single product would be challenging, if not impossible, 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.
Ultimately, it is important to remember that novel 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. Any legislation that is put forward should acknowledge this and not dis-incentivize innovation.

**Advance notification provisions could be harmful to the market and to future innovation.**

SB 265 requires prescription drug manufacturers to provide 90 days advance notice of a planned price increase to the wholesale acquisition cost (WAC) that is greater than the Consumer Price Index, Medical Care Component, for the 12-months immediately preceding the date which notification is required, to the each third-party – an insurer, a health benefit plan, a participating public agency, or any other insurer or organization that provides health coverage. SB 265 requires the Department of Health and Human Services, in consultation with the Commissioner of Insurance, to maintain a database of third-parties in Nevada and provide this information to manufacturers when requested. Antitrust and other laws prevent competitors from “signaling” pricing decisions to competitors or engaging in conduct with competitors that could be viewed as collusion. By requiring manufacturers to report price increases, SB 265 creates potential for signaling to competitors (or testing the market regarding) planned pricing and price changes. This could encourage action by the company providing notice and its competitors that could lead to parallel price increases (as only one example of possible behavior). This can create an artificial price floor rather than a price ceiling, with the result that the advance notice requirement could actually unwittingly lead to an overall increase in such costs to the detriment of health insurance plans and their participants locally and, more importantly, nationwide.

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 a number of 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.

The CPI for medical care, unadjusted for the 12 month period ending in February 2017 was 3.5%. Notification of a 3.5% WAC increase on any drug during a 12 month period does not reflect a true understanding of the current practices of drug pricing and rebating in the county. 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. The proposal also has significant practical limitations. For instance, a given company may not take a price increase on all of its 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.
Requiring nonprofit organizations that advocate on behalf of patients or funds medical research to disclose contributions received from a manufacturer could be detrimental to research activities.

At a time when the public is relying on services provided by nonprofit organization that advocate on behalf of patients or fund medical research, state should not create perceived obstacles that prevent nonprofit organizations from receiving funds for their activities that advocate for patients or fund medical research. According to the Internal Revenue Service, “A tax-exempt organization is generally not required to disclose publicly the names or addresses of its contributors set forth on its annual return, including Schedule B.” IRS regulations specifically exclude this information from the definition of “disclosable documents.”

Pharmaceutical sales representative licensure provisions are unnecessary in light of extensive federal regulation of drug marketing.

The federal Food Drug and Cosmetic Act and extensive associated regulation apply to prescription drug manufacturers’ marketing to physicians. SB 265 creates unnecessary additional bureaucracy and administrative costs around marketing. It also defines a pharmaceutical sales representative in an overly broad manner that could potentially include individuals who do not carry out a marketing or sales function on behalf of a manufacturer or distributor, such as medical science liaisons, medical managers, regional scientific managers, or scientific affairs managers.

SB 265 requires that a pharmaceutical sales representative who conducts business in the State for fifteen days or more per calendar year must hold a valid license. There is no instruction on how to calculate fifteen days of business. This bill could have the net effect of discouraging activities, such as product launches, annual and regional sales meetings, and medical educational symposium and conferences that pharmaceutical sales representatives are likely to attend.

The biopharmaceutical industry is committed to working with Nevada lawmakers, patients, health care providers and other health care stakeholders to pursue policies that promote innovation and help ensure consumers have access to needed medicines. However, SB 265 is not the way to accomplish this important goal. Instead, SB 265 would stifle innovation and damage marketplace competition between manufacturers. It would mandate potentially harmful price caps, on the basis of prices that do not reflect the true amounts that purchasers actually pay. And there is no guarantee that any “refunds” under the bill would accrue to consumers – who should ultimately be the target of any legislation addressing health care costs. Therefore, PhRMA respectfully urges lawmakers to oppose SB 265.

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iii Centers for Medicare and Medicaid Services: 2015 CMS-64 reports.

