PhRMA
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August 8, 2017

Dear Members of the Colorado Commission on Affordable Health Care:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is writing in regard to the recently released Colorado Commission on Affordable Health Care 2017 Final Report, issued on June 30, 2017. As the trade association representing the country's leading innovative biopharmaceutical research and biotechnology companies, we want to address some of our concerns surrounding recommendations pertaining to pharmaceuticals and increased costs for payers and consumers.

Discussions about 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 misleading – and it ignores the significant cost savings that medicines provide to the overall healthcare system. Medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable measures – all of which translate to lower health care costs. New medicines are making crucial contributions to medical advances. This report overlooks cost offsets, benefits to patients and could discourage innovation.

Increasing Transparency

Publicly traded companies, including publicly traded biopharmaceutical firms, already make financial disclosures to the public on a quarterly basis[1] regarding costs for research & development (R&D), manufacturing/production, and a range of other business expenses. Specific data reported by biopharmaceutical companies to the federal Securities and Exchange Commission includes:

- **R&D expenses, including clinical development costs, costs of R&D acquired through mergers and acquisitions, as well as information about R&D pipelines.** The R&D costs are provided at the aggregate level and do not reflect the often substantial additional investments that pre-date the clinical phase nor reflect some of the investments that may inform research across a range of therapeutic areas.
- **Aggregate data on cost of manufacturing goods produced and sold,** also referred to as "cost of goods sold" or "cost of sales." This includes the costs of materials that are used to manufacture prescription medicines as well as labor, and overhead costs.
- **Aggregate data on "selling, general and administrative costs" reported by companies,** which includes but is not limited to marketing costs, costs associated with Patient Assistance Programs, and the Affordable Care Act prescription drug fee.

Further, a range of information on drug prices and sales are available through a wide range of sources, including:

[1] The Securities and Exchange Commission (SEC) requires quarterly reporting via 10-Q forms and annually via 10-K forms. Special notices for significant events, e.g., mergers or major acquisitions, are included at http://www.sec.gov/edgar.shtml.

- **List prices** are widely reported and available through online tools.[2] However, list or invoice prices do not reflect rebates and other discounts. In addition, pharmacy benefit managers may require patients to pay coinsurance based on the list price rather than on the price paid net of rebates and other discounts.[3]
- **Rebate and related data at an aggregate level** is included in companies' financial statements. The information can include aggregate information on rebates as well as cash discounts and other deductions.
- **Average sales price paid for drugs covered by Medicare Part B** is publicly reported by the Centers for Medicare & Medicaid Services (CMS).[4] As a condition of participating in federal healthcare programs, biopharmaceutical companies are required to provide such data.
- **Gross sales** (before rebates, wholesaler chargebacks, and other discounts are considered) **and net sales** (after the rebates and other discounts are taken out) are reported by publicly traded biopharmaceutical companies.[5]
- **Earnings** (also called net income or profit/loss) are reported in publicly traded companies' financial disclosure statements.

The report focuses on drugs and does not seek transparency across broader healthcare costs and will not guarantee any patient savings at the pharmacy counter. Drugs represent only a limited share of healthcare spend and the report does not look at other sectors, such as hospital costs, provider expenditures, long term care and others which make up a larger portion of health care spend in Colorado. In fact, in 2015, Medicaid spending on all pharmaceuticals in Colorado was only 4.6% of the total Medicaid spending.

Drug Importation

The report extolls the idea that reimportation may be an answer for patients to get access to lower cost drugs. However, importation could harm patients by introducing counterfeit, misbranded or substandard medicines into the United States' secure drug supply chain. There are numerous examples of unscrupulous individuals and entities attempting to do precisely that, which puts the lie to the claim that this is just a hyped-up concern. Imported drugs can look different (e.g., tablet color, shape, and size) and be offered in different strengths or dosage forms; this can cause confusion and uncertainty among patients if switched from an FDA-approved drug to an imported version.

Currently, 21 U.S.C. § 384 enacted in 2003, lays the groundwork for an exception that could allow personal importation of prescription drugs from Canada. This exception only becomes effective if the Secretary of HHS determines that such importation would pose no additional risk to the public's health and safety and that it would result in a significant reduction in the cost of covered products to the American consumer. Secretaries appointed by both Democratic and Republican administrations have declined to make any such determination. In fact, an HHS Task Force determined that such a program would not be cost effective, and that "American consumers making individual purchases from foreign

[2] See, for example, OptumRx's Drug List Price Search; https://www.optumrx.com/RxSolWeb/mvc/discountDrugPricing.do.
[3] K Begley. "WorldatWork You and Your PBM: Improving Discounts, Fees and Rebates, and Beyond." Aon Hewitt, 2009 Total Rewards Conference & Exhibition.
[4] Medicare Part B Average Sales Price: Manufacturer reporting of Average Sales Price (ASP) data. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html?redirect=/McrPartBDrugAvgSalesPRice/10_VaccinesPricing.asp
[5] Some companies record chargebacks and rebates separately under accrued liabilities.

sources outside our regulatory system, in particular those making long-distance purchases from internet sites or by fax or phone, face safety hazards that would be extraordinarily difficult to effectively address and prevent."[6]

Safer alternatives to importation include utilizing existing patient savings programs. In April 2005, PhRMA established the Partnership for Prescription Assistance (www.pparx.com) which offers a single point of access to more than 475 public and private patient assistance programs. PPARx brings together America's pharmaceutical companies, doctors, other health care providers, patient advocacy organizations, and community groups to help qualifying patients who lack prescription coverage get the medicines they need through the public or private program that is right for them. Many will get free or nearly free prescription drugs.

Additionally, nearly 9 out of 10 prescriptions in the U.S. are filled with generic versions of the most commonly used medicines, and are already available at much lower cost here than overseas. Generics save U.S. residents far more than any proposed importation scheme would – in 2015 alone, generics saved U.S. patients $227 billion. Generics saved Americans a staggering $1.46 trillion over the ten year period 2006 to 2015.[7] Most importantly, these savings were obtained without the risks of purchasing medicines from unknown overseas vendors or questionable Internet websites.

Biosimilars

Unlike traditional medicines which are chemically synthesized, biologic medicines are complex and manufactured from living organisms. A biosimilar product is highly similar to, but not the same as, its FDA-licensed reference biological medicines. Recent federal legislative and regulatory activity has created an abbreviated regulatory pathway for the approval of biosimilar products and states are beginning to consider legislation to ensure that patient health and safety is protected when biosimilar interchange occurs.

It is imperative that the FDA has determined a biosimilar as interchangeable and PhRMA supports provisions that place patient safety first, affirm the decision-making authority of physicians, and require that proper safeguards are in place in case of a future need for information on prior substitution of medicines.

Opportunistic Behaviors

The Commission's report calls out certain price increases for drugs such as Epi-Pen and Naloxone. Among the options presented to address this scenario, the Commission recommends that one option is to require drug manufacturers to devote a minimum percentage of revenue to research and development (R&D). In May, PhRMA made the decision to require member companies to commit to a three-year average global R&D to global sales ratio of 10 percent or greater; and a three-year average global R&D spending of at least $200 million per year. PhRMA's action to eliminate almost half of its members based on this strict research and development criteria demonstrated the commitment of the

[6] HHS Task Force on Drug Importation, Report on Prescription Drug Importation (December 2004) at XIII, *available at* http://archive.hhs.gov/importtaskforce/Report1220.pdf.

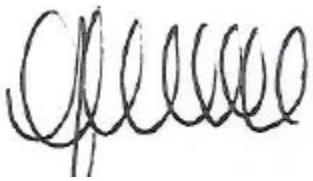
[7] Generic Pharmaceutical Association, 2016 Generic Drug Savings & Access in the United States Report, http://www.gphaonline.org/media/generic-drug-savings-2016/index.html.

industry to self-police and show a commitment that the existing members are indeed focused on innovation of products that can improve and save lives.

The Commission also makes reference to Maryland's recently enacted price gouging law. The law is poorly worded with regards to due process and the dormant commerce clause and is currently under litigation from the generic trade association, the Association for Accessible Medicines. Governor Hogan allowed the bill to become law without his signature, for this and other reasons. Additionally, the law gives broad and ambiguous powers to the Attorney General.

PhRMA appreciates the opportunity to raise some of our concerns surrounding this report and would welcome further discussions.

Sincerely,



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