STATEMENT

PhRMA
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In Opposition to Maine LD 673 (Senator Breen)

April 13, 2021

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. Since 2000, PhRMA member companies have invested nearly $1trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.

Today, rapid acting insulin, including an inhalable insulin, is offering patients dosing directly before and even after meals, rather than in anticipation of meals. For pediatric patients, inhalable insulin and insulin pens offer greater convenience, without subjecting patients to multiple needle sticks while improving adherence and reducing complications. Long-acting insulin now provides 24-hour coverage and greater flexibility in dosing, thereby reducing the risk of dangerous blood sugar drops. With more than 170 medicines in the pipeline to treat Type I and Type II diabetes, there is more hope than ever for future innovative treatments for patients.

PhRMA recognizes that too many patients struggle to afford insulin and other medicines at the pharmacy counter. However, LD 673 ignores the robust programs that insulin manufacturers already offer to help patients access needed insulin, and PhRMA does not believe that LD 673 offers a viable solution to the problems of insulin access and affordability. LD 673 directs manufacturers to provide insulin to pharmacies and patients without compensation. As explained below, that confiscatory scheme is a textbook example of a per se taking under the Fifth Amendment of the U.S. Constitution and could hinder access to and chill development of life-saving insulin-based treatments, undermining the patient access goals it is intended to serve.

The Fifth Amendment protects pharmaceutical products, including insulin, from Unconstitutional Takings.

The Fifth Amendment prohibits the government from "tak[ing]" private property without paying "just compensation" to the owner. As the U.S. Supreme Court has recognized, "the plain language of the Takings Clause 'requires the payment of compensation whenever the government acquires private property for a public purpose.'"[1] This protection is a core element of our Nation's legal fabric and traces its roots "back at least 800 years to the Magna Carta, which specifically protected" products such as "agricultural crops from uncompensated takings" by the government.[2]

[1] *Murr v. Wisconsin*, 137 S. Ct. 1933, 1942 (2017) (applying Fifth Amendment to state governments).
[2] *Horne v. Agriculture*, 135 S. Ct. 2419, 2426 (2015).

The bill creates two new programs: (1) the urgent need safety net program and (2) a manufacturer-administered insulin assistance program. The urgent need program requires pharmacies to immediately provide qualifying individuals a 30-day supply of insulin and permits pharmacies to bill the insulin manufacturer or require the manufacturer to send "a replacement supply" of the product dispensed. Similarly, the manufacturer-administered program entitles qualifying individuals to receive 90-day supplies of insulin on an ongoing basis, and requires manufacturers to provide this insulin "at no cost to the individual or the pharmacy," although the pharmacy may charge the patient an administration fee. The State does not compensate manufacturers for the insulin provided under either of these programs.

The upshot is that LD 673 requires manufacturers to give away their insulin for free, without any compensation whatsoever. We believe such a mandate constitutes a per se taking under the Fifth Amendment.

LD 673 ignores the fact that all insulin manufacturers currently have patient assistance programs.

All three of our member companies that manufacture insulin offer patient assistance programs, and patients can access information on those and other programs through PhRMA's Medication Assistance Tool (www.mat.org), a search engine that combines information on over 900 public and private programs that provide free or nearly free medicines to eligible patients. This resource also links patients, caregivers and providers to member company websites where information about the cost of the medicine is available. In addition, member companies offer coupons that can help lower the patient's out of pocket costs.

LD 673 largely disregards these resources that improve patient access to medicines and instead creates a program that is so confusing and administratively burdensome, patients may not get the help they need. This legislation unnecessarily diverts existing resources devoted to furthering innovation to a state program that lacks comprehensive detail and fails to help the diabetic patient in the way intended.

Drug spend and prices for insulin, on a net basis, are growing slower than inflation.

According to IQVIA, net prices for all medicines grew just 1.7 percent in 2019, less than the rate of inflation. Further, according to SSR Health[3], after discounts and rebates, net prices for the most commonly used insulin classes are declining because manufacturers give substantial rebates and discounts to pharmacy benefit managers (PBMs) and insurers that significantly lower the net price of medicines.

Unfortunately, it doesn't always feel that way for patients because insurers don't always share these savings with patients at the pharmacy counter in the same way they share negotiated discounts for physician or hospital services with their plan members. Despite these significant manufacturer discounts, patients' out-of-pocket costs continue to go up. Insulin is one of many examples of medicines where health insurers are not always sharing the rebates and discounts they receive with patients. Market analysts report prices for insulin after discounts and rebates

stayed flat or declined in recent years. According to these analysts, discounts can lower the net price of insulin by 70% or more; net prices of long acting insulin have decreased 30% after discounts and rebates; and net prices for long acting insulins are less expensive now than in 2010.[3,4] This means that all or almost all of insulin list price increases are being returned to payers and supply chain entities.

The US Department of Health & Human Services, Med PAC, and others have recognized that there are misaligned incentives in the current system that may result in insurers and pharmacy benefit managers (PBMs) favoring medicines with high list prices in order to profit off of drug manufacturer rebates. In 2019, manufacturers paid approximately $175 billion in rebates and discounts.[5]

PhRMA supports state policies that ensure patients receive and benefit from drug manufacturer rebates, and we would welcome the opportunity to discuss these policy solutions with Maine legislators.

For these reasons, we urge legislators to oppose LD 673.

[3] SSR Health. "US Rx net prices fall 4.8 percent in y/y 4Q18" March 18, 2019
[4] SSR Health. "US Brand Net Pricing Growth 0.2% in 3Q17," December 2017.
[5] Fein, A. "The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2020.