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Hon Donna Bailey, Senate Chair
Hon Anne Perry, House Chair
Joint Standing Committee on Health Coverage, Insurance, and Financial Services
100 House State House Station
Augusta, ME 04333

Re L D 1816, An Act Requiring Reference-based Pricing to Reduce Prescription Drug Costs

L D 1829, An Act to Reduce Prescription Drug Costs by Requiring Reference-based Pricing

Dear Senator Bailey and Representative Perry

I write on behalf of Pharmaceutical Research and Manufacturers of America ("PhRMA") in opposition to L D 1816, An Act Requiring Reference-based Pricing to Reduce Prescription Drug Costs, and L D 1829, An Act to Reduce Prescription Drug Costs by Requiring Reference-based Pricing (together, the "Legislation")

I am a litigation partner at Pierce Atwood, where I co-chair Pierce Atwood's appellate litigation practice and specialize in complex commercial litigation, administrative law, and constitutional 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, including cases where my clients have prevailed in striking down Maine state statutes as unconstitutional I am admitted to practice before the United States Supreme Court and have authored and submitted amicus briefs to the 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, the Legislation presents numerous constitutional concerns, including but not limited to

First, the Legislation prohibits a drug manufacturer from withdrawing its drugs from the Maine market to avoid the fines set forth in the Legislation for selling drugs above the so-called reference price and, thus, *compels* drug manufacturers to

continue supplying drugs into Maine when they do not wish to do so Because no manufacturers of medications intended for human use are in Maine, the Legislation's requirement that out-of-state drug manufacturers introduce drugs into the state regulates *only* out-of-state actors This extraterritorial effect of the Legislation violates the United States Constitution's prohibition on a state regulating conduct that occurs wholly outside of its borders The Supreme Court, in *Healy v Beer Institute, Inc* , made this principle clear, holding that the Commerce Clause of the Constitution "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders " 491 U S 324, 336 (1989) The common sense underlying this doctrine can be illustrated with a simple example How would this Legislature react if Massachusetts passed a statute regulating the prices at which the Maine lobster industry sold lobsters in Massachusetts? Courts have applied principles of extraterritoriality to strike down state legislation that sought to regulate increases in prescription drug prices For instance, in *Association for Accessible Medicines v Frosh*, 887 F 3d 664 (4th Cir 2018), the United States Court of Appeals for the Fourth Circuit struck down a Maryland statute that sought to prohibit "unconscionable" prescription drug price increases on the grounds that the statute regulated economic activity that occurred wholly outside the state The Legislation violates the Constitution in the same way in its efforts to regulate out-of-state transactions and compel out-of-state drug manufacturers to continue supplying prescription drugs to Maine against their wishes

Second, 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 or stands as an obstacle to 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 the patented invention for a limited period *See* 35 U S § 154(d) (rights of patent holders) Patent law thus permits the patent recipient to operate in the marketplace without competition before the patent protection ends and others may freely disseminate 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 imposing price controls or otherwise limit pharmaceutical prices For instance, after the District of Columbia passed legislation that would have made it unlawful to sell prescription drugs in the District "for an excessive price," the Court of Appeals for

the Federal Circuit invalidated the law because it improperly sought to "re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs " *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 seeks to limit the economic benefits associated with the patent rights of pharmaceutical manufacturers

Third, the Legislation raises additional preemption issues related to the Employee Retirement Income Security Act ("ERISA"), a federal statute that sets certain requirements for retirement plans in private industry ERISA preempts a state that may "relate to" a private benefit plan *See* 29 U S C § 1144(a) The Supreme Court, in analyzing whether a state law is preempted by ERISA, looks to whether the law "has a connection with or reference to such a plan " *Egelhoff v Egelhoff*, 532 U S 141, 147 (2001) The result of this analysis is that ERISA preempts any state law that "regulates a key facet of plan administration " *Gobeille v Liberty Mut Ins Co* , 136 S Ct 936 (Thomas, J , concurring)

The Legislation includes an ERISA Plan opt-in provision which allows an ERISA Plan to opt-in to the Legislation by notifying the Superintendent of Insurance Such a provision, which would allow state law to affect the price ERISA plans are able to charge for prescription drugs, would certainly "relate" to a state health plan, and thus be preempted by ERISA While a voluntary opt-in may have less of an effect on private plans, it is nevertheless a state law regulating a "key facet" of the plan—namely, the price of prescription drugs The effects of even voluntary regulation of such a critical component of plan administration could have unforeseen consequences and effects not considered by Congress when it devised ERISA, which in turn could threaten the stability and efficacy of private plans For example, the Legislation does not provide any means for a private health plan to opt-out of the pricing scheme once it has consented, although the inclusion of an opt-out provision would not be sufficient to remedy the foregoing Supremacy Clause flaws in the Legislation A regulatory scheme that would dramatically alter the administration of a private plan and that lacks an opt-out provision in case that regulation threatened to undermine plan administrator's ability to provide effective coverage to employees undermines Congress's intent for ERISA to supersede state law Notably, ERISA does not set a 'floor' for state regulation of private plans, but instead prohibits regulation concerning private plans entirely The Legislation attempts to do just that, and thus is preempted by ERISA

Finally, Governor Mills cited the same "potential Constitutional claims" when she vetoed pharmaceutical price cap legislation in the 130th Legislature *See* Veto Letter to the 130th Legislature, June 29, 2021 Like the Legislation, then-L D 675 sought to limit pricing changes on certain drugs and sought to prohibit out-of-state manufacturers from withdrawing drugs from the Maine market The Governor

concluded that L D 675 was "vulnerable to a challenge based on the dormant Commerce Clause" because of its extraterritorial effect, citing the Supreme Court's decision in *Healy v Beer Institute*, discussed above *See id* The Governor further cited the Federal Circuit's decision in *Biotechnology Indus Org v District of Columbia*, also discussed above, in support of her view that L D 675 was "vulnerable to claims related to patent preemption " *See id* The Legislation presents the precisely same constitutional defects on which the Governor relied to veto similar bills in the past

For the foregoing reasons, PhRMA respectfully urges the Committee to vote Ought Not to Pass with respect to L D 1816 and L D 1829 Thank you for your attention to these comments

Sincerely,

Nolan L Reichl