PIERCE ATWOOD LLP

NOLAN L. REICHL

Merrill's Wharf
254 Commercial Street
Portland, ME 04101

P 207.791.1304
F 207.791.1350
nreichl@pierceatwood.com
pierceatwood.com

Admitted in: ME, MA, NY

February 15, 2022

Hon. Heather Sanborn, Senate Chair
Hon. Denise Tepler, House Chair
Joint Standing Committee on Health Coverage, Insurance, and Financial Services
100 House State House Station
Augusta, ME 04333

Re: L.D. 1636, An Act to Reduce Prescription Drug Costs by Using International Pricing

Dear Senator Sanborn and Representative Tepler:

I write on behalf of Pharmaceutical Research and Manufacturers of America ("PhRMA") in opposition to L.D. 1636, An Act to Reduce Prescription Drug Costs by Using International Pricing.

I am a litigation partner at Pierce Atwood, where I specialize in complex commercial litigation, administrative law, and appellate litigation. In connection with my work, I have argued numerous constitutional questions before the Law Court, the United States District Court, and the United States Court of Appeals. I also am admitted to practice before the United States Supreme Court and have authored and submitted amicus briefs to the Supreme Court in connection with matters of constitutional law. Prior to entering the private practice of law, I served as a law clerk on the United States Court of Appeals for the Third Circuit.

Having reviewed the legislation and applicable law, L.D. 1636 presents numerous constitutional concerns, including but not limited to:

First, the Legislation violates the Supremacy Clause of the United States Constitution, found in Article VI, clause 2, which states that laws made by the United States Congress "shall be the supreme Law of the Land." The Supremacy Clause has given rise to the doctrine of preemption, under which a court must strike down a state law that impermissibly conflicts with federal law. Here, the Legislation impermissibly conflicts with United States patent laws with respect to its efforts to regulate the prices drug manufacturers may charge with respect to drugs that remain subject to patent protection. United States patent law grants patent recipients the "right to exclude" others from the making, using, or selling of the patented invention for a limited period of time. *See* 35 U.S. § 154(d) (rights of patent holders). Patent law thus permits the patent recipient to operate in the marketplace and to realize anticipated economic returns before the patent protection ends and others may freely copy the invented product. This approach

balances the societal interest in incentivizing the creativity of inventors with the competing interest in seeing new inventions widely exploited. State laws that disrupt this delicate balance by limiting the economic benefits associated with patent protection conflict with United States patent laws and thus are preempted by the Supremacy Clause. Courts have adopted this reasoning when striking down local laws that seek to limit pharmaceutical price increases. For instance, after the District of Columbia passed legislation that made it unlawful to sell prescription drugs in the District "for an excessive price," the Court of Appeals for the Federal Circuit held that the law sought to improperly "re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs" and affirmed a lower court decision striking the law down on that basis. *See Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1364 (Fed. Cir. 2007). The Legislation violates the Supremacy Clause in the same way, as, with respect to patented medications, it expressly and directly limits the economic benefits associated with the patent rights of pharmaceutical manufacturers.

Second, the Legislation exceeds the territorial reach of the Maine Legislature's authority, triggering Dormant Commerce Clause and constitutional concerns regarding extraterritoriality. First, the bill seeks to cap transaction prices for drugs "to be dispensed or delivered to a consumer in the state, whether directly or through a distributor." But to our knowledge no manufacturers of medications intended for human use make drugs in Maine. Manufacturers instead sell to wholesalers located outside of Maine, who then sell drugs to various purchasers in the State. As a result, the Legislation would force out-of-state parties to change the terms of their out-of-state transactions to comply with Maine's price cap. Second, the Legislation prohibits a drug manufacturer from withdrawing its drugs from the Maine market to avoid the reference-pricing scheme set forth in the Legislation and, thus, *compels* out-of-state drug manufacturers to continue supplying drugs into Maine when they do not wish to do so. Both of these extraterritorial features violate the United States Constitution's prohibition on a state regulating conduct that occurs wholly outside of its borders. *See Healy v. Beer Inst., Inc.*, 491 U.S. 324, 335-36 (1989). Third, courts have struck down state legislation that imposes reference pricing schemes under the Dormant Commerce Clause, *see Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986), and have struck down such schemes specifically in the prescription drug context where the statute at issue had the "practical effect" of significantly impacting the price at which a good may be sold outside of the state which has adopted the statute, *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018). The common sense underlying all of these examples can be illustrated with a simple example: How would Maine react if Massachusetts passed a statute regulating the prices at which the Maine lobster industry sold lobsters in Massachusetts? The Constitution prohibits the Legislation from imposing such extraterritorial effects.

Third, by pegging Maine's drug prices to those in Canada the Legislation creates a severe disincentive for drug manufacturers to export drugs to Canada: if a drug is not sold in Canada, then no Canadian price can serve as a reference price with

respect to drug sales in Maine. In that case, the Legislation would peg the Maine price solely to the U.S. wholesale acquisition price. In this respect, the Legislation—particularly if proliferated elsewhere—threatens trade relations between the United States and Canada. The United States and Canada have reached trade deals which concern both pharmaceutical products (such as in the World Trade Organization's Pharma Agreement) and protections for patented technologies (such as in the United States-Mexico-Canada Agreement, formerly NAFTA), which *encourage* cross-border trade in pharmaceuticals between the countries. By discouraging such trade with respect to 250 different prescription drugs, the Legislation threatens to disturb and interfere with U.S./Canada trade relations, and, in turn, could intrude so significantly on U.S. foreign relations as to violate the foreign affairs provisions of the United States Constitution. *See, e.g., Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363 (2000) (striking down Massachusetts statute that penalized companies doing business with Burma as interfering with foreign relations powers committed to the federal government).

Additionally, the Legislation would intrude on interstate and foreign commerce in violation of the Foreign Commerce Clause of the United States Constitution, which provides that Congress and Congress alone may "regulate Commerce with foreign Nations." U.S. Const. art.1, § 8, cl. 3. Tying Maine's drug prices to those in Canada will impose significant burdens on foreign commerce, where it creates an incentive for drug manufacturers either to sell drugs at a higher cost in Canada or, if that is not possible due to Canadian law, to withdraw those drugs from the Canadian market.

For the foregoing reasons, PhRMA respectfully urges the Committee to vote Ought Not to Pass on L.D. 1636. Thank you for your attention to these comments.

Sincerely,

Nolan L. Reichl