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To: Hon. Heather Sanborn, Senate Chair
Hon. Denise Tepler, House Chair
Date: February 18, 2022
Re: Supplemental Memorandum on L.D. 1636 Constitutionality

It is my understanding that the Joint Standing Committee on Health Coverage, Insurance, and Financial Services is interested in the additional views of the National Academy for State Health Policy concerning constitutionality of L.D. 1636 in light of the additional constitutional objections raised by the Pharmaceutical Research and Manufacturers of America (PhRMA) in the memorandum of Nolan L. Reichel, dated February 15, 2022 (PhRMA Memo). In my opinion, neither patent law nor the dormant Foreign Commerce Clause should pose a barrier to this proposed legislation.

Patent Preemption. Relying exclusively upon a divided, 15-year-old decision from a different U.S. Court of Appeals, PhRMA argues that the "right to exclude" others from the making, using, or selling a patented invention for a limited period of time under 35 U.S.C. § 154(d) means that states are powerless to regulate drug prices. *See* PhRMA Memo at 1–2 (citing *Biotechnology Industry Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir.), *petition for rehearing en banc denied*, 505 F.3d 1343 (Fed. Cir. 2007) (*BIO*)). As the dissenting judge at the time trenchantly noted, however, "[a] patent grant is designed not to allow the patent holder to exploit the grant for the maximum profit that the market will bear, but merely to confer a right of exclusivity." *BIO*, 505 F.3d at 1350 (Dyk, J., dissenting from rehearing en banc). Even more so today, the *BIO* court is out-of-step with current Supreme Court jurisprudence.

Not to get too far into the weeds, but there is substantial doubt that the Federal Circuit would even be an appropriate court to address this issue today. Although the Federal Circuit took a fulsome approach to the breadth of its patent jurisdiction in *BIO*, *see* 496 F.3d at 1366–69, the Supreme Court concluded otherwise a few years later in

Gunn v. Minton, 568 U.S. 521 (2013). Based on this much narrower interpretation, the Federal Circuit has more recently acceded to the inevitable and transferred cases that do not require interpretation of patent claims to the regional circuits. *See, e.g., Chandler v. Phoenix Servs. LLC*, 1 F.4th 1013 (Fed. Cir. 2021). Suffice it to say, the First Circuit has a much more nuanced view of preemption than the Federal Circuit. *See, e.g., Consumer Data Indus. Assoc. v. Frey*, 2022 WL 405956 (1st Cir. Feb. 10, 2022) (upholding Maine consumer protection statute against preemption challenge).

Although *BIO* represents the high-water mark of preemption based on patent law, even *BIO* does not signal preemption of the proposed legislation. To begin, *BIO* only applies to *patented* drugs, so patent preemption does not apply to the prices of non-patented, *i.e.*, generic, drugs. Likewise, because the bill applies to both patented and generic drugs, it does not even target patented drugs. Furthermore, the bill is not a price cap imposed on the patentholder, *i.e.*, the manufacturer, but rather a rate imposed on the drug purchasers and payers. This distinction matters because the Federal Circuit acknowledged that patent law does not ordinarily trump consumer protection and other state statutes. *See, e.g., Dow Chemical Co. v. Exxon Corp.*, 139 F.3d 1470 (Fed. Cir. 1998); *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318 (Fed. Cir. 1998) (overruled en banc on other grounds by *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1358–59 (Fed. Cir. 1999)).

The statutes are also different. Unlike the proposed legislation, as the dissenting judge explained, the principal failing of the drug pricing regulation invalidated in *BIO* was its misguided attempt "to determine what price is necessary to spur innovation, a policy determination that Congress surely did not intend to leave to the states." *BIO*, 505 F.3d at 1350 (Dyk, J., dissenting). In sum, even if *BIO* was properly decided 15 years ago, and even if *BIO* is controlling precedent—neither of which is true—it would not doom the proposed legislation.

In contrast to the heavily-criticized Federal Circuit approach to preemption, the Supreme Court does not start with the assumption that state law is preempted: "In preemption analysis, courts should assume that the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress." *Arizona v. United States*, 567 U.S. 387, 400 (2012) (citations omitted). The *BIO* court

recognized that the patent laws did not expressly preempt state regulation of patented drug prices. *BIO*, 496 F.3d at 1372. Furthermore, the *BIO* plaintiff did not argue—nor could it—that patent law preempted the field "so comprehensively that it has left no room for supplementary state legislation." *Murphy v. NCAA*, 138 S. Ct. 1461, 1480 (2018) (quotation omitted). That leaves "conflict" preemption. That, too, is unavailing.

"[C]onflict pre-emption exists where compliance with both state and federal law is impossible, or where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Oneok, Inc. v. Learjet, Inc*., 575 U.S. 373, 377 (2015) (citations omitted). In contrast here, there is *no* conflict, much less impossibility, between complying with the federal patent laws' grant of exclusivity to the manufacturer and complying with the Maine state law regulating drug prices paid by Maine consumers in Maine.

Similarly, the proposed legislation does not stand as an obstacle to the purpose and objectives of the patent laws. To be sure, Congress intended to grant patentholders the right to exclude others from making or selling the patented drugs. But that does not mean that Congress intended to grant patentholders the right to extract unlimited profits from its monopoly. Quite simply, the federal purpose and objective of granting exclusivity does not conflict with the state purpose and objective of making life-saving drugs available and affordable to Maine consumers. The proposed legislation is not preempted by federal patent law.

Foreign Commerce Clause. PhRMA further argues that the proposed legislation would violate the dormant Foreign Commerce Clause. Even its cited authority does not support this proposition.

It is disheartening, to say the least, that PhRMA would argue that the proposed legislation would cause a "severe disincentive" for its members to import their drugs to Canada, and that to avoid complying with the proposed legislation, its members might instead "withdraw those drugs from the Canadian market." PhRMA Memo at 3. One would hope that it is merely overheated rhetoric to suggest that drug manufacturers would stop importing life-saving drugs to Canada in order to maximize their profits in the United States.

As noted in my prior testimony, there is substantial question whether the current Supreme Court would recognize today a dormant commerce clause theory. *See also Baston v. United States*, 137 S. Ct. 850 (2017) (Thomas, J., dissenting from the denial of certiorari) (questioning the scope of the Foreign Commerce Clause). But even if it retains validity today, it is inapplicable to the proposed legislation.

The single case cited by PhRMA, *Crosby v. Nat'l Foreign Trade Council,* 530 U.S. 363 (2000), expressly did *not* concern the application of a dormant Foreign Commerce Clause theory to invalidate a state statute. *See id*. at 374 n.8 ("[W]e decline … to pass on the First Circuit's rulings addressing … the dormant Foreign Commerce Clause.") (ellipses added and citation omitted). That case instead involved a straightforward application of the preemption doctrine to invalidate a Massachusetts statute that went further than a federal statute and a presidential executive order in applying sanctions to Burma.

The handful of cases applying the dormant Foreign Commerce Clause to state law are based on "the Framers' overriding concern that the Federal Government must speak with one voice when regulating commercial relations with foreign governments." *Japan Line Ltd. v. Los Angeles County*, 441 U.S. 434, 449 (1979) (citations omitted). To describe the theory is to refute it. The proposed legislation does not even attempt to regulate commercial relations with foreign governments—it simply ties the prices of drugs paid in Maine by Maine consumers under health care plans approved in Maine to international drug prices.

In this case, all roads lead to Rome. None of the constitutional theories advanced by PhRMA should prevent Maine from adopting the proposed legislation.