# A TEST CASE FOR RE-EVALUATION OF THE DORMANT COMMERCE CLAUSE: THE MAINE RX PROGRAM

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#### INTRODUCTION

In May 2000, the governor of Maine, in an attempt to address the problem of skyrocketing prescription drug prices in that state, signed into law an Act to Establish Fairer Pricing for Prescription Drugs<sup>1</sup> (hereinafter "the Act"). The Pharmaceutical Research and Manufacturers of America ("PhRMA") challenged this law, designed to coerce drug manufacturers into charging lower prices to Maine's uninsured residents, as being in violation of both the dormant Commerce Clause<sup>2</sup> and the Supremacy Clause<sup>3</sup> of the United States Constitution.<sup>4</sup> The Federal District Court of Maine preliminarily sided with PhRMA, enjoining enforcement of specified parts of the law pending adjudication on the merits.<sup>5</sup> In granting the injunction, the district court found the likelihood of PhRMA's success on the merits to be "overwhelming."<sup>6</sup>

On appeal, a three judge panel on the Court of Appeals for the First Circuit found there to be no constitutional violation at all and overturned the injunction in its entirety.<sup>7</sup> Since then, the First Circuit has refused PhRMA's request for a full court review, and the organization has taken its challenge to the Supreme Court.<sup>8</sup> As of the time

<sup>6</sup> *Id.* 

<sup>4</sup> See Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 85 (1st Cir. 2001).

<sup>8</sup> See, e.g., Drug Program's Success Depends on Participation: Fairer Prescription Prices Are Now Within Reach, PORTLAND PRESS HERALD, June 18, 2001, at 6A (claiming that the Court's refusal to visit the matter is "another sign that the law rests on solid constitutional ground").

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<sup>&</sup>lt;sup>1</sup> 2000 Me. Legis. Serv. 786 (West).

<sup>&</sup>lt;sup>2</sup> U.S. CONST. art. I, § 8, cl. 3.

<sup>&</sup>lt;sup>3</sup> U.S. CONST. art. VI, § 1, cl. 2.

<sup>&</sup>lt;sup>4</sup> See Plaintiff's Motion for Preliminary Injunction with Incorporated Memorandum of Law, Pharm. Research & Mfrs. of Am. v. Comm'r, Me. Dep't of Human Serv. (D. Me. Oct. 26, 2000) (No. 00-157-B-H).

<sup>&</sup>lt;sup>5</sup> See Pharm. Research & Mfrs. of Am. v. Comm'r, Me. Dep't of Human Serv., No. 00-157-B-H, 2000 U.S. Dist. LEXIS 17363, at \*25 (D. Me. Oct. 26, 2000) (order granting preliminary injunction). The relevant sections of the statute and the initially enjoined portions are discussed in Part II, *infra.* 

of this writing, the Court has not yet decided whether it will hear the case.<sup>9</sup>

Against this backdrop, this Comment will assess the constitutionality of the Act, principally under the dormant Commerce Clause doctrine. I will also more briefly analyze the law under the Supremacy Clause.

My legal conclusion is that the challenged portions of the Act are unconstitutional under both of these constitutional provisions, as the district court found. In making this assessment, however, this Comment will argue that the actual conclusion should be somewhat different from that drawn by the district court, although not for the reasons given by the First Circuit when it vacated the district court's injunction.

My principal argument is that the law should be found constitutional under the dormant Commerce Clause through a revision of dormant Commerce Clause doctrine. While a portion of the law also violates the Supremacy Clause, other challenged portions do not and only have dormant Commerce Clause implications. Therefore, should this case reach the Supreme Court, the Court should take this opportunity to reassess dormant Commerce Clause doctrine and find this law within the State of Maine's legitimate police power to the extent it is not preempted.<sup>10</sup>

I will start with the generally accepted idea that the dormant Commerce Clause doctrine was developed to prevent states from engaging in economic protectionism vis-à-vis other states.<sup>11</sup> I will then argue that in past decisions, the Court has framed the dormant Commerce Clause doctrine to cast too wide a net, by delivering opinions whose language is unnecessarily broad for the cases at issue, thus laying the groundwork for invalidation of a non-protectionist state law, such as the Act.

I will also argue that the possible discriminatory effect on citizens of other states should not be a basis for invalidation of a state law that has no protectionist motive. I will then bolster these assertions with the view that judicial invalidation of non-protectionist state laws that serve important social ends, such as the Act, would be particularly harmful because (1) states do not have the political voice to make sure that such invalidation is reversed when called for; and (2) invalidation of such laws would rob the states of their role as social policy innovators, a role that is gaining increasing importance in the national effort to fashion a viable solution to the problem of access to affordable prescription drugs.

<sup>&</sup>lt;sup>9</sup> See Statement by Marjorie Powell, Assistant General Counsel of PhRMA, (July 31, 2001), http://www.phrma.org/press/newsreleases//2001-07-31.247.phtml (explaining that the organization has filed a petition for certiorari with the United States Supreme Court).

<sup>&</sup>lt;sup>10</sup> See discussion infra Part III.A.

<sup>&</sup>lt;sup>11</sup> See discussion infra Part III.B.

## I. THE ACT

The Act directs the Commissioner of the Maine Department of Health Services to negotiate lower drug prices on behalf of its eligible residents by seeking rebates from participating pharmaceutical manufacturers.<sup>12</sup> This is what is known as the Maine Rx Program.<sup>13</sup> If manufacturers balk at giving the rebates, the law directs the Commissioner (1) to require "prior authorization" under Maine's Medicaid program for all drugs sold by the recalcitrant manufacturer to Maine under its Medicaid program, and (2) to make public the names of these uncooperative parties.<sup>14</sup> Prior authorization essentially means that a doctor may not prescribe the medication at issue without first getting it approved by the state.<sup>15</sup> Under the Medicaid law, Maine has the authority to require such prior authorization for the use of any prescription drug in its Medicaid program.<sup>16</sup>

The Act also prohibits "illegal profiteering"<sup>17</sup> and provides that such illegal profiteering is also an "unfair trade practice" as defined by the Maine Unfair Trade Practices Act.<sup>18</sup> The law authorizes the state to punish such illegal profiteering through court action and civil penalties.<sup>19</sup>

<sup>&</sup>lt;sup>12</sup> See ME. REV. STAT. ANN. tit. 22, § 2681(4) (West 2000). The law directs the Commissioner to negotiate "an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program ...." Id. at § 2681(4)(B). The rebate calculated under the Medicaid program is set by federal law. See 42 U.S.C.A. § 1396r-8 (West 1992 & Supp. 2001) (requiring drug manufacturers who sell drugs to state Medicaid programs to enter into rebate agreements for specified discounts). The state would then pass that rebate on to pharmacies, which in turn would pass it on the Maine Rx participants in the form of a discount. See ME. REV. STAT. ANN. tit. 22, § 2681(1) (West 2000).

ME. REV. STAT. ANN. tit. 22, § 2681 (West 2000).

<sup>&</sup>lt;sup>14</sup> See id. at § 2681(7).

<sup>&</sup>lt;sup>15</sup> See 42 U.S.C.A. §§ 1396r-8(d)(1)(A), 1396r-8(d)(5) (West 1992 & Supp. 2001).

<sup>&</sup>lt;sup>16</sup> See id. (authorizing a state to require approval of a drug before its dispensing as a condition of coverage or payment for a covered drug).

<sup>&</sup>lt;sup>17</sup> ME. REV. STAT. ANN. tit. 22, § 2697 (West 2000). Illegal profiteering includes exacting unconscionable prices, discrimination in the sale of prescription drugs, and limiting or restricting sales in retaliation for enforcement of this law. See id. at § 2697(2).

Id. at § 2697(5). Such an unfair trade practice is prohibited by the Maine Unfair Trade Practices Act. See id.

See ME. REV. STAT. ANN. tit. 22, § 2697(3), (4) (West 2000).

Finally, the Act allows for the imposition of price controls in three years if prices are not reduced sufficiently by enforcement of the aforementioned provisions.<sup>20</sup> The district court preliminarily enjoined enforcement of the prior authorization portion of the rebate program in its entirety and the illegal profiteering portion as it applies to transactions occurring outside the state of Maine.<sup>21</sup>

### II. THE ACT'S CONSTITUTIONALITY UNDER THE SUPREMACY CLAUSE AND THE DORMANT COMMERCE CLAUSES

Under current Supremacy Clause and dormant Commerce Clause doctrine, the initially enjoined provisions of the Act do not pass constitutional muster. In this section, I will establish this under each constitutional provision. I will concentrate the bulk of my analysis on the dormant Commerce Clause.

### A. The Act Is Preempted by the Supremacy Clause

The Act's requirement<sup>22</sup> that drugs manufactured by "nonparticipating manufacturers"<sup>23</sup> be subject to prior authorization under the state's Medicaid program is preempted under the Supremacy Clause<sup>24</sup> by federal Medicaid law. Preemption of a state or local law under the Supremacy Clause occurs in three situations: (1) when federal law expressly preempts it;<sup>25</sup> (2) where the scheme of federal regulation is

However, the statute says the Department *shall* impose the prior authorization requirement. See ME. REV. STAT. ANN. tit. 22, § 2681(7) (West 2000). This is important because the statute's requirement that prior authorization be imposed is automatically triggered when a drug manufacturer does not participate in the rebate program, without regard to whether or not the patient needs the particular drug. This is what PhRMA argues contravenes the purpose of the statute. See Plaintiff's Motion at 18, Pharm. Research & Mfrs. of Am. (No. 00-157-B-H). Thus, Maine's attempt to characterize this requirement as a mere recommendation is an attempt to get around this flaw.

<sup>&</sup>lt;sup>20</sup> See ME. REV. STAT. ANN. tit. 22, § 2693 (West 2000).

<sup>&</sup>lt;sup>21</sup> See Pharm. Research & Mfrs. of Am. v. Comm'r, Me. Dep't of Human Serv., No. 00-157-B-H, 2000 U.S. Dist. LEXIS 17363, at \*25. The prior authorization provision was found to potentially violate the Supremacy Clause with respect to all transactions and the Commerce Clause with respect to out-of-state transactions, and the illegal profiteering provisions were found to most likely violate the Commerce Clause with respect to out-of-state transactions.

<sup>&</sup>lt;sup>22</sup> Maine has attempted to characterize the prior authorization provision as a recommendation and not a requirement. It has proposed rules for implementation of the Maine Rx Program that direct the Department of Health Services to *recommend* prior authorization of nonparticipating companies' drugs to the Medicaid Drug Utilization Committee. *See* Defendants' Memorandum in Opposition to Plaintiff's Motion for Preliminary Injunction at 3, Pharm. Research & Mfrs. of Am. v. Comm'r, Me. Dep't of Human Serv. (D. Me. Oct. 26, 2000) (No. 00-157-B-H).

<sup>&</sup>lt;sup>23</sup> ME. REV. STAT. ANN. tit. 22, § 2681(7) (West 2000).

<sup>&</sup>lt;sup>24</sup> U.S. CONST. art. VI, § 1, cl. 2.

<sup>&</sup>lt;sup>25</sup> See, e.g., Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372-73 (2000) (citations omitted) (holding that the Court "will find preemption ... where '[the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress").

sufficiently comprehensive to make reasonable the inference that "Congress left no room" for supplementary state or local regulation;<sup>26</sup> and (3) where the state or local law conflicts with the federal law.<sup>27</sup>

PhRMA has argued that the prior authorization provision is in conflict with federal Medicaid law.<sup>28</sup> Its principle contention is that the Act's use of the prior authorization provision of the Medicaid statute contravenes the Medicaid law's purpose of providing access to medical care for poor people by impeding dispensation of prescription drugs to Medicaid beneficiaries in order to effectuate a non-Medicaid program.<sup>29</sup>

The First Circuit was not persuaded by this argument, finding no conflict because (1) the Act, like Medicaid, seeks to provide medical care for the poor; (2) the Medicaid statute explicitly permits prior authorization; (3) the Act only imposes prior authorization as permitted by the Medicaid law; and (4) PhRMA did not present sufficient proof that the prior authorization provision would work to the detriment of Medicaid recipients.<sup>30</sup>

This reasoning can be contested on several grounds, however. Conflict preemption generally occurs when the state or local law is inconsistent with congressional objectives for the federal law.<sup>31</sup> In this case, the congressional objective for the Medicaid statute is to enable states to provide necessary medical care to poor people in accordance with each participating state's medical assistance plan.<sup>32</sup> Specifically, the congressional purpose for allowing states to require prior authorization under their Medicaid programs is to allow states to prevent unnecessary utilization of certain drugs and to assure that Medicaid payments for prescription drugs are "consistent with efficiency, economy and quality of care."33

See, e.g., Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983) (citations omitted).

See, e.g., Crosby, 530 U.S. at 363 (holding that the Court "will find preemption where it is impossible for a private party to comply with both State and federal law").

See Plaintiff's Motion at 16-17, Pharm. Research & Mfrs. of Am. (No. 00-157-B-H) ("Requiring prior authorization under the Medicaid program and restricting Medicaid patients' access to drugs for this purpose-to penalize nonparticipation in an unrelated state program that benefits a different, non-Medicaid population-is inconsistent with, and thus preempted by, federal Medicaid law."). The district court agreed with this argument. See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*20. However, the First Circuit found no conflict between the Act and the Medicaid statute's structure and purpose.

See Plaintiff's Motion at 16-17, Pharm. Research & Mfrs. of Am. (No. 00-157-B-H).

<sup>&</sup>lt;sup>30</sup> See Pharm. Researchers & Mfrs. of Am. v. Concannon, 249 F.3d 66, 75-78 (1st Cir. 2001). 31

See Crosby, 530 U.S. at 372-73 (articulating this principle by saying that a state law is preempted when it works as an obstacle to the execution of Congress' objectives).

See 42 U.S.C.A. § 1396 (West 1992). Such medical assistance includes prescription drugs. See 42 C.F.R. § 456.703 (Government Printing Office 2000) (discussing the drug use review program for the Health Care Financing Administration). See also Atkins v. Rivera, 477 U.S. 154, 156 (1986) (noting that Medicaid provides "medical assistance to persons whose income and resources are insufficient to meet the costs of necessary care and services").

<sup>&</sup>lt;sup>33</sup> H. Rep. NO. 101-881, at 98 (1990).

It is inconsistent with these purposes to use the prior authorization provision to force drug manufacturers to participate in a separate state program. Indeed, it effectively allows Maine to unilaterally alter the effect of the federal statute. Even if the Maine Rx Program has the same general objective as the Medicaid statute,<sup>34</sup> the Medicaid law sets specific parameters to govern specific situations. Once Maine acts to alter those parameters, it has acted in conflict with the congressional purpose to give effect to the legislative provisions as they are set out in the federal statute. Thus, the prior authorization provision conflicts with the purpose of the Medicaid law itself.<sup>35</sup> This must be true even if Congress, in enacting the law, did not think of every possible use that the state could make of that law; <sup>36</sup> the alternative would be that Congress would never be able to predict with any cer-tainty the effect of its laws.<sup>37</sup> Thus, the fact that the prior authorization provision is not on a collision course with congressional objectives for Medicaid does not obviate its inconsistency with the Medicaid law.

While court decisions in the area of preemption under the Medicaid law are limited in scope,<sup>38</sup> they support this analysis.<sup>39</sup> Although prior authorization was not the subject of these cases, the topics that were addressed evidenced an agreement among the courts that state regulation under the Medicaid law must be consistent with Medicaid objectives.<sup>40</sup> And, as the district court pointed out, forcing the par-

<sup>36</sup> As the district court in Maine noted, "[i]t may never have occurred to Congress that the Medicaid program could be hijacked to provide leverage for other purposes." *Pharm. Research* & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*20 n.12.

<sup>57</sup> Implicit in this statement is the assumption that Congress cannot *ex ante* think of every use the states might make of the Medicaid law.

<sup>33</sup> There are only two Supreme Court cases on the issue, both addressing the issue of state funding of abortion. *See infra* note 39.

<sup>59</sup> See Beal v. Doe, 432 U.S. 438 (1977) (holding that state law that denied payment for nontherapeutic abortions was not preempted as it did not contravene federal purpose to provide medically necessary services); Dalton v. Little Rock Family Planning Serv., 516 U.S. 474 (1996) (holding that injunction of state constitutional provision denying payment under state programs for any abortions other than those necessary to save the mother's life was improperly broad as it may apply to programs that are entirely state funded, and as it may apply to future periods when Congress may not provide funding for abortions other than those necessary to save the mother's life).

<sup>40</sup> Examples of areas that have been addressed are state resource requirements for Medicaid eligibility and state laws restricting funding for non-therapeutic abortions under Medicaid. *See, e.g.*, Keith v. Rizzuto, 212 F.3d 1190 (10th Cir. 2000); Mathews v. Comm'r of Pub. Welfare, 476 N.E.2d 213 (Mass. 1985); Whitfield v. King, 364 F. Supp. 1296 (M.D. Ala. 1973) (addressing resource requirements). *See also* Planned Parenthood Affiliates v. Engler, 860 F. Supp. 406 (W.D. Mich. 1994); Roe v. Casey, 623 F.2d 829 (3d Cir. 1980) (addressing abortion funding). In addition, the Supreme Court has weighed in on the issue of abortion funding under Medicaid and has not disagreed with this analysis. *See supra* note 39.

<sup>&</sup>lt;sup>34</sup> As noted, this general objective is to provide necessary medical care—in this case, prescription drugs—to poor people.

<sup>&</sup>lt;sup>55</sup> See, e.g., Seittelman v. Sabol, 697 N.E.2d 154, 158 (N.Y. 1998) (holding that because the state requirement limited Medicaid reimbursement further than the federal Medicaid statute, the state requirement undermined the purposes of the federal law, and was therefore invalid).

ticipation of drug manufacturers in the Maine Rx Program is not a Medicaid objective.41

An additional factor that weighs in favor of finding that the prior authorization provision is preempted is the fact that the Medicaid statute provides specifically for permissive alterations of the general Medicaid program through the grant of waivers.<sup>42</sup> These waivers allow states to be exempted from certain Medicaid requirements or to alter the Medicaid structure in certain ways upon application to and permission from the federal government.<sup>43</sup> The purpose of these waivers is to give a state the opportunity to tailor its Medicaid program to suit local needs more effectively, or to allow it to experiment with new healthcare programs.<sup>44</sup> The fact that a state must get specific permission to waive the application of non-discretionary<sup>35</sup> provisions of the Medicaid law is strong support for the argument that states may not alter these provisions independently through a separate law.46

Finally, while the agency that administers the federal Medicaid program, the Health Care Financing Administration, has not issued regulations regarding the prior authorization provision of the Medicaid program,<sup>47</sup> it has issued proposed regulations indicating that the use of this provision to limit coverage to specified prescription drugs violates the Medicaid statute.48

What the foregoing argument shows is that under the current regulatory framework, Maine may not use the federal Medicaid law to

<sup>43</sup> See LaGuarda, supra note 42, at 178-79.

<sup>44</sup> See id. at 178 (noting that such waivers allow states to try different approaches to finance and delivery of healthcare and to meet special local needs). <sup>45</sup> States have some discretion over what they cover under the Medicaid statute. For exam-

ple, they are not required to provide nursing facilities or home health services for those who are not categorically needy. See BARRY R. FURROW ET AL., HEALTH LAW 870 (3d ed. 1997). <sup>46</sup> It is important to note here that the Act, designed to be a program separate from Medi-

caid, was not the subject of a Medicaid waiver application. However, in the wake of the preliminary injunction of enforcement of the Act, Maine did apply for and receive a waiver from the Health Care Financing Administration allowing it to extend the Medicaid prescription drug discount to certain Maine residents who are not eligible for Medicaid. This waiver was modeled after the one recently granted to Vermont. See Press Release, Maine Department of Human Services, Maine Receives Federal Prescription Drug Waiver (Jan. 19, 2001), available at http://janus.state.me.us/dhs/pressdd.htm. PhRMA has challenged the legality of the Vermont waiver. See discussion infra note 254.

See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*20 n.12.

<sup>48</sup> See Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, 60 Fed. Reg. 48,454 (Sept. 19, 1995) (stating the administration's belief that states should be prevented from "using a prior authorization program as a proxy for a closed formulary" allowing for coverage of only certain specified drugs).

<sup>&</sup>lt;sup>41</sup> See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*19 (observing that Maine can point to no Medicaid purpose for the prior authorization requirement). <sup>42</sup> See 42 U.S.C.A. § 1396n(b)1 (West 1992)(authorizing a variety of waivers). See also 42

U.S.C.A. § 1315(a) (West 1992) (authorizing the Secretary of Health and Human Services to waive any part of the Medicaid law for state demonstration projects); Fernando R. LaGuarda, Note, Federalism Myth: States As Laboratories of Health Care Reform, 82 GEO. L.J. 159, 179 n.113 (1993) (discussing the Section 1315(a) waiver).

induce manufacturer participation in the Maine Rx Program without violating the Supremacy Clause. But the anti-profiteering provisions of the Act (as well as the price control provisions which have not as yet been the subject of litigation) are not preempted. Therefore, the fact that the prior authorization provision is preempted does not end the analysis, and the dormant Commerce Clause must also be considered.<sup>49</sup>

## B. The Act Is Prohibited Under Current Dormant Commerce Clause Doctrine

Before beginning my analysis of the Act under the dormant Commerce Clause, I will first provide a short discussion of the background and purpose of the dormant Commerce Clause. This discussion will illustrate that enjoining the Act would not further the purposes that the dormant Commerce Clause is meant to serve.

## 1. History and Background

The United States Constitution provides that Congress shall have the power "[t]o regulate commerce . . . among the several States . . . ."<sup>50</sup> This language speaks directly to the powers of Congress and nowhere implies any limitations on the power of the states to regulate commerce. However, the Supreme Court has inferred two such limitations. One is that in an area that Congress has explicitly regulated pursuant to its commerce power, the Supremacy Clause preempts any state regulation.<sup>51</sup> This limitation has direct constitutional authority<sup>52</sup> and is relatively uncontroversial.

The other limitation is that even in areas of interstate commerce that Congress has not expressly regulated, states may not impose laws that facially discriminate against<sup>53</sup> interstate commerce, nor may they impose laws that excessively burden<sup>54</sup> interstate commerce even if

<sup>52</sup> U.S. CONST. art. VI, § 1, cl. 1.

54 See Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970) (setting forth what is now known

<sup>&</sup>lt;sup>49</sup> For the sake of completeness, the prior authorization provision will be examined under the dormant Commerce Clause, even though, as just discussed, it is unconstitutional under the Supremacy Clause.

<sup>&</sup>lt;sup>50</sup> U.S. CONST. art. I, § 8, cl. 3.

<sup>&</sup>lt;sup>51</sup> See Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 211 (1824). See also infra Part III.A (discussing how Maine's prior authorization requirement fails under this portion of the Constitution).

<sup>&</sup>lt;sup>53</sup> See, e.g., West Lynn Creamery, Inc. v. Healy, 512 U.S. 186, 193 (1994) ("The paradigmatic example of a law discriminating against interstate commerce is the protective tariff or customs duty, which taxes goods imported from other States, but does not tax similar products produced in State."). Another name for discrimination against interstate commerce is economic protectionism. See, e.g., Philadelphia v. New Jersey, 437 U.S. 617, 624 (1978) ("where simple economic protectionism is effected by state legislation, a virtually per se rule of invalidity has been erected"). As both names imply, state laws of this type have the purpose of discriminating, or protecting a particular state's economy vis-à-vis the economies of other states. As stated unequivocally in *Philadelphia v. New Jersey, supra*, such laws will be automatically invalidated.

they do not facially discriminate. These two prohibitions form the foundation of dormant Commerce Clause doctrine. The principal reason given for the necessity of the inferred limitation on state power is to prevent the "economic Balkanization"<sup>55</sup> that would result from individual states enacting legislation for the purpose of protecting their own interests at the expense of out-of-state interests.<sup>156</sup> This state self-interest has been termed a "protectionist purpose" by constitutional scholar Donald Regan.<sup>57</sup>

At this juncture it is appropriate to define exactly what is meant by protectionist purpose. In this Comment, it has a much narrower meaning than a state simply enacting legislation that it intends to benefit its residents and impose a cost on out-of-state actors. As Regan describes it, "the immediate intended means to improvement of local well-being is the transfer of certain profitable activities from foreign to local hands," analogous to a tariff, embargo or quota.<sup>58</sup> In other words, the state must intend to take away from out-of-state actors in order to give to its local residents.<sup>59</sup> This definition does not

<sup>55</sup> Hughes v. Oklahoma, 441 U.S. 322, 325 (1979) (discussing economic Balkanization in reference to the colonies). 56 See, e.g., Camps Newfound/Owatonna, Inc. v. Town of Harrison, 520 U.S. 564, 578 (1997)

("By encouraging economic isolationism, prohibitions on out-of-state access to in-state resources serve the very evil that the dormant Commerce Clause was designed to prevent."); Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 522 (1935) ("We are reminded in the opinion below that a chief occasion of the commerce clauses was 'the mutual jealousies and aggressions of the States, taking form in customs barriers and other economic retaliation."") (internal citations omitted).

<sup>57</sup> See Donald H. Regan, The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause, 84 MICH. L. REV. 1091, 1095 (1986). I rely extensively on Regan's article in my discussion throughout this Comment. His thesis is that when the Court decides dormant Commerce Clause cases, while it claims to strike down laws that unduly burden interstate commerce using a balancing test, in reality it does not, and should not, balance burdens. Instead, Regan says, the Court only invalidates state laws that have a protectionist purpose. His argument is that this is all the Court does and should do. See id. at 1092. In this Comment I extend this reasoning to state laws with an extraterritorial reach. That is, the fact that a state law has an extraterritorial reach should not be sufficient to invalidate it without a protectionist purpose.

See id. at 1113; see also id. at 1095.

<sup>59</sup> Another way that I have described this concept elsewhere in this Comment is as a state's purpose to improve the economic position of its residents vis-à-vis the residents of other states. I have also described the parties being benefited or harmed by a protectionist law interchangeably as residents, citizens, or economic actors. These parties could be individuals or entities in business for economic gain. See Regan, supra note 57, at 1095 (using the catchall term of economic actors to describe producers, workers, consumers, distributors, etc.). I have only incorporated part of Regan's definition of protectionist purpose, which is even narrower than what I have described. He further says that the state's purpose must be to advantage local actors at the expense of foreign actors who perform the same economic function in the foreign economy. Another example would be benefiting local producers at the expense of out-of-state producers. See id. at 1095. I will not go this far as it appears such a definition might not include as protectionist the laws at issue in Brown-Forman Distillers Corp. v. New York State Liquor Authority, 476 U.S. 573 (1986) and Healy v. Beer Institute, 491 U.S. 324 (1989), both discussed in Part

as the Pike balancing test: a legitimate law that regulates evenhandedly will be upheld unless the burden on interstate commerce is "clearly excessive" in relation to local benefits). This task of judicial balancing has generated criticism, notably from one of the Court's own members, Justice Antonin Scalia. See discussion infra Part V.

include mere incidental harm to out-of-state interests in the process of conferring an independent local benefit.60

The other reason often cited for the necessity of the dormant Commerce Clause limitation on state power is the need to maintain the unimpeded flow of national commerce. Thus, a state law that unduly burdens this flow also cannot stand.<sup>61</sup> A balancing test is used to determine whether a state law imposes an undue burden on national commerce.<sup>62</sup> It is not clear that this second reason is fully distinguishable from the first one. However, Donald Regan has argued that in the movement-of-goods cases, even laws purportedly struck down under the "burden to interstate commerce" rubric were actually eliminated because of their protectionist purpose.<sup>63</sup> He supports this conclusion with an extensive analysis of Supreme Court dormant Commerce Clause cases, where state laws that had a protectionist purpose were struck down for being too burdensome to interstate commerce.<sup>64</sup> Moreover, the goal of maintaining the unimpeded flow of interstate commerce is closely related to preventing economic pro-tectionism by states.<sup>65</sup> It appears that in most instances, the second goal-that of maintaining the free flow of interstate commerce-is a restatement of the first one-that of preventing economic protectionism.

There is another twist that must be considered in determining whether a state law exceeds its constitutional limitations. It is the idea the states do not have the right to directly regulate transactions occurring outside their borders whether or not their purpose is to discriminate against interstate commerce. This idea is often called

IV.A.1., infra, which I argue are protectionist. These laws advantaged local consumers vis-à-vis out-of-state consumers and, but also at the expense of, foreign distributors.

See Regan, supra note 57, at 1113.

<sup>&</sup>lt;sup>61</sup> See Martin H. Redish & Shane V. Nugent, The Dormant Commerce Clause and the Constitutional Balance of Federalism, 1987 DUKE L.J. 569, 570 (1987) (noting that this is one of the Supreme Court's two primary justifications for the dormant Commerce Clause). See also Beer Inst., 491 U.S. at 335-36 (noting the Constitution's special concern with the maintenance of a national economic union).

See Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970) (introducing the modern balancing test).

See Regan, supra note 57, at 1108 (noting that the matter is not so straightforward for other cases, such as those involving interstate transportation or state taxes, and limiting his argument to movement-of-goods cases involving the buying and selling of goods in interstate commerce). I will likewise limit my analysis to movement-of-goods cases since the sale of pharmaceuticals fits within that category.

<sup>&</sup>lt;sup>54</sup> See id. at 1209-33 (discussing the leading precedent for balancing burdens and benefits under the dormant Commerce Clause, and showing that most of the state laws that were invalidated under a balancing test actually had a protectionist purpose).

See id. at 1128 (arguing that what he calls the "concept-of-union" objection to state regulation rests on the idea that economic actors should not be shut out of a state's market by preferential trade regulations, but that such preferential laws do not include a state legislature's nondiscriminatory determination of what should and should not be sold in its market simply because that determination may exclude someone).

extraterritorial regulation.<sup>66</sup> Before the advent of the balancing test, this analysis had historically been used when there was an empirical showing that the burden on interstate commerce was too great.<sup>67</sup> However, this analysis was recently used in Brown-Forman Distillers Corp. v. New York State Liquor Authority<sup>68</sup> to invalidate a New York law that set price ceilings for liquor sold in-state based on the seller's lowest price in other states. The Court held that a state law that "directly regulates or discriminates against interstate commerce" will generally be struck down "without further inquiry."<sup>69</sup> Based on the Court's lan-guage in *Brown-Forman* and its progeny,<sup>70</sup> there is no need to decide if such a law unduly burdens interstate commerce; such a law, like a law with a protectionist purpose, is subject to a "virtually *per se* rule of invalidity"<sup>71</sup> under the dormant Commerce Clause.<sup>72</sup> Finding that the Act does directly regulate interstate commerce, it is this standard that the district court in Maine relied on to grant the preliminary injunction in favor of PhRMA.73

### 2. Analysis of the Act Under the Dormant Commerce Clause

In this section, I will apply the Brown-Forman analysis to the Act, as the district court did, to show that it fails under current dormant Commerce Clause doctrine. In the next Part, I will show why an analysis that invalidates a state law simply for reaching across state lines is unnecessarily broad, given that the principal aim of the dormant Commerce Clause is to prevent states from engaging in economic protectionism.

<sup>&</sup>lt;sup>66</sup> See Baldwin v. G.A.F. Seelig, 294 U.S. 511, 521 (1935) (holding that states have no power to project their legislation into other states by regulating the price to be paid for goods acquired in other states).

See GERALD GUNTHER & KATHLEEN M. SULLIVAN, CONSTITUTIONAL LAW 268 (13th ed. 1997) (discussing the application of the "direct"-"indirect" distinction as an empirical showing of the burden on interstate commerce).

<sup>476</sup> U.S. 573 (1986).

<sup>69</sup> See id. at 579. The Court set forth this standard even though in this case there clearly was a protectionist purpose-giving local consumers the advantage of the same or a lower price for liquor as consumers in any other state, at the expense of out-of-state distributors.

See Healy v. Beer Inst., 491 U.S. 324 (1989) (holding that a Connecticut statute requiring sellers of beer to sell to Connecticut consumers at the lowest price that beer was sold to consumers in bordering states violated the dormant Commerce Clause).

Philadelphia v. New Jersey, 437 U.S. 617, 624 (1978).

<sup>&</sup>lt;sup>72</sup> Thus a law that regulates outside the state will be invalidated the same way a law that discriminates against interstate commerce would. See supra note 53 and accompanying text. Donald Regan asserts that the Commerce Clause does not even apply to what he calls genuinely extraterritorial state regulation, but rather that such regulation violates our federal structure in general. See Regan, supra note 57, at 1280 (discussing a plurality (but not majority) endorsement of the extraterritoriality theory in Edgar v. MITE Corp., 457 U.S. 624 (1982) (plurality opinion)). But what Regan is speaking of here is extraterritorial legislation that burdens other states, not private parties. See id. at n.164. See discussion infra notes 129-31 and accompanying text. 73

See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*\*15-16.

The district court in Maine enjoined specified portions of the statute on the ground that after a full proceeding on the merits, these portions would be held unconstitutional.<sup>74</sup> The provisions that the court found problematic under the dormant Commerce Clause were the illegal profiteering provision and the rebate program (the Maine Rx Program) as enforced by the prior authorization provision.<sup>75</sup> The court enjoined both of these provisions because they effectively regulated transactions conducted outside of the state of Maine.<sup>76</sup> Since at this stage the court had merely issued a preliminary injunction, it did not reach the issue of price controls, which are only a backup provision of the Act.<sup>77</sup> Presumably if price controls were enforced, they would be problematic for the same reason.<sup>78</sup>

On appeal, the First Circuit vacated the injunction with respect to the prior authorization provision (Maine did not appeal the injunction of the anti-profiteering provisions) by finding that it does not regulate extraterritorially.<sup>79</sup> Since the prior authorization provision and the anti-profiteering provisions are discussed separately below, a more detailed discussion of the First Circuit's holding is saved for the section addressing the prior authorization provision. In that section, I will argue that the First Circuit was only able to reach this conclusion by disregarding recent Supreme Court precedent describing the standard for impermissible extraterritorial regulation. This discussion will show that this precedent unmistakably encompasses the Act's prior authorization provision.

In contrast to the First Circuit's holding, the district court's conclusion is in harmony with current dormant Commerce Clause analysis. The Court has stated as recently as 1989 that the "Commerce Clause... precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, . . . [and] a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority, and is invalid....<sup>360</sup> The Court reiterated that the state's motive in enacting legislation is irrelevant in this regard and that what is critical is the statute's extraterritorial effect.<sup>81</sup>

<sup>&</sup>lt;sup>74</sup> See id. at \*25.

<sup>&</sup>lt;sup>75</sup> See id. at \*\*5-7, \*\*15-16.

<sup>&</sup>lt;sup>76</sup> See id. An explanation of how the Act regulates extraterritorially follows.

<sup>&</sup>lt;sup>77</sup> The price control provision of the Act is only to be resorted to if the other mechanisms, i.e., the anti-profiteering provision and the rebate program, do not sufficiently lower drug prices in the next three years. See ME. REV. STAT. ANN. tit. 22, § 2693 (West 2000).

<sup>&</sup>lt;sup>78</sup> The price control provision is what attracted the most media attention. However, it was not specifically challenged, nor was it addressed by either the district or the appellate court, most likely because the imposition of price controls is speculative at this point.

<sup>&</sup>lt;sup>19</sup> See Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 81 (1st Cir. 2001).

<sup>&</sup>lt;sup>80</sup> Healy v. Beer Inst., 491 U.S. 324, 336 (internal citations omitted). In making this statement, the Court cites *Brown-Forman*, *Edgar v. MITE Corp.* and *G.A.F. Seelig. See* discussion *infra* Part IV.A.

<sup>&</sup>lt;sup>1</sup> See id. (quoting Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S.

### a. The Extraterritorial Reach of the Anti-Profiteering Provisions Violates the Dormant Commerce Clause

Application of the above principles to the anti-profiteering provision of the Act invalidates it without much analysis. The antiprofiteering provision subjects drug manufacturers to ramifications for transactions entered into entirely outside of Maine, because all of the major drug manufacturers and most of their direct customers wholesalers and distributors—are located outside of Maine.<sup>82</sup> The provision indirectly punishes out-of-state manufacturers for charging "excessive" prices to these out-of-state distributors and wholesalers.<sup>83</sup> Since this clearly constitutes regulation of an extraterritorial transaction, the provision cannot be enforced with respect to out-of-state actors.<sup>84</sup>

### b. The Rebate Program Also Has an Impermissible Extraterritorial Effect

The rebate program is somewhat less straightforward. However, if the prior authorization requirement is analyzed as a regulatory sanction as opposed to a market inducement,<sup>85</sup> it fails under the same analysis. The rebate program essentially requires<sup>86</sup> drug manufacturers to provide the statutorily mandated discounts or be subject to the prior authorization provision. The state has attempted to frame the program as voluntary,<sup>87</sup> but in reality the state is subjecting a manufacturer to what is essentially a regulatory sanction. That this requirement is really legal coercion and not a market inducement is clarified by examining the state's participation argument.

The state argues that the rebate program is merely an exercise of its market power as a volume purchaser of prescription drugs under

<sup>573 (1986)).</sup> 

<sup>&</sup>lt;sup>82</sup> See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*13 (noting that there are no drug manufacturers located in Maine).

<sup>&</sup>lt;sup>83</sup> These wholesalers and distributors will then pass the excessive prices on to Maine pharmacies and ultimately to Maine consumers.

<sup>&</sup>lt;sup>84</sup> Presumably, if title passes in Maine to any wholesaler or distributor located in Maine, this provision could be enforced against the selling manufacturer. See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*6 (noting that there is one distributor in Maine, so this scenario is possible).

<sup>&</sup>lt;sup>85</sup> Maine has tried to characterize the rebate program as a market inducement in order to bring the Act under the market participation exception to the dormant Commerce Clause. The market participation exception is explained fully beginning in the next paragraph.

<sup>&</sup>lt;sup>86</sup> See ME. REV. STAT. ANN. tit. 22, § 2681(3) (West 2001). This provision says that drug manufacturers who sell drugs to any state drug assistance programs (including Medicaid) shall enter into a rebate agreement. See also ME. REV. STAT. ANN. tit. 22, § 2681(7) (West 2001). This provision says the Department shall impose the prior authorization requirement on non-participators. The two provisions combined can only be construed as a requirement.

<sup>&</sup>lt;sup>8'</sup> See Defendants' Memorandum at 25, Pharm. Research & Mfrs. of Am. (No. 00-157-B-H) (arguing that Maine is simply requesting rebates).

its Medicaid program.<sup>88</sup> The state claims that in giving the drug manufacturers this choice between participating in the Maine Rx Program and granting the rebates or being subject to the prior authorization requirement under its Medicaid program, the prior authorization requirement is just a bargaining chip that the state uses to negotiate with them.<sup>89</sup> The Supreme Court has created an exception to the strictures of the dormant Commerce Clause when a state participates in the market as an ordinary buyer or seller.<sup>90</sup> The Court reasons that when the state is acting as a market participant (i.e., buyer or seller), it is neither regulating nor legislating. Therefore, the state should be free to do business with whomever it chooses like any other participant in the market.<sup>91</sup> In this case, however, the state is not buying or selling anything. It is simply using the Medicaid scheme to achieve a separate regulatory goal—reducing prescription drug prices for its uninsured citizens.<sup>92</sup> The Supreme Court has expressly held that a state law using the state's leverage in one market where it does participate to achieve a separate regulatory purpose is subject to the dormant Commerce Clause as a state regulation, and is not market participation.<sup>93</sup> As the district court in Maine pointed out, the result might well be different if the state were actually buying the prescription drugs in question.<sup>94</sup> In this case, however, the State of Maine is not in fact acting as a market "participant" but rather as a regulator, and thus is not exempted from the dormant Commerce Clause.

<sup>91</sup> See Alexandria Scrap, 426 U.S. at 810 ("Nothing in the purposes animating the Commerce Clause prohibits a State, in the absence of congressional action, from participating in the market and exercising the right to favor its own citizens over others.").

<sup>92</sup> See ME. REV. STAT. ANN. itt. 22, § 2681(1) (West 2001) (laying out program goal of the Maine Rx Program as that of making prescription drugs more affordable for qualified Maine residents).

<sup>33</sup> See South-Central Timber Dev., Inc. v. Wunnicke, 467 U.S. 82, 96-98 (1984) (holding that Alaska's statute limiting buyers of its timber to those who agreed to process the purchased timber in Alaska to be subject to the dormant Commerce Clause).

<sup>94</sup> See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS, at \*12 n.8. Donald Regan also points out that when the state is acting as a market participant, it is spending money. See Regan, supra note 57, at 1193. Maine is spending no money in the Maine Rx Program, it is simply requiring drug manufacturers to charge a lower price to their Maine customers. The First Circuit agreed with this analysis, noting that since Maine is not a market buyer of prescription drugs, except as required by its Medicaid program, the state cannot be a market participant. See Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 81 (1st Cir. 2001).

<sup>&</sup>lt;sup>88</sup> See id.

<sup>&</sup>lt;sup>89</sup> See id.

<sup>&</sup>lt;sup>90</sup> See, e.g., White v. Mass. Council of Constr. Employers, 460 U.S. 204, 214 (1983) (holding that city is a market participant and not subject to the Commerce Clause when it only gives city funded work projects to work forces comprised of at least 50% city residents); Reeves, Inc. v. Stake, 447 U.S. 429 (1980) (upholding state policy restricting sale of cement from a state-owned plant to state residents); Hughes v. Alexandria Scrap Corp., 426 U.S. 794, 808 (1976) (holding that state acted as a market participant when it paid a bounty for destruction of abandoned cars and required less paperwork of in-state processors (destroyers) than it did of out-of-state processors).

The foregoing analysis illustrates that the prior authorization provision of the rebate program is not a market inducement, but is in fact a regulatory sanction. Once this is determined, the provision fails dormant Commerce Clause analysis for the same reason the antiprofiteering provision does: the Act regulates extraterritorial economic transactions by imposing either a rebate agreement or prior authorization requirement on drugs that are part of an out-of-state sale between out-of-state manufacturers who do not grant rebates, and out-of-state wholesalers and distributors.<sup>95</sup>

The First Circuit rejected this approach, however, finding that the prior authorization provision is simply not extraterritorial regulation. The court focused on the statutory language calling for negotiated rebate amounts under the rebate agreements rather than on the language subjecting drug manufacturers to outright price controls or mandating the tying of drug prices in Maine to drug prices in other states, both features of state laws previously invalidated for regulating extraterritorially. The court held that Maine is simply "negotiating" rebates, and therefore was not "regulating" prices.96 The court discounted the fact that a drug manufacturer's decision whether to enter into a rebate agreement is essentially non-negotiable by virtue of the prior authorization provision, disposing of this argument by call-ing the rebate program "voluntary."<sup>97</sup> It then held that since the purchase of a prescription drug triggering the rebate occurs in-state (at a local pharmacy), and since the negotiation of the rebate amount or the subjecting of the manufacturer's drugs to prior authorization occurs in-state, the statute not only does not "regulate" transactions between manufacturers and wholesalers, it does not do so out-of-state.<sup>98</sup>

After determining that the Act does not regulate extraterritorially, the First Circuit evaluated it under the *Pike* balancing test. The court determined that the Act has only incidental effects on interstate commerce and that the Act's benefits to Maine residents outweigh any burden on interstate commerce.<sup>99</sup>

This decision puts form over substance, and fails to follow established Supreme Court precedent dealing with extraterritorial regulation. As noted previously, Supreme Court precedent is quite clear

<sup>&</sup>lt;sup>95</sup> An analysis of the extraterritorial nature of the anti-profiteering provision is discussed above. See supra notes 83-84 and accompanying text. <sup>96</sup> See Pharm. Research & Mfrs. of Am., 249 F.3d at 82. The previous cases referred to are Healy

<sup>&</sup>lt;sup>50</sup> See Pharm. Research & Mfrs. of Am, 249 F.3d at 82. The previous cases referred to are Healy v. Beer Institute, 491 U.S. 324 (1989) (price tying); Brown-Forman Distillers Corp. v. New York State Liquor Authority, 476 U.S. 573 (1986) (price tying); and Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935) (price controls).

<sup>&</sup>lt;sup>97</sup> See Pharm. Research & Mfrs. of Am., 249 F.3d at 82.

<sup>98</sup> See id.

<sup>&</sup>lt;sup>99</sup> See id. at 83-84 (citing Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970)). The *Pike* balancing test refers to the Supreme Court's construction of the balancing test, which says that a legitimate law that regulates evenhandedly and has only incidental effects on interstate commerce will be upheld unless the burden on interstate commerce is "clearly excessive" in relation to local benefits.

that the dormant Commerce Clause prohibits a state's regulation of transactions occurring wholly outside its borders.<sup>100</sup> Moreover, this precedent establishes that the critical inquiry in determining a state law's validity is whether it has the "practical effect" of regulating commerce occurring outside the state's borders.<sup>101</sup> Thus it does not matter if the statute does not on its face regulate out-of-state transactions. The First Circuit failed to follow this precedent by ignoring the Act's purpose and practical effect of reaching out-of-state transactions between drug manufacturers and distributors. No drug manufacturers are located in Maine, and only one distributor resides there. The Act's purpose and effect is to lower the revenues received by these out-of-state manufacturers on drugs to be sold in Maine.<sup>102</sup> These revenues are received from out-of-state distributors in sales transactions occurring outside of Maine. No valid argument can be made that the Act, in its intent or practical effect, does not reach these transactions.

The court of appeals also put form over substance by characterizing the rebate program as voluntary. While the statute calls for negotiation of the actual rebate amount,<sup>103</sup> the manufacturers' choice of whether to either enter into a rebate agreement or allow their drugs to be subject to prior authorization is essentially non-negotiable.<sup>104</sup> Moreover, the court made no mention of PhRMA's evidence that prior authorization often has a substantial negative effect on market share.<sup>105</sup> That aside, this analysis fails to recognize that Maine did not intend these agreements to be voluntary—in deciding to subject uncooperative manufacturers to the prior authorization requirement, the state had obviously determined that a voluntary program would not be sufficiently effective.<sup>106</sup>

Since the Act regulates extraterritorially through the use of the prior authorization provision, the First Circuit's use of the *Pike* balancing test is also inappropriate. As previously discussed, the Supreme Court seems to have closed the door on balancing for state

<sup>&</sup>lt;sup>100</sup> See Beer Inst., 491 U.S. at 336.

<sup>&</sup>lt;sup>101</sup> See id. at 332. Additionally, the Supreme Court has held that dormant Commerce Clause analysis requires a case-by-case analysis of the purposes and effects of the state law at issue, not the formalistic approach employed by the First Circuit. See West Lynn Creamery, Inc. v. Healy, 512 U.S. 186, 201 (1994).

<sup>&</sup>lt;sup>102</sup> See Pharm. Research  $\Im$  Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*15 (observing that the practical effect of the Act is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that are destined for Maine).

<sup>&</sup>lt;sup>63</sup> See ME. REV. STAT. ANN. tit. 22, § 2681(4) (West 2001).

<sup>&</sup>lt;sup>104</sup> See supra note 22 (discussing the automatic consequence of the prior authorization requirement if a manufacturer fails to enter into a rebate agreement with the state).

<sup>&</sup>lt;sup>105</sup> This is one of the factors the district court relied on to determine that the rebate program was not voluntary. See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*22.

<sup>&</sup>lt;sup>106</sup> See id. (noting that it is common sense to conclude that the requirement was put in to give the statute some "bite").

laws that regulate extraterritorially.<sup>107</sup> Even if it had not done so directly, the current balancing test employed by the Court calls for the state regulation to have only an "incidental" effect on interstate commerce before balancing the benefits and burdens.<sup>108</sup> This indicates that the test applies where the challenged law only seeks to regulate locally but has an incidental side effect on interstate commerce.<sup>109</sup> This is not the case here, where the local law seeks to regulate extraterritorial transactions directly, notwithstanding the First Circuit's assertion to the contrary.<sup>110</sup> Its statement that the Act's effects on interstate commerce are incidental was made without analysis, and is belied by the Act's extraterritorial purpose and effect.

In summary, the relevant portions of the Act violate the dormant Commerce Clause simply because they constitute extraterritorial regulation. Having established this, I now turn to the central focus of this Comment, that the Act should be upheld under the dormant Commerce Clause, not (as the First Circuit did) by attempting to change its character, but through re-evaluation of dormant Commerce Clause doctrine.

# III. THE ACT SHOULD BE FOUND CONSTITUTIONAL UNDER DORMANT COMMERCE CLAUSE DOCTRINE

While the district court in Maine properly found a violation of the dormant Commerce Clause under current doctrine, when evaluated in light of the history and rationale behind the development of dormant Commerce Clause doctrine, the Act should be upheld. This is true for several reasons. First, and most important, the Act has no unlawful protectionist purpose, against which the dormant Commerce Clause is meant to protect.<sup>111</sup> Therefore the doctrine that

<sup>109</sup> See, e.g., Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456 (1981) (upholding a law requiring milk sold locally to be in recyclable containers if the containers were non-returnable, despite the incidental imposition on out-of-state sellers who sold milk within the state).

<sup>110</sup> See Pharm. Research & Mfrs. of Am., 249 F.3d at 83. The Act is extraterritorial in its purpose because it is designed to reach the prices charged by manufacturers, no matter where they conduct their sales. No doubt the Maine legislature knew that they would be conducting most of these sales outside of Maine. <sup>111</sup> For a full discussion of why the dormant Commerce Clause should only be used to pre-

<sup>111</sup> For a full discussion of why the dormant Commerce Clause should only be used to prevent implementation of state laws enacted with a protectionist purpose, *see infra* Part IV.A. In making this argument I essentially extend Donald Regan's theory that the Court does not and should not balance to extraterritorial regulation. He argues that the Court, while employing a balancing rubric, strikes down only protectionist state laws. *See* Regan, *supra* note 57, at 1092. Similarly, as I will show, the Court also strikes down protectionist state laws while dubbing them extraterritorial. To be sure, their reach is "extraterritorial," but that is not why they are invalid.

<sup>&</sup>lt;sup>107</sup> See Beer Inst., 491 U.S. at 336 (internal citations omitted) (holding that a state law that regulates wholly outside the state's borders is invalid simply because such a law exceeds the enacting state's inherent authority). See also supra text accompanying notes 80-81 (quoting Healy v. Beer Inst., 491 U.S. 324 (1989)).

<sup>&</sup>lt;sup>108</sup> See Pike, 397 U.S. at 142 (requiring state law to regulate evenhandedly and have only an incidental effect on interstate commerce before the Court will balance its benefits against the burden on interstate commerce).

would invalidate it is overly broad. Nor is a possible discriminatory effect sufficient grounds for invalidation, since this should only be relevant if there is an unlawful purpose.<sup>112</sup> In a related vein, the law's effect on private interests is not a valid reason in itself to strike down the law, because this is not what the dormant Commerce Clause is in place to prevent.<sup>113</sup> Also, since states are often at a political disadvantage in relation to private interests, it becomes especially important for the Court to uphold state laws that do not offend dormant Commerce Clause principles.<sup>114</sup> Furthermore, the instant issue is healthcare, a traditional area of state responsibility.<sup>115</sup> Related to this, and what makes this entire issue novel, is that while healthcare has traditionally been a state issue, healthcare reform is now on the national agenda. Moreover, the federal government, having been thus far unable to come up with a viable reform strategy, is looking to states to lead the way.<sup>116</sup> It therefore makes no sense to employ an unnecessarily broad interpretation of dormant Commerce Clause doctrine to curtail their efforts. Each of these reasons is addressed in turn.

# A. The Act Should Not Exceed the State's Commerce Power Because Maine Has No Unlawful Protectionist Motive<sup>117</sup>

Since Maine seeks no unlawful economic advantage for its residents through the passage of the Act, the law should be upheld under the dormant Commerce Clause. The lack of any protectionist purpose has not been disputed, and was acknowledged by the Maine district court.<sup>118</sup> However, the court looked to the leading case of *Baldwin v. G.A.F. Seelig, Inc.*,<sup>119</sup> a case involving New York's attempt to prohibit the sale of milk within its borders if the milk had been purchased outside the state at a price below New York's statutorily imposed minimum. This effectively regulated the price of any milk

<sup>116</sup> See infra Part IV.C.

<sup>118</sup> See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*13 (acknowledging no attempt by Maine to favor in-state business over out-of-state business). For the majority of this discussion, I will apply the district court's analysis, which is more consistent with dormant Commerce Clause doctrine than that of the First Circuit.

<sup>119</sup> 294 U.S. 511 (1935).

Thus, striking down the Act without finding a protectionist purpose, while consistent with the Court's language, is generally not consistent with the modern Court's practice.

<sup>&</sup>lt;sup>112</sup> See discussion infra Part IV.B.

<sup>&</sup>lt;sup>113</sup> See id.

<sup>&</sup>lt;sup>114</sup> See infra Part IV.C.

<sup>&</sup>lt;sup>115</sup> See infra Part IV.D.

<sup>&</sup>lt;sup>117</sup> For purposes of this discussion, "protectionist purpose" should be given the precise meaning defined earlier. This definition does not include cases where the harm to out-of-state interests is a known, but incidental effect of the benefit to in-state interests. It only includes instances where the detriment to out-of-state interests is an intended means to achieve local wellbeing. See supra notes 58-59 and accompanying text.

bought outside of New York if there was an intention to sell it to New York consumers.

The district court found a parallel situation with the antiprofiteering provision of the Act, because if a drug manufacturer engages in the profiteering deemed illegal by the statute when it sells drugs destined for Maine to a wholesaler or distributor located outside of Maine, the drug manufacturer will have violated the Act without ever having transacted business in Maine. The court found this to be no different than what the state of New York did in G.A.F. Seelig.<sup>120</sup> The court acknowledged, however, that there was no intent to advantage Maine businesses over out-of-state businesses.<sup>121</sup> This makes G.A.F. Seelig different from the instant case, because in G.A.F. Seelig, the clear purpose of the statute was to give New York milk producers an advantage over their out-of-state competitors.<sup>122</sup> However, the court pointed to more recent decisions of the Supreme Court that expressly state that states have no authority to regulate outside their borders regardless of purpose.<sup>123</sup> Specifically, the court quoted language from two cases involving state regulation of alcoholic beverage prices that tied the prices that sellers could charge to prices charged in other states.<sup>124</sup> In these cases, the Court extrapolates from earlier decisions<sup>125</sup> to make the sweeping statement that it does not matter what a state's motive is for the law at issue; any extraterritorial regulation is automatically disallowed as beyond the states' constitutional authority.<sup>126</sup>

The problem with the Court's analysis is that a true application of this principle would have an overinclusive result. Perhaps there is no reason for concern, however, if the Court does not really apply its

See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*14 (substituting prescription drugs for milk and finding G.A.F. Seelig to apply). The court made this comparison when analyzing the prior authorization provisions, but the opinion references this analysis when discussing the illegal profiteering provisions. As discussed in Part III, the dormant Commerce Clause applies to both in exactly the same way.

See id. at \*13. Nevertheless, applying Supreme Court precedent, the district court held that since Maine has no power to regulate extraterritorially, it is irrelevant whether the Act actually discriminates against interstate commerce. See id. at \*\*15-16.

See G.A.F. Seelig, 294 U.S. at 522 (noting that the purpose of the New York milk law was to protect its farmers from interstate competition). <sup>123</sup> See supra text accompanying notes 80-81 (quoting Healy v. Beer Inst., 491 U.S. 324

<sup>(1989)).</sup> <sup>124</sup> See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*\*14-15 (quoting from Healy v. Beer Inst., 491 U.S. 324 (1989) and Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573 (1986)).

These previous decisions are Edgar v. MITE Corp., 457 U.S. 624 (1982); Raymond Motor Transportation, Inc. v. Rice, 434 U.S. 429 (1978); Philadelphia v. New Jersey, 437 U.S. 617 (1978); and Shafer v. Farmers Grain Co., 268 U.S. 189 (1925). All of these cases will be discussed below.

<sup>&</sup>lt;sup>126</sup> See Beer Inst., 491 U.S. at 336 (internal citations omitted) (quoting Brown-Forman and holding that a state law that regulates wholly outside the state's borders is invalid simply because such a law exceeds the enacting state's inherent authority); Brown-Forman, 476 U.S. at 579 (holding that when a state law directly regulates interstate commerce, it is struck down without further inquiry).

stated doctrine. In his argument against the use of the balancing test, Donald Regan proposes that this test has grown up through language from precedent that has been taken out of context, and that in practice, the Court does not engage in a true application of its balancing doctrine.<sup>127</sup> He proposes this to support the theory that the Court should not and does not engage in a balancing test when deciding the constitutionality of state laws, and instead only invalidates laws with a protectionist purpose.<sup>128</sup> I will apply this theory against the extraterritoriality doctrine, illustrating that the Court has not in the past struck down extraterritorial state laws simply for being so; that every extraterritorial state law that it has struck down on this basis has also been protectionist; and that the Court has likewise fashioned this extraterritoriality doctrine from language in prior decisions taken out of context. Consistent with its practice, if not its language, the Court should uphold state laws with an extraterritorial reach, if there is no unlawful purpose.

Before suggesting such a revision in dormant Commerce Clause doctrine, I must emphasize that I am not advocating a doctrine that allows states to impose their legislation on other states. As Donald Regan observes, such "genuinely extraterritorial" legislation offends the structure of the federal system as a whole by allowing states to burden the autonomy interests of other states.<sup>129</sup> That is not, however, a Commerce Clause issue. As Regan notes, states are forbidden to legislate extraterritorially (as opposed to enacting legislation with an extraterritorial reach) whether or not the regulation has anything to do with commerce.<sup>150</sup> However, there is a difference between passing legislation intended to have independent legal force in other jurisdictions and passing laws that reach out-of-state activity, such as the Act. As the First Circuit correctly noted, "[t]he Act does not interfere with regulatory schemes in other states."<sup>151</sup> If it did, it would be impermissible, no matter what it regulated and no matter what the motivation.

<sup>151</sup> Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 82 (1st Cir. 2001). If the Act did interfere with other states' regulatory schemes, other state governments would be challenging it. As noted below, the opposite is happening here, where other state governments support Maine and hope to follow its example. *See infra* note 222 and accompanying text.

<sup>&</sup>lt;sup>127</sup> See Regan, supra note 57, at 1108-09.

<sup>&</sup>lt;sup>128</sup> See id. at 1108.

<sup>&</sup>lt;sup>129</sup> See Regan, supra note 57, at n.164. A corollary to this concept is the Full Faith and Credit Clause, which requires state courts to respect the judgments of its sister state courts. See U.S. CONST. art. IV, § 1.

<sup>&</sup>lt;sup>139</sup> See Regan, supra note 57, at 1280. He notes that outside of the interstate commerce arena, the Court has often located the prohibition on extraterritorial state action in the due process clause. An example of impermissible extraterritorial legislation might be if Pennsylvania, which requires its dog owners to register their pets, decided to subject New Jersey dog owners to this requirement as well. Clearly, Pennsylvania has no right to do this. The legal issues surrounding this type of extraterritorial legislation, notions such as procedural due process and personal jurisdiction, are complex and beyond the scope of this Article. The reader should, however, be able to intuitively see the distinction that I have made.

## 1. An Analysis of the Cases Upon Which the Supreme Court Has Relied To Expand the Dormant Commerce Clause Reveals That This Expansion Is Too Broad

In Brown-Forman Distillers Corp. v. New York State Liquor Authority, the first of the alcoholic beverage cases referenced above, the Court states that "[w]hen a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry."<sup>132</sup> To back this statement up, it cites *Philadelphia v. New Jersey*,<sup>133</sup> a case involving a statute that favored in-state interests over out-of-state interests;<sup>134</sup> *Shafer v. Farmers* Grain Co.,<sup>135</sup> a 1925 case that applied the old direct-indirect distinction<sup>136</sup> to a North Dakota law that did not regulate outside its borders, but imposed what the Court determined to be a "direct" burden on interstate commerce;<sup>137</sup> Edgar v. MITE Corp.,<sup>138</sup> a plurality opinion that invalidated a state anti-takeover statute as an excessive burden on interstate commerce;<sup>139</sup> and Raymond Motor Transportation, Inc. v. Rice,<sup>140</sup> a case involving in-state regulation that the Court also determined imposed an impermissible burden on interstate commerce.<sup>141</sup> Of these cases, *Philadelphia* involved a clearly protectionist purpose,<sup>142</sup> and evidence of a protectionist purpose influenced the Court's decision in Raymond.<sup>143</sup> That leaves Farmers Grain and MITE. Farmers Grain, while involving a non-protectionist state law, is an old case, decided under what is generally believed to be an obsolete doctrine.<sup>144</sup> Donald Regan believes that if this case were decided today under modern doctrine,<sup>145</sup> it would have been decided differently.<sup>146</sup>

<sup>143</sup> See Raymond, 434 U.S. at 446-47.

<sup>144</sup> This doctrine is the direct-indirect distinction under which a law might be upheld if its effect on interstate commerce was not direct. See supra note 136 (discussing the early use of this

<sup>&</sup>lt;sup>132</sup> Brown-Forman, 476 U.S. at 579.

<sup>&</sup>lt;sup>133</sup> 437 U.S. 617 (1978).

<sup>&</sup>lt;sup>134</sup> See id. at 626-27 (holding that New Jersey law banning waste coming from out-of-state from being deposited in its landfills was protectionist and therefore violated the Commerce Clause).

 <sup>&</sup>lt;sup>135</sup> 268 U.S. 189 (1925).
<sup>136</sup> Under this distinction, a law might be upheld if its impact on interstate commerce was not direct. However, this was really just a way of measuring the extent of the burden on interstate commerce. See GUNTHER & SULLIVAN, supra note 67, at 268. The doctrine's usefulness was questioned by several Justices, and later gave way to the modern balancing test. See id. at 269. See also Regan, supra note 57, at 1213 ("Shafer was written before the modern era by a Justice (Van Devanter) who believed in the direct/indirect test ....").

See Farmers Grain, 268 U.S. at 199-200 (holding that North Dakota's law requiring grading of wheat bought within the state imposed a direct burden on interstate commerce since about 90% of North Dakota's wheat was bought in order to be shipped in interstate commerce).

<sup>457</sup> U.S. 624 (1982) (plurality opinion).

<sup>&</sup>lt;sup>139</sup> See id. at 646 (holding that Illinois Act imposed a substantial burden on interstate commerce and that such burden outweighed its putative local benefits).

<sup>&</sup>lt;sup>140</sup> 434 U.S. 429 (1978). <sup>141</sup> See id. at 447.

<sup>&</sup>lt;sup>142</sup> See Philadelphia, 437 U.S. at 626-27. See supra note 134 for a description of the law at issue.

MITE is the only case the Court cites in Brown-Forman that implicates a state law even remotely resembling the Maine law. The Illinois anti-takeover law required a person making a tender offer for a target company<sup>147</sup> to notify the target and the Secretary of State of his intent to tender twenty days before the offer became effective.<sup>148</sup> The offer would become effective after the twenty days unless the Secretary called a hearing to adjudicate the fairness of the offer.<sup>149</sup> These requirements were a little more restrictive than the federal anti-takeover requirements.<sup>150</sup> The Court agreed that the law was uncon-stitutional, but had a hard time agreeing on why.<sup>151</sup> The official theory is that the law imposed an excessive burden on interstate commerce under the *Pike* balancing test.<sup>152</sup> But Justice White, joined by three others, opined that it was also an impermissible extraterritorial regulation because a tender offeror would have to employ interstate commerce facilities in communicating the offer,<sup>153</sup> and the law could be applied to regulate a tender offer that did not involve any Illinois shareholders.<sup>154</sup> He also theorized that the statute was preempted by the federal anti-takeover law.<sup>155</sup> It is the extraterritorial regulation theory that is cited by *Brown-Forman*.<sup>156</sup> But this theory was not endorsed by a majority of the Court. This is significant given that, as noted previously, this is the only modern<sup>157</sup> dormant Commerce

<sup>147</sup> A "target company" was defined generally in the statute as a company 10% owned by Illinois shareholders or a company (1) incorporated in Illinois, (2) having its principal executive office in Illinois, or (3) having at least 10% of its capital represented in Illinois. See MITE, 457 U.S. at 627. <sup>148</sup> *Id.* <sup>149</sup> *Id.* 

test and its later decline).

<sup>&</sup>lt;sup>5</sup> Modern doctrine would strike down a law that (1) discriminated against interstate commerce, (2) unduly burdened interstate commerce under the Pike balancing test, (3) or regulated across state lines. See supra Part III.B.1 for a full discussion of the modern dormant Commerce Clause doctrine. The North Dakota law in Farmers Grain did not regulate extraterritorially, so the third arm of the analysis would not be implicated. See supra note 137 for a description of the law.

Regan, supra note 57, at 1213.

<sup>&</sup>lt;sup>150</sup> See Regan, supra note 57, at 1279.

<sup>&</sup>lt;sup>151</sup> The decision was a plurality in which five of the Justices agreed that the law unduly burdened interstate commerce, and four decided it was also impermissible extraterritorial regulation. See MITE, 457 U.S. at 626 (breaking down the opinion into sections and noting the parts joined by each Justice).

<sup>&</sup>lt;sup>152</sup> This was the theory that five of the Justices could agree on. See id. at 646.

<sup>&</sup>lt;sup>153</sup> Such interstate facilities included the mail. See id. at 641.

<sup>&</sup>lt;sup>154</sup> This was because a target company was defined by the statute to be a company owned by at least 10% Illinois shareholders or having its principal office in Illinois. Thus, a transaction with shareholders of a target company would be unlikely to be with only Illinois shareholders. Justice White also cited Hughes v. Alexandria Scrap Corp., 426 U.S. 794 (1976), a case involving the market participation exception discussed earlier, Southern Pacific Co. v. Arizona, 325 U.S. 761 (1945), a case that invalidated a state regulation of interstate trains as an impermissible burden on interstate commerce, and Farmers Grain.

 <sup>&</sup>lt;sup>155</sup> See MITE, 457 U.S. at 634.
<sup>156</sup> See Brown-Forman, 476 U.S. at 579.

<sup>&</sup>lt;sup>157</sup> This term is borrowed from Donald Regan, who based his theory on cases after 1934. See

Clause case involving a state law that is not overtly protectionist. The Court could not agree that the law should be invalidated simply for regulating beyond its borders. One might ask why it was invalidated at all given that it is not clearly protectionist. The theory that the finding of a protectionist purpose is necessary to invalidate state laws under the dormant Commerce Clause would only support invalidation of this law if it were preempted. Justice White articulated this thought, so there was certainly some support for it. In any event, this case is not unequivocal precedent for per se invalidation of extraterritorial regulation, and, were there no preemption issue, it should not have been struck down at all. In fact, this case does not clearly stand for any particular doctrine.<sup>158</sup> Faced with a non-protectionist statute,<sup>159</sup> the Court could not agree that it violated the dormant Commerce Clause solely because of its supposedly extraterritorial reach.

The statement the Court makes in Brown-Forman is that it is irrelevant that a state regulation is addressed only to in-state actors if the "practical effect" is to control prices in other states.<sup>160</sup> As authority for this statement the Court cites Southern Pacific Co. v. Arizona,<sup>161</sup> a 1945 case involving state regulation of interstate trains that was determined to impose an impermissible burden on interstate commerce. But once again, it is not at all clear that this case is a persuasive authority. Southern Pacific is a transportation case, which the Court cites as support in a movement-of-goods decision. Donald Regan argues that transportation cases raise different interstate commerce issues than do movement-of-goods cases, and that they should not be analyzed under the same standards.<sup>162</sup> This is so, he says, because as a country we have a national interest in effective transportation linking the states in addition to our national interest in avoiding state protectionism, which he claims is the only national interest to be protected in movement-of-goods cases. If one accepts this distinction, the Court should not use transportation cases as precedent for deciding movement-of-goods cases. Also, other constitutional scholars distinguish between interstate commerce cases involving instrumentalities in in-

Regan, supra note 57, at 1093-94.

<sup>&</sup>lt;sup>158</sup> This is because it could have rested on three different theories. Donald Regan believes that the Court wanted to reach the result of invalidation of the law. Given the disparate theories, however, one cannot place too much stock in how the Court reached this result. See Regan, supra note 57, at 1279.

<sup>&</sup>lt;sup>159</sup> Regan notes that you could make a case for protectionism in that the law disproportionately protected corporations located in Illinois and that the purpose of the law was to attract businesses to locate in Illinois. *See id.* at 1279. This is a dubious position since state corporate laws are often designed to attract corporations to a particular state and no one argues that this violates the dormant Commerce Clause. *See* MELVIN ARON EISENBERG, CORPORATIONS AND OTHER BUSINESS ORGANIZATIONS 101-03 (8th ed. 2000) (discussing states' incentives to design corporation laws to attract corporations).

<sup>&</sup>lt;sup>160</sup> Brown-Forman, 476 U.S. at 583.

<sup>&</sup>lt;sup>161</sup> 325 U.S. 761 (1945).

<sup>&</sup>lt;sup>162</sup> Regan, *supra* note 57, at 1184.

terstate commerce and those involving goods being bought and sold in interstate commerce, so as to suggest that there is an analytical distinction.<sup>163</sup> What this is, then, is a clear example of the Court taking the words "practical effect" from a case arising out of a completely different context than the Brown-Forman case did, with a resulting expansion of the dormant Commerce Clause that is unjustified. The effects of state regulation on interstate commerce will be discussed in more detail in section B, below.

In *Healy v. Beer Institute*,  $^{164}$  the second alcoholic beverage case, the Court relied principally on Brown-Forman and MITE.<sup>165</sup> This opinion goes even further than the extraterritorial "practical effect" and states that the law will be invalid regardless of the intent of the legislature.<sup>166</sup>

In both Brown-Forman and Beer Institute, as well as in G.A.F. Seelig, the Court found it easy to invalidate the state laws in question because they all involved clear state protectionism.<sup>167</sup> But in invalidating these laws, the Court unnecessarily rested its analysis on the extrater-ritorial effect of these laws.<sup>168</sup> Instead, it should have simply invalidated all of them on grounds of economic protectionism.

Since the Court unnecessarily expanded its dormant Commerce Clause analysis beyond economic protectionism, it has laid the unfortunate groundwork for invalidation of the Act and laws similar to it. When deciding cases involving the movement of goods in interstate commerce, the Court has not had the need to invalidate nonprotectionist laws simply for their extraterritorial reach, nor has it unequivocally done so.

The reason for this is that invalidation of such laws serves no dormant Commerce Clause purpose. The principal purpose of the dormant Commerce Clause is to prevent states from engaging in eco-nomic protectionism.<sup>169</sup> Invalidation of the Act under the dormant

Indeed, in Beer Institute, Justice Scalia says as much, declining to endorse the majority's extraterritorial effect analysis, and joining the holding on the grounds that the law was discriminatory. See Beer Inst., 491 U.S. at 345.

<sup>&</sup>lt;sup>163</sup> See GUNTHER & SULLIVAN, supra note 67, at 299 (analyzing transportation cases separately under a section called "State Burdens on Transportation").

<sup>491</sup> U.S. 324 (1989).

 <sup>&</sup>lt;sup>165</sup> Beer Inst., 491 U.S. at 336 (citing both cases in its holding).

See id.

<sup>&</sup>lt;sup>167</sup> See id. at 329 (discussing the same type of law for beer); Brown-Forman, 476 U.S. at 576 (discussing the New York liquor pricing law which required sellers to charge its consumers the lowest price charged to consumers in other states, thereby requiring out-of-state distributors to surrender any economic advantage they may have had in other states); G.A.F. Seelig, 294 U.S. at 522 (discussing the New York Milk Control Act, the purpose of which was to protect New York farmers from out-of-state competition).

<sup>&</sup>lt;sup>169</sup> See, e.g., Camps Newfound/Owatonna, Inc. v. Town of Harrison, 520 U.S. 564, 580-81 (1997) (reiterating that economic isolationism is what the dormant Commerce Clause is there to prevent). PhRMA refers to the goal of the dormant Commerce Clause as that of preventing "Balkanization." See Plaintiff's Motion at 7, Pharm. Research & Mfrs. of Am. (No. 00-157-B-H). Such "Balkanization" is prevented by preventing state protectionism, not extraterritorial regulation, however. See id.

Commerce Clause does not serve this purpose. Maine does not seek to give its industry or its consumers any economic advantage over the industry or consumers of other states.<sup>170</sup> The only goal in passing this legislation is to make what is an increasingly fundamental<sup>171</sup> healthcare need available to its residents.<sup>172</sup> It wishes to do this to ensure their health and well-being, a policy well within its traditional police power.<sup>173</sup> Since the law seeks to do this and nothing more, the dormant Commerce Clause should not be grounds for its invalidation.

# 2. A Comparison of the Act with State Laws That Have Been Struck Down As Extraterritorial Reveals That These Invalidated Laws Could Have Been Struck Down As Protectionist

A comparison of the Act with the liquor cases and G.A.F. Seelig helps to illustrate that invalidated laws could have been struck down as protectionist. The liquor cases reflected New York and Connecticut's desire to obtain the lowest prices for liquor and beer for their consumers vis-à-vis the consumers of other states.<sup>174</sup> These laws could not be characterized as having anything but a protectionist purpose since there is no convincing health or welfare purpose for making liquor in New York or Connecticut as cheap or cheaper than it is in other states.

Similarly, the law at issue in G.A.F. Seelig involved New York's desire to protect its milk producers from out-of-state competition, i.e., to improve their economic position vis-à-vis milk producers in neighboring states. In this case, New York attempted to justify its law as a health and safety measure by claiming that it gave local producers the financial wherewithal to produce clean and wholesome milk. The Court was rightly unconvinced, since this theory would justify eco-

<sup>&</sup>lt;sup>170</sup> See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*13 (acknowledging no attempt by Maine to favor in-state business over out-of-state business, or to favor Maine consumers over out-of-staters). <sup>171</sup>See GAO/T-HEHS-99-153, MEDICARE: CONSIDERATIONS FOR ADDING A PRESCRIPTION DRUG

BENEFIT (U.S. General Accounting Office 1999) (reporting that in the five years preceding 1999, the rise in prescription drug expenditures has more than doubled that of health care expenditures overall, and noting the growing importance of prescription drugs as part of health care). See also Health Insurance Association of America, State Pharmaceutical ASSISTANCE PROGRAMS CONTINUE TO GROW (September 18, 2000) (citing increased importance of drug therapy in modern medicine leading to increased utilization of prescription drugs as one of the most important factors in the rising cost of prescription drugs).

<sup>&</sup>lt;sup>172</sup> See ME. REV. STAT. ANN. tit. 22, § 2681(1) (West 2000) (citing the legislative finding that affordability is critical in providing access to prescription drugs and stating that therefore the goal of the Maine Rx Program is to make prescription drugs more affordable). <sup>173</sup> See Hill v. Colorado, 530 U.S. 703, 715 (2000) ("It is a traditional exercise of States' 'police

powers to protect the health and safety of their citizens.") (internal citations omitted). <sup>174</sup> This could only be regarded as an economic purpose; these states could not likely cite a

health or safety reason for making alcoholic beverages more affordable.

nomic protectionism whenever a state could come up with a vaguely plausible health and safety justification.<sup>175</sup>

In its motion, PhRMA compared the Act to the liquor cases and suggested that Maine wished to obtain the lowest price possible for prescription medications for its citizens vis-à-vis buyers of prescription medication in other states, just as the states of New York and Connecticut did for their liquor and beer consumers in Brown-Forman and Beer Institute.<sup>176</sup> In making this argument, PhRMA pointed to the provision in the Act that directs the Commissioner to seek rebates equivalent to those that Maine receives under its Medicaid program.<sup>177</sup> The rebates received under the Medicaid program are set by federal law and are therefore applied nationally.<sup>178</sup> PhRMA argued that Maine's "benchmarking" of rebates under the Maine Rx Program to the federal Medicaid rebate program is impermissible under Brown-Forman and Beer Institute.<sup>179</sup>

The states in Brown-Forman and Beer Institute required distributors of liquor and beer to tie the maximum price charged to consumers of New York and Connecticut to the lowest price charged to consumers in other states.<sup>180</sup> In Brown-Forman, distributors were required to limit their prices to the lowest price charged nationwide.<sup>181</sup> In *Beer Institute*, distributors were required to tie their prices to the lowest price charged in neighboring states.<sup>182</sup> The clear goal of these laws was to improve the economic position of New York and Connecticut consumers vis-à-vis consumers of other states.<sup>183</sup>

In contrast, Maine has no concern that its residents pay less or the same price for prescription drugs than the residents of other states.<sup>184</sup> The state's sole purpose is to make prescription drugs more accessible to its residents through the use of a manufacturer's rebate.<sup>185</sup> The

See G.A.F. Seelig, 294 U.S. at 523 ("Let such an exception be admitted, and all that a state will have to do in times of stress and strain is to say that its farmers and merchants and workmen must be protected against competition from without, lest they go upon the poor relief lists or perish altogether.").

See Plaintiff's Motion at 11, Pharm. Research & Mfrs. of Am. (No. 00-157-B-H).

<sup>&</sup>lt;sup>177</sup> See ME. REV. STAT. ANN. it. 22, § 2681(4) (West 2000).

<sup>&</sup>lt;sup>178</sup> See 42 U.S.C.A. § 1396r-8(c) (1992) (detailing the rebate calculation for all state Medicaid programs).

See Plaintiff's Motion at 12, Pharm. Research & Mfrs. of Am. (No. 00-157-B-H).

<sup>&</sup>lt;sup>180</sup> See Brown-Forman, 476 U.S. at 576 (discussing the New York liquor pricing law). See also Beer Inst., 491 U.S. at 329 (discussing the same type of law for beer).

See Brown-Forman, 476 U.S. at 575. 182

See Beer Inst., 491 U.S. at 326.

<sup>&</sup>lt;sup>183</sup> See Brown-Forman, 476 U.S. at 579 (noting that New York's asserted interest is obtaining the lowest possible prices for its residents). The lowest possible price was to be no higher than the price charged anywhere else. See id. at 575. See also Beer Inst., 491 U.S. at 326 (noting Connecticut's purpose of eliminating a price differential between beer sold in Connecticut and beer sold in surrounding states so that its residents would not go to neighboring states to buy it). 184

See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*13 (noting that there is no suggestion that Maine is trying to benefit the local economy).

The state has non-regulatory alternatives. For example, it could rely solely on its market

Act simply uses a national standard to determine the amount of this rebate. This is not prohibited "economic provincialism";<sup>186</sup> if anything it is the opposite. Economic provincialism would exist if Maine required rebates for its residents without having any regard for the rebates that are sought nationally, and such rebates were greater than the national norm.

This comparison reveals that in making this argument, PhRMA put form over substance. The Court in *Brown-Forman* and *Beer Institute* did not invalidate the liquor and beer laws simply because they "benchmarked." For example, it is doubtful that the Court would have been as troubled by these laws if they had simply required the distributors to set prices in New York and Connecticut in accordance with a nationally accepted liquor pricing standard. What the Court found offensive in these cases was the states' purpose: to improve the economic position of their citizens vis-à-vis that of the citizens of other states.<sup>187</sup> The Act's use of the Medicaid rebate amounts shows that this so-called "benchmarking" can be done without a purpose that offends the dormant Commerce Clause.

Comparison of the Maine statute to G.A.F. Seelig is also instructive because here we have a state law, similar to the law in G.A.F. Seelig, that seeks to regulate prices. But here, unlike in G.A.F. Seelig, the state has a genuine health and welfare purpose, and no concurrent protectionist purpose. The G.A.F. Seelig case thus illustrates the erroneous breadth of the dormant Commerce Clause doctrine. The Court in G.A.F. Seelig was not confronted with the situation under the dormant Commerce Clause where a state attempts to regulate prices for purely health and welfare reasons, but its language unnecessarily includes such efforts.<sup>188</sup> The Court could have simply invalidated the New York law on the ground that it was protectionist without making the sweeping statement that any state law affecting extraterritorial transactions violates the dormant Commerce Clause.<sup>189</sup> As the Court's language suggests, its decision would have been much more difficult had the State of New York passed its Milk Control Act for purely health and welfare reasons as the Court clearly recognized the impor-

power without the addition of regulatory enforcement. In fact, Maine has explored this avenue as well. See Maine Department of Human Services Press Release, Maine Joins Vermont, New Hampshire in Tri-State Drug Program (Oct. 24, 2000) available at http://www.state.me.us/dhs/

pressx.htm. The three states have formed a purchasing coalition to negotiate discounts for residents of all three states. See id. <sup>186</sup> Brown-Forman, 476 U.S. at 590 (discussing G.A.F. Seelig as a classic case of such provincial-

Brown-Forman, 476 U.S. at 590 (discussing G.A.F. Seelig as a classic case of such provincialism).

<sup>&</sup>lt;sup>187</sup> See Beer Inst., 491 U.S. at 339 (citing Brown-Forman and stating that states may not deprive out-of-state consumers and businesses of whatever economic advantage they may possess in their local markets).

<sup>&</sup>lt;sup>188</sup> See G.A.F. Seelig, 294 U.S. at 521 ("New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there.").

tance of the states' role in this area.<sup>190</sup> It certainly could not have foreseen<sup>191</sup> that one day these words would be used to prohibit states from enacting important health policy.<sup>192</sup> If this case should ever come before the Court, it will have to either narrow its current doctrine, or decide that the Constitution prohibits states from regulating drug prices, even when they find such regulation necessary in order to fulfill their responsibility to ensure their citizens' health. Since this perverse outcome does not serve any dormant Commerce Clause purpose,<sup>193</sup> and in fact prevents the states from fulfilling their duties,<sup>194</sup> the Court should choose the former course.

The above comparisons show that the Act is not like the laws invalidated in the earlier cases, in that it has no protectionist purpose. In addition, it has a social welfare purpose that is well within Maine's police power and responsibility.<sup>195</sup> Since the principal purpose of the dormant Commerce Clause is to prevent state economic protectionism, the Court's dormant Commerce Clause doctrine is too broad because it would invalidate a state law that not only does not offend this principal, but which furthers a state's social responsibility to its citizens.

## B. A Speculative Discriminatory Effect Alone Should Not Invalidate the Act

Up to this point the argument has been that a dormant Commerce Clause doctrine that is true to the principles behind its development would only invalidate state laws that have a protectionist, or discriminatory, purpose.<sup>196</sup> The last section has been spent making the case for why a law with an extraterritorial effect should not be struck down on those grounds, if it lacks a protectionist purpose.

<sup>&</sup>lt;sup>190</sup> The Court listed several state regulations that affect interstate commerce but that were held to be legitimate exercises of police power, such as regulations governing the importation of diseased livestock or decayed food, and regulations prohibiting fraudulent advertising. None of the regulations listed involved price regulation. *See id.* at 525.

<sup>&</sup>lt;sup>191</sup> See id. The fact that none of the regulations that the Court recited as within the states' police power involve price regulation indicates an assumption by the Court that economic regulation and health and welfare regulation are generally mutually exclusive.

<sup>&</sup>lt;sup>192</sup> See Robert Kuttner, The American Health Care System: Health Insurance Coverage, 340 NEW ENG. J. MED. 163, 166 (1999) (noting the trend toward a reduction in insurance coverage, notably in pharmaceutical coverage, whose costs are rapidly rising; and that among the elderly, who are the most dependent on prescription drugs, about half of Medicare enrollees have no prescription drug coverage). Given these trends and statistics, governmental intervention is certainly needed.

<sup>&</sup>lt;sup>193</sup> This is because the purpose of the dormant Commerce Clause is to prevent state economic protectionism. As noted previously, it is undisputed that Maine is not engaging in economic protectionism.

<sup>&</sup>lt;sup>194</sup> States have been traditionally charged with social welfare responsibilities, including the health of their citizens. *See* MICHAEL S. SPARER, MEDICAID AND THE LIMITS OF STATE HEALTH REFORM 185 (1996) (discussing the drawbacks of state-controlled health care policy).

<sup>&</sup>lt;sup>195</sup> See supra note 173 (discussing states' police power).

<sup>&</sup>lt;sup>196</sup> I use both words interchangeably to mean protectionist.

However, one argument that can be made against the Act is its potentially discriminatory effect. The Court has invalidated laws that are non-discriminatory on their face but that discriminate in favor of the state in operation.<sup>197</sup> In this case, it may be argued that if the Act were allowed to go into effect, the drug makers would respond by raising their prices for the residents of other states. There are several reasons for dismissing this argument.

First, as previously discussed, in past cases where the Court has invalidated a law with a discriminatory effect, there was also evidence of a protectionist purpose.<sup>198</sup> Donald Regan, in his effort to place all offending laws under the protectionist purpose rubric, has proposed that a discriminatory effect should only be evidence of such a purpose.<sup>199</sup> In this case, we already know there is no protectionist purpose.<sup>200</sup> Therefore, if one subscribes to Regan's view, any discriminatory effect of the Act should be irrelevant.

Even without the use of Regan's theory, since the Court has typically inferred a protectionist purpose when it invalidates laws due to a discriminatory effect,<sup>201</sup> it would seem that an effect alone should not be a basis for invalidating the Act. As an aside, the Court has also measured the disparate effects of state laws using the *Pike* test,<sup>202</sup> which does not apply to the Act.<sup>203</sup> And in the balancing context of the *Pike* test, as Regan observes, the Court usually finds a protectionist purpose as well.<sup>204</sup>

<sup>198</sup> See, e.g., *id.* at 351-52 (including a statement by the North Carolina Agriculture Commissioner suggesting he thought there was a protectionist purpose, and the fact that the main supporters of the law were North Carolina apple producers). Donald Regan goes through all of the major cases and finds a similar protectionist purpose where the Court purportedly struck the law at issue down for its discriminatory effect. See Regan, supra note 57, at 1209-84.

<sup>199</sup> See Regan, supra note 57, at 1095. Since he argues that the Court has only invalidated laws with a protectionist purpose, he is saying that the Court has in practice only used a protectionist effect as such evidence. See supra note 198 (discussing laws struck down for having a discriminatory effect that had a protectionist purpose).

<sup>200</sup> See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS 17363, at \*13 (acknowledging no attempt by Maine to favor in-state business over out-of-state business, or to favor Maine consumers of prescription drugs over out-of-state consumers).

<sup>201</sup> See GUNTHER & SULLIVAN, supra note 67, at 289 (noting that it is used to uncover a discriminatory motive or where the Court avoids attributing a discriminatory motive but wishes to invalidate the law).

<sup>204</sup> Donald Regan's argument that the Court finds a protectionist purpose in the state laws it strikes down as too burdensome is discussed above. *See* discussion *supra* note 198.

<sup>&</sup>lt;sup>197</sup> See, e.g., Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 350-53 (1977) (invalidating a North Carolina law that forbade the selling of apples in the state that did not bear a USDA grade on the package, thereby excluding Washington, and its apples bearing state grades, from the North Carolina market).

<sup>&</sup>lt;sup>02</sup> See Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

<sup>&</sup>lt;sup>203</sup> The *Pike* test applies when a law has only an incidental effect on interstate commerce, not one that directly regulates in interstate commerce, such as the Act. *See supra* note 108 and accompanying text. As previously noted, my assessment that the Act directly regulates in interstate commerce disagrees with the First Circuit's analysis, which found no direct regulation, thus allowing it to apply the *Pike* test.

In sum, whether or not the Court overtly uses a discriminatory effect as evidence of a protectionist purpose, such a purpose seems to be necessary to the conclusion that a law with such effect is unconstitutional. Since we know there is no such purpose in enactment of the Maine law, any disparate effect should not be a basis for invalidation of it.

Second, any discriminatory effect is pure speculation. While there is some evidence that the drug makers' response to a price regulation would be a price increase in some other sector,<sup>205</sup> and policymakers have raised this concern in attempting to formulate federal prescription drug laws,<sup>206</sup> it is not a viable basis for preemptively invalidating a law without any evidence of a protectionist motive.

As noted previously, when the Court invokes a protectionist effect, it usually infers a protectionist purpose and often does so in the context of balancing the benefits and burdens of the law. Here, there is no protectionist *motive*, so the Court could only raise the issue of protectionist effect in the context of a balancing test. Balancing, however, does not apply to this case. But even if it were to apply, how can the Court balance a hypothetical discriminatory effect?<sup>207</sup> And since whether such a discriminatory effect occurs depends on the actions of the parties challenging this law, isn't such an effect somewhat suspect? We can dispose of the idea that the Court should balance hypothetical harms also by simply remembering that the Court does not make a practice of answering questions that have not yet arisen.<sup>208</sup> Such questions of policy are generally left to legislatures,<sup>209</sup> and if

<sup>206</sup> See GAO/HEHS-00-118, supra note 205, at 3-4 (acknowledging that this report is in response to Congress' request for a study of the possible impact of a Medicare drug benefit on drug prices).

<sup>207</sup> For example, in *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333 (1977), the Court was faced with a state law that had a discriminatory effect that was manifest, not hypothetical. North Carolina's facially neutral labeling law effectively prevented Washington State from selling apples in North Carolina. This is very different from the present case where any possible disparate pricing effect in favor of Maine is no more than a guess.

<sup>203</sup> See, e.g., Ernst & Young v. Depositors Econ. Prot. Corp., 45 F.3d 530, 538 (1st Cir. 1995) (noting that courts should avoid answering hypothetical questions). See also U.S. CONST. art. III, § 2, cl. 1 (limiting federal courts' jurisdiction to cases and controversies that have actually arisen).

<sup>209</sup> See Redish & Nugent, supra note 61, at 581 (arguing against use of the dormant Commerce Clause by stating that when courts decide whether the nature of a type of interstate commerce requires national regulation, it is making an intrinsically legislative determination). See also RONALD A. CASS ET AL., ADMINISTRATIVE LAW 426 (3d ed. 1998) (distinguishing between

<sup>&</sup>lt;sup>205</sup> See GAO/HEHS-00-118, EXPANDING ACCESS TO FEDERAL PRICES COULD CAUSE OTHER PRICE CHANGES (U.S. General Accounting Office 2000) (reporting on the possibility that drug manufacturers could raise their prices overall in response to addition of a prescription drug benefit under Medicare if the Medicare plan extracted the same discounts that other current federally-funded prescription drug plans do). See also FIONA SCOTT MORTON, THE STRATEGIC RESPONSE BY PHARMACEUTICAL FIRMS TO THE MEDICAID MOST-FAVORED CUSTOMER RULES 29 (Nat'l Bureau of Econ. Research, Working Paper No. 5717, 1996) (reporting that the rules, which required drug manufacturers to give most favored customer discounts to state Medicaid programs, resulted in higher prices in some drugs to non-Medicaid consumers). However, the results of her study were not overwhelming. See id.

Congress were to determine that this potentially discriminatory effect was a danger, it could preempt the Maine law.<sup>210</sup>

Finally, weighing in a hypothetical discriminatory effect without any protectionist purpose does not serve any constitutional purpose. We have seen that the Court has not deviated from this principle by only invoking a discriminatory effect when there is also a protectionist purpose.<sup>211</sup>

Donald Regan has also looked at the protectionist effect from the standpoint of the national interest that the dormant Commerce Clause is meant to serve. He discusses it in the context of balancing, which he and I would both argue should not apply here.<sup>212</sup> But it is worth discussing as a practical matter because the effect of legislation on drug prices is of such concern.<sup>213</sup> In Regan's view, the only national interest to be served by the dormant Commerce Clause where the movement of goods is involved is that of preventing purposeful state protectionism.<sup>214</sup> All other interests are constitutionally irrelevant, including the interests of private parties. Such private interests, Regan says, are to be considered by legislatures—whether they be state or federal—not by courts.<sup>215</sup>

In this case, the district court in Maine noted that the effect of the Act might be to raise drug prices in other sectors.<sup>216</sup> Applying Regan's argument, this private interest of drug consumers outside of Maine should not be relevant to a reviewing court. Since a discriminatory effect on a private interest should not be relevant to a court, whether or not lower drug prices in Maine effect drug prices elsewhere should have no significance at all in determining whether there is a constitutional violation.

<sup>11</sup> See Regan, supra note 57, at 1104.

adjudicative facts as those about the parties to a particular proceeding that help a tribunal decide a particular issue regarding that particular party; and legislative facts as more general ones that help a tribunal decide questions of law or policy).

<sup>&</sup>lt;sup>210</sup> See Redish & Nugent, supra note 61, at 573-74 (arguing that state laws affecting interstate commerce should only be overturned by Congress).

<sup>&</sup>lt;sup>211</sup> This is discussed more fully above. See supra text accompanying notes 201-04.

<sup>&</sup>lt;sup>212</sup> Regan would say it does not apply here because balancing should never apply. See Regan, supra note 57, at 1108. See also supra text accompanying note 128. But even if the Court should balance, balancing cannot apply here, where the Act's effects on interstate commerce are not incidental. See supra note 108 and accompanying text.

<sup>&</sup>lt;sup>213</sup> See GAO/HEHS-00-118, supra note 205, at 3 (acknowledging Congress' concern about the drug makers' response to price regulation).

<sup>&</sup>lt;sup>215</sup> See id. at 1103 (arguing that private interests are for legislative consideration and constitutionally irrelevant). Regan also notes that it is antithetical to our system of separate states to require the state legislators to consider unrepresented out-of-state interests when it enacts legislation. Nor is it practical, since such a requirement effectively transfers to state governments responsibilities equivalent to those of the federal government, without the corresponding resources or expertise. See id. at 1165.

<sup>&</sup>lt;sup>216</sup> See Pharm. Research & Mfrs. of Am., 2000 U.S. Dist. LEXIS, at \*13 n.10.

The argument that any discriminatory effect should not invalidate the Maine law can also be supported from the point of view of other states. Should a state regulation have the effect of infringing on other state interests as opposed to private interests, it becomes constitutionally relevant because such a law is much more likely to have a protectionist purpose.<sup>217</sup> In fact, Christopher Drahozal has observed that the Supreme Court is more likely to strike down a state law when another state government participates in its challenge.<sup>218</sup> States usually participate by joining suits by private parties to invalidate discriminatory state laws.<sup>219</sup> Drahozal based his observation on his study of several important Supreme Court dormant Commerce Clause cases.<sup>220</sup> This conclusion makes sense because if a state law economically disadvantages other states, as opposed to private parties within the other states, it is a paradigm case of protectionism.<sup>221</sup> There is certainly no party in a better position to determine if such protectionism exists than another state. But if we look to the reaction of other states to the Act, we do not see opposition; we instead see a desire to follow suit.<sup>222</sup> This strongly suggests that allowing the law to stand will not offend the basic purpose of the dormant Commerce Clause.

<sup>219</sup> See id. at 249.

<sup>&</sup>lt;sup>217</sup> See supra text accompanying notes 214 and 215 (discussing the constitutional relevance of preventing purposeful state protectionism as opposed to protecting private interests).

<sup>&</sup>lt;sup>218</sup> Christopher R. Drahozal, Preserving the American Common Market: State and Local Governments in the United States Supreme Court, 7 SUP. CT. ECON. REV. 233, 236 (1999). Drahozal makes this observation to support his theory that states act as "fire alarms," bringing dormant Commerce Clause violations to the attention of the Court. See id. at 278.

<sup>&</sup>lt;sup>20</sup> See id. at 254-55 (explaining the sample of cases that Drahozal used).

<sup>&</sup>lt;sup>221</sup> See Drahozal, supra note 218, at 269 (noting that the presence of private party litigants in dormant Commerce Clause cases had no relationship to the outcome of the case). An excellent example of a state participating in litigation opposing a state law is *Philadelphia v. New Jersey*, 437 U.S. 617 (1978), which pitted the City of Philadelphia against the state of New Jersey. In this case, the New Jersey law at issue prohibited out-of-state waste from being dumped in New Jersey's landfills. In addition to the fact that a local government was a party opposing the New Jersey law, other states participated by submitting amicus briefs in opposition. Consistent with Drahozal's theory, the New Jersey law was struck down. See Drahozal, supra note 218, at app. A (the appendix is a table of the cases Drahozal studied, showing the participating parties and the outcome of the case).

<sup>&</sup>lt;sup>222</sup> See, e.g., Tony Pugh, States Try To Limit Rises in Drug Prices, PHILA. INQUIRER, Oct. 28, 2000, at C4 (quoting Peter Shumlin, Chairman of the Northeast Legislative Association on Drug Prices, on the "tremendous" interest from other states in new state prescription drug price control policy initiatives); Marketletter, Seniors Slam Stay on Maine Rx Drug Price Bill, Nov. 20, 2000 (quoting National Council of Senior Citizens president George Kourpias' prediction that "other states will soon follow Maine's lead"); Rachel Zimmerman & Laura Johannes, SmithKline Maine Move Finds Support, WALL ST. J., Aug. 7, 2000, at B6 (quoting Maine Rx sponsor Chellie Pingree saying that "at least 20 states have expressed interest in passing a similar law" to that of Maine). There has been support from other states as well. See Carey Goldberg, Maine Enacts a Law Aimed at Controlling Cost of Drugs, N.Y. TIMES, May 12, 2000, at A30 (quoting a member of the Vermont senate as saying that the Maine legislation is a "victory").

## C. Current Dormant Commerce Clause Doctrine Rests On Inaccurate Structural Assumptions About the States' Political Power

One of the possible justifications for the dormant Commerce Clause (or any other judicially imposed limitation on state power)<sup>223</sup> is that Congress can override any limits imposed by it.224 This. of course, assumes that states can convince Congress that such overriding is necessary. Martin Redish and Shane Nugent have persuasively argued that this assumption is erroneous due to inherent congressional inertia.<sup>225</sup> Fernando LaGuarda has gone a step further and argued that in the area of health policy, states lack the political power necessary to be heard over powerful private interest groups who oppose them.<sup>226</sup> This would only exacerbate inherent Congressional inertia where these powerful private interest groups favor the status quo. This section of the Comment will show the legitimacy of these arguments through their application to the current healthcare crisis that fostered the enactment of the Act.

# 1. To Combat Congressional Inertia and To Perform Their Roles As Policy Innovators, States Need To Be Able To Enact Non-Protectionist Laws, Even If Those Laws Affect Interstate Commerce

Beginning with Redish and Nugent, as an initial matter, they argue that the dormant Commerce Clause is illegitimate in its entirety.<sup>227</sup> Absent the dormant Commerce Clause, states would be free to legislate where such legislation is not preempted.<sup>228</sup> Congress has the power, preemptively or subsequently, to preempt any state laws it determines to impinge too greatly on interstate commerce.<sup>229</sup> This, they maintain, comports with our federalist ideal of concurrent power between sovereign states and the federal government with accompanying structural checks and balances because states have the power to legislate on behalf of their constituents, and Congress has

<sup>228</sup> See id. at 592. <sup>229</sup> See id.

<sup>&</sup>lt;sup>223</sup> Such a limitation would be, for example, a judicial determination of federal preemption.

<sup>&</sup>lt;sup>224</sup> See Redish & Nugent, supra note 61, at 570 (noting that it is accepted that Congress may choose to overrule the judicial invalidation of a particular state regulation by statutorily authorizing it).

See id. at 573.

<sup>&</sup>lt;sup>226</sup> See LaGuarda, supra note 42, at 171 (describing the massive activity of private interest groups).

See Redish & Nugent, supra note 61, at 572. I do not adopt this argument, because, based on its decisions, the Supreme Court appears to believe that there is a place for the dormant Commerce Clause. Also, consistent with the discussion below, states lacking political power may have difficulty convincing Congress to invalidate a protectionist state law that directly harms them, and would thus benefit from the Court's intervention. However, the Redish and Nugent argument is fully applicable to the Act because, as a non-protectionist law, the dormant Commerce Clause should not apply to it.

the preemptive check on that power.<sup>230</sup> The dormant Commerce Clause shifts this balance away from the states by allowing the Court, on challenge by a (usually) private party, to invalidate state legislation.<sup>231</sup> The states, in order to achieve their legislative goal, must then approach Congress and convince it to reverse the Court's decision.<sup>232</sup> Beyond the fact that this shift is inconsistent with our federalist structure,<sup>233</sup> inherent congressional inertia prevents states from succeeding much in getting the Court's decision reversed.<sup>234</sup> Redish and Nugent further add that this shift stifles the states' ability to act as "small-scale social laboratories, so that other states—or the federal government itself—might benefit from the experience without incurring all of the possible risks that might result from a similar nationwide experiment."<sup>235</sup>

Application of some of these principles to the healthcare debate and to the Act supports these scholars' contentions. Congressional inertia cannot be disputed in the area of healthcare reform, notably in the area of prescription drugs.<sup>236</sup> The debate over how to provide a prescription drug benefit to senior citizens has been raging for some time<sup>237</sup> without resolution.<sup>238</sup> The fact that Congress has been unable to devise a meaningful solution to this problem is one of the princi-

<sup>234</sup> See Redish & Nugent, supra note 61, at 593. Inherent congressional inertia is used to describe the extremely slow and uncertain legislative process, and the fact that Congress has more of a propensity not to act than to act. See id.

<sup>237</sup> This debate centers on how to add a prescription drug benefit to Medicare. Members of Congress have been proposing solutions at least as far back as 1993. See, e.g., H.R. 2673, 103rd Cong. (1993) (introducing a law that would add a prescription drug benefit to Medicare). See also Mark McClellan et al., Designing a Medicare Prescription Drug Benefit: Issues, Obstacles, and Opportunities, 19 HEALTH AFFAIRS 26 (2000) (outlining some of the various prescription drug proposals that have been introduced beginning in 1998); Ramesh Ponnuru, Dr. Feelgood: Bush and Gore Peddle Their Drug Plan, NATIONAL REVIEW (Sept. 25, 2000), at http://www.findarticles.com/ cf\_0/m1282/18\_52/66106572/print.jhtml (discussing the presidential candidates' competing prescription drug plans during the 2000 election).

<sup>258</sup> Congress was able to come up with one piece of legislation. In 2000, President Clinton signed a law that would allow wholesalers to import drugs from abroad, in order to take advantage of the lower prices in other countries. See Robert Lenzner & Tomas Kellner, Corporate Saboteurs, FORBES, Nov. 27, 2000, at 156. However, outgoing Health and Human Services Secretary Donna Shalala refused to implement the law, which required her endorsement, citing "flaws and loopholes." See Marc Kaufman, Shalala Rejects GOP Drug Price Law, WASH. POST, Dec. 27, 2000, at A1. As of this writing, Shalala's successor under the Bush administration Tommy Thompson has also decided to put implementation of the law on hold. See Health Care and Benefits in Brief, Health Costs: Thompson Dubious About Possibility of Certifying Safety of Reimported Drugs, PENSION & BENEFITS DAILY REP., May 30, 2001, at 16. Thus for now, we are back to uncontrolled drug prices and, of course, still no Medicare drug benefit. See A Conversation with Gail R. Wilensky, POLICY & PRACTICE OF PUBLIC HUMAN SERVICES, 2000 WL 18991175 (June 1, 2000) (noting that Medicare does not cover prescription drugs).

<sup>&</sup>lt;sup>230</sup> See id.

<sup>&</sup>lt;sup>231</sup> See id.

<sup>&</sup>lt;sup>232</sup> See id. at 592-93.

<sup>&</sup>lt;sup>233</sup> This is discussed above. See supra text accompanying note 228.

<sup>&</sup>lt;sup>235</sup> *Id.* at 598.

<sup>&</sup>lt;sup>226</sup> A discussion of this phenomenon follows.

pal reasons for enactment of the Maine law.<sup>239</sup> If a court holds that Maine may not exercise its regulatory powers to control the cost of prescription drugs, Maine will have to wait for Congress to arrive at its own solution, something Congress has thus far been unable to do. Alternately, Maine will have to try to convince Congress to reverse the court's decision by passing legislation allowing states to regulate drug prices across state lines,<sup>240</sup> a process that is inherently expensive, timeconsuming, and uncertain.24

Alternatively, if Maine is able to implement its cost-control scheme, other states and the federal government could observe the law's success or failure and benefit from Maine's experience.<sup>242</sup> The state governments can use this knowledge to devise their own programs to control prescription drug costs, while the federal government can use it to learn what works and what does not without the dangers of entering into a national experiment.

This idea that states should act as "laboratories" for enactment of social or economic policy innovations is not just rhetoric.<sup>243</sup> It is actually used by states and the federal government, nowhere more noticeably than in the area of health care reform.<sup>244</sup> In its ongoing effort to devise a prescription drug benefit under Medicare, Congress has looked carefully at state pharmacy benefit programs to see how they address cost and access issues and what administrative problems they face, with an eye to incorporating features of the more successful state efforts.<sup>245</sup> Likewise, states that wish to add price regulation of prescription drugs to their own pharmacy benefit programs, or who have yet to implement one, are watching this case closely. If the Maine law is ultimately upheld, many states will follow Maine's lead.<sup>246</sup>

See Rebecca Lentz, Drug (Price) Rehab: States Get a Handle on Controlling Pharmaceutical Costs, MODERN PHYSICIAN (Aug. 1, 2000), 2000 WL 8130512 (quoting a Maine Department of Human Services spokesperson as saying "'[w]e were tired of waiting" for Congress to act and a Vermont official as saying "[i]f there were federal relief, the state wouldn't have to get into it'").

<sup>&</sup>lt;sup>240</sup> This could be done via either the Medicaid prior authorization provision or through direct regulation.

See Redish & Nugent, supra note 61, at 592-93 (discussing the long and uncertain process of introducing, passing, and getting a bill signed into law, and the slim odds of success in this endeavor).

<sup>242</sup> See LaGuarda, supra note 42, at 160 (arguing that states should act as laboratories for

healthcare reform). <sup>243</sup> This idea originated from the famous quote by Justice Louis Brandeis in *New State Ice Co.* v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). 244 See Robert Pear, Shifting of Power from Washington Is Seen Under Bush, N.Y. TIMES, Jan. 7,

<sup>2001,</sup> at 18 (noting that health care is a notable example of states leading the way on domestic policy issues). See also SPARER, supra note 194, at 28-29 (explaining the bipartisan turn to the states to implement health care reform in the 1990's).

<sup>245</sup> See GAO/HEHS-00-162, STATE PHARMACY PROGRAMS: ASSISTANCE DESIGNED TO TARGET COVERAGE AND STRETCH BUDGETS, (U.S. General Accounting Office 2000) (reporting to the House of Representatives Commerce Committee on what were in 1999 fourteen state pharmacy programs).

See supra note 222 and accompanying text (discussing other states' interest in the success of the Act and a desire to follow Maine's lead).

# 2. The Court Should Uphold Non-Protectionist State Laws in Recognition of the States' Political Disadvantage Since Those Laws Do Not Offend the Dormant Commerce Clause

An exacerbation of the problem of Congress' inability to act in the prescription drug arena is the political power of the pharmaceutical industry in comparison to that of the states. Fernando LaGuarda argues that the Court has inaccurately supposed that states have the political advantage when it has ruled to limit state power.247 He argues that the Court has assumed that since our federal structure and the Constitution provide inherent safeguards for states in the political arena, principally by delegating control of the electoral process to them, that this protection ensures that laws that unduly burden them will not be promulgated.<sup>248</sup> He contends that this assumption is incorrect, and that in reality, states are no more influential in the political process than private interest groups.<sup>249</sup> In fact, since they represent a wider array of interests and have less money, they are less politically influential than private interest groups.<sup>250</sup> This is not the position our Constitution and federal structure intended for the states to be in.<sup>251</sup> Therefore, since it is the Court's responsibility to maintain the proper balance of power between the states and the federal government,<sup>252</sup> it should stop assuming that states can prevail politically on even equal footing with other interest groups, and account for this inadequacy when it rules on the limits of state power.<sup>253</sup> LaGuarda then applies his argument to healthcare reform<sup>254</sup> to

show that federal laws and regulations have impeded states in their efforts to enact important health policy.<sup>255</sup> And they have been un-

See LaGuarda, supra note 42, at 165.

<sup>248</sup> See id. at 168. LaGuarda examines the opinion in Garcia v. San Antonio Metropolitan Transit Authority, 469 U.S. 528 (1985) to support his argument. In that case, the Court held that the federal Fair Labor Standards Act applied to state and local governments. In support of this decision, the Court said that if the federal law intruded too much on states, the political process would correct this, not the Court. See id. at 556 ("The political process ensures that laws that unduly burden the States will not be promulgated.").

See LaGuarda, supra note 42, at 170 (arguing that the legislative process is not more inherently deferential to states than it is to other interest groups). See also Pear, supra note 244 (offering the hope that the new administration will recognize that states are political entities and not interest groups).

<sup>250</sup> See LaGuarda, supra note 42 (describing how states are like interest groups without money, while having to satisfy both national constituencies and local voters).

<sup>&</sup>lt;sup>251</sup> See id. at 163 (arguing that the federal government was intended to co-exist with independent sovereign states).

See id. at 166 (arguing that the Framers' ideals of state sovereignty must be guarded by the courts). The proper federal balance in LaGuarda's view would have the states, as sovereign entities, exerting more influence than private interests. See id.

See id. at 190-91 (contending that the Court should heed the argument that states are disregarded in the political process, and intervene on their behalf).

LaGuarda's argument is based on the situation as it stood in 1993.

 <sup>&</sup>lt;sup>255</sup> Notable obstacles that LaGuarda cites are the Employee Retirement Income Security Act

able to convince Congress to alter or repeal these legal obstacles<sup>256</sup> because they are opposed by powerful private interest groups who have a stake in maintaining the status quo.<sup>257</sup>

LaGuarda's argument resonates strongly today in the context of access to prescription drugs, despite its relative antiquity in the universe of rapidly changing health policy. The situation is somewhat different in that here, the area in which states have been unsuccessful is convincing the federal government to enact legislation addressing this problem, as opposed to convincing it to remove an existing statutory or regulatory obstacle. Nevertheless, the states face a pharmaceutical industry with a tremendous interest in maintaining the status quo.<sup>258</sup> Congress' actions leave little doubt as to who has the political advantage. The states, with their limited budgets and various inter-

However, ERISA remains a powerful obstacle for states because it precludes states from requiring employers to provide their employees with health coverage, the so-called "employer mandate." See SPARER, supra note 194, at 6. It also precludes participants in employee benefit plans who are injured by plan administrators from seeking any meaningful relief under state laws. See FURROW ET AL., supra note 45, at 808-16 (discussing ERISA preemption of state laws and beneficiaries' limited rights under the statute). Despite a great deal of hostile commentary, the fact that federal judges are forced to deny relief to sympathetic claimants, and the fact that states perceive the statute as an obstacle to state health care reform, the law has not been amended and is unlikely to be amended any time soon. See id. at 815.

<sup>56</sup> See supra note 255 (discussing obstacles to state health care reform efforts).

<sup>257</sup> The interest groups opposing an amendment to ERISA are principally large employers and unions. *See* LaGuarda, *supra* note 42, at 183. Opposition to state Medicaid waivers has come from various healthcare provider groups. *See id.* at 188 (recounting opposition to Oregon's request for a Medicaid waiver that would have eliminated coverage for certain services ordinarily covered by Medicaid). The pharmaceutical industry has joined this action too, as its challenge to the Vermont waiver illustrates. *See supra* note 255. <sup>258</sup> The status quo is the drug manufacturers' profit margins, currently the highest among

<sup>2.5</sup> The status quo is the drug manufacturers' profit margins, currently the highest among U.S. industries. See Merrill Goozner, The Price Isn't Right, AMERICAN PROSPECT, Sept. 11, 2000, at 25, available at 2000 WL 4739423. The drug companies claim that they need to charge high prices in order to invest in research and development for new cures. However, this does not explain a need for such high *profits*, since profit numbers are net of research and development expenditures. In addition, taxpayers pay for a good portion of the cost of research for new cures. See id.

of 1974 ("ERISA") and the Medicaid waiver process, both of which he claims severely limit state health care reform efforts. See LaGuarda, supra note 42, at 170. I will update his account of these federal obstacles here. The comprehensive Medicaid waiver about which LaGuarda primarily speaks has become easier to obtain in recent years as the health care crisis has become more pronounced. See FURROW ET AL., supra note 45, at 879. Waivers are also obtained by application to the Health Care Financing Administration ("HCFA") and are not the subject of legislation. See id. Thus HCFA can approve a waiver even if it is opposed politically. For example, PhRMA has challenged the HCFA's recent waiver grant to Vermont that allows its residents without prescription drug coverage to take advantage of the state's Medicaid discount. See Ross Snevd. Drug Industry Sues To Block Vt. Program, RUTLAND HERALD ONLINE (Dec. 14, 2000), http://rutlandherald.nybor.com/to\_print/16955.htm. PhRMA has been more successful in this effort than it was with its Maine Rx challenge. In June, 2001, the Court of Appeals for the District of Columbia Circuit reversed a district court's refusal to enjoin implementation of Vermont's Medicaid waiver, holding that the HCFA did not have authority under the Medicaid law to allow non-Medicaid beneficiaries to benefit from the Medicaid rebate. See Pharm. Research & Mfrs. of Am. v. Thompson, 251 F.3d 219 (D.C. Cir. 2001).

ests,<sup>259</sup> compete for the ears of Congress with pharmaceutical companies, their seemingly unlimited budgets,<sup>260</sup> and their single interest of seeing nothing change. Since Congress has done nothing,<sup>261</sup> it thus appears that the drug makers have won.

The intervention of the Supreme Court is therefore necessary. If it is the Court's role to maintain a federal-state balance of power where the states truly have more political significance than interest groups,<sup>262</sup> the Court must recognize the states' disadvantage in Washington and protect them.<sup>263</sup>

The Court should recognize that Maine passed this law because Congress has done nothing to make prescription drugs more affordable for the citizens of Maine. Congress, instead, has chosen to continue to protect the interests of the pharmaceutical industry.<sup>264</sup> The Court should correct this imbalance by finding the law constitutional, rather than further subverting the political significance of the states with the limitations of the dormant Commerce Clause.

#### D. Who Says Uniform Laws Are Essential?

This Comment will address one final argument for limiting Maine's power to regulate drug prices. The pharmaceutical industry argues that a "patchwork" of state laws would be too burdensome, and if there is to be any regulation, it must be national.<sup>265</sup>

Indeed, over the years, Congress has passed a series of laws that have directly benefited the pharmaceutical industry. See AMERICAN POLITICAL NETWORK, INC., POLITICS & POLICY RX DRUG COSTS II: INDUSTRY HAS UNSEEN INFLUENCE, AMERICAN HEALTH LINE 6 (2000) (noting that the pharmaceutical industry has had a decade of legislative successes such as tax breaks, speedier approval of drugs and patent extensions). But see supra note 238 for a discussion of Congress' so far failed effort to reduce drug costs through importation from foreign countries.

See LaGuarda, supra note 42, at 165; see also supra note 254 (discussing LaGuarda's argument that maintaining a federal and state balance is a role of the Supreme Court).

This disadvantage is discussed above. See supra text accompanying notes 257-60.

See LaGuarda, supra note 42, at 170 (arguing that states are like interest groups without the money while having to satisfy both national constituencies and local voters).

See, e.g., Julian Borger, Dying for Drugs: Industry That Stalks the U.S. Corridors of Power, THE GUARDIAN, Feb. 13, 2001, at 3 (noting that no interest group wields as much political power as PhRMA, a group he describes as "breathtaking for its deep pockets and aggression, even by the standards of U.S. politics"); PBS NewsHour with Jim Lehrer (PBS television broadcast, Sept. 21, 2000) (discussing the fact that the campaign spending by the pharmaceutical industry for the Bush-Gore election approached that of a political party); Jeff Leeds, Health Care Firms Spend Big To Head Off Reforms, L.A. TIMES, July 23, 2000, at A1 (reporting that the pharmaceutical and health insurance industries waged "the largest national advertising campaign ever conducted by a political special interest" for the Bush-Gore election).

See supra note 261 (discussing the various ways that Congress has benefited the pharmaceutical industry).

See Lentz, supra note 239, at 1 (quoting a PhRMA spokesperson saying that the "last thing we need is a patchwork of differing and conflicting state laws" and asserting that the problem of access to prescription drugs requires a "national solution"). Supporters of the drug industry also argue against price regulation as offending the free market. See Glenn G. Lammi, Maine Drug Price Control Act Vulnerable To Legal Challenge, LEGAL OPINION LETTER, July 14, 2000, at 2 (calling the Maine law an "awkward attempt to replace the market mechanism"). However, the

The pharmaceutical industry, however, is not the body charged with making that determination; Congress is. Congress has not said that a patchwork of laws is unworkable.<sup>266</sup> Until it does, the "patchwork" argument should not be used in support of invalidation of state laws under the dormant Commerce Clause. As discussed previously, the pharmaceutical industry has plenty of means to persuade Congress that it is unworkable; it does not need to have a court decide this.

Nor should a court consider this factor. Donald Regan's argument remains strong; the only interest of constitutional significance with respect to the movement of goods in interstate commerce is the prevention of economic protectionism.<sup>267</sup> The private interest that pharmaceutical companies have in remaining free from multiple state laws should be completely irrelevant in a determination of whether Maine's law is constitutional.

Perhaps one of the reasons why Congress has not yet decided multiple state laws are unworkable is that maybe they are not.<sup>268</sup> States have traditionally been responsible for their citizens' health, and some nationally operated private businesses in health-oriented fields are subject to multiple regulatory schemes.<sup>269</sup> Until Congress determines otherwise, no exception should be made for pharmaceutical manufacturers.

drug industry is not operating in a free market now. Instead, the market is completely rigged, it just happens to be in favor of the drug manufacturers. The industry asks consumers to rely only on market tools, such as volume discounts, to combat the industry's non-market arsenal of patent protection laws, which allow it to charge consumers monopoly prices; government-funded research whereby the industry can develop new drugs, largely at taxpayer expense to then sell to consumers at monopoly prices; and tax breaks. *See* Goozner, *supra* note 258 (discussing the regulatory phenomenon of patent protection for drug company discoveries that are largely the result of government-funded research resulting in monopoly pricing to American consumers); AMERICAN POLITICAL NETWORK, *supra* note 261 (noting the pharmaceutical industry's decade of success in Washington). If anything, some laws on the consumer side could help level the playing field and make the pharmaceutical market resemble a free market more closely.

<sup>&</sup>lt;sup>200</sup> Indeed, as noted earlier, Congress is looking to the current patchwork of state laws in its search for a national law. *See* GAO/HEHS-00-162, *supra* note 245 (reporting to Congress on the states' pharmacy benefit programs).

<sup>&</sup>lt;sup>267</sup> See supra text accompanying notes 214 and 215 (discussing Regan's argument on this point).

<sup>&</sup>lt;sup>268</sup> Even if a uniform national law would work better, the fact is that at this point, there is no such uniform law. *See supra* Part IV.C. (discussing Congress' inability to pass prescription drug legislation). It is not an answer to the senior citizens who cannot afford prescription drugs and the state governments that are trying to assist them, to say that the only way to regulate the cost of prescription drugs is with national legislation when none is forthcoming. Even if one were to concede that state regulation is not the best way, right now it may be the only way.

concede that state regulation is not the best way, right now it may be the only way. <sup>269</sup> A notable example is health insurance. For example, national health insurance companies are subject to state solvency laws. *See* FURROW ET AL., *supra* note 45, at 797. Another example is medical malpractice, governed by state tort regimes. *See id.* at 152 (noting that the medical profession's standards are enforced in tort suits).

#### CONCLUSION: A LOOK AHEAD

This Comment has applied old arguments to a new issue to show that the dormant Commerce Clause doctrine should be re-evaluated. This application reveals that current doctrine is too broad because it would prevent states from enacting important health policy without furthering any constitutional purpose. It also shows that the doctrine is overbroad because it would prevent states from carrying out their domestic duty simply because, in the process, they would impinge upon the private interests of a powerful few. Finally, the current doctrine would unnecessarily subvert the states' political significance, preventing them from effectively playing their role as policy innovators.

Will the Act ultimately be upheld? That remains to be seen, but in the end, the pharmaceutical industry may lose its real battle-the battle to maintain the current favorable regulatory framework. 270 The soaring cost of prescription drugs coupled with their ever-increasing significance in American healthcare make it imperative that something be done to make prescription drugs more accessible. Add to this the fact that the pharmaceutical industry enjoys the highest profit margins of any industry in America<sup>271</sup> and you have a recipe for action. Whether the action will be at the state or federal level remains to be seen, but there are some factors that seem to favor the states.

One factor favoring the states is the Supreme Court. As a general matter, the majority of the Court is considered conservative, and as such is expected to favor more power for states. The Court's conservatives have generally been true to form, showing a propensity to vote in favor of states in recent cases.<sup>272</sup>

With respect to the dormant Commerce Clause, there are members of the Court who are openly opposed to it, namely Justices Scalia and Thomas.<sup>273</sup> In addition, Justice Rehnquist has consistently voted

See supra note 261 (discussing this regulatory framework).

<sup>&</sup>lt;sup>271</sup> See Goozner, supra note 258 (discussing the drug company's claim that it needs to charge high prices to be able to invest in research).

See, e.g., Bd. of Tr. for the Univ. of Alabama v. Garrett, 121 S. Ct. 955, 966 (2001) (holding that suits for damages in federal court against states under the Americans With Disabilities Act are barred by the Eleventh Amendment); Coll. Sav. Bank v. Florida Prepaid Postsecondary Educ. Bd., 527 U.S. 666 (1999) (invalidating a federal statute enacted to abrogate state sovereign immunity against patent and trademark actions as beyond Congressional power). Of course the Court could also go against the states because of a competing conservative cause, which is the protection of private business, including the pharmaceutical industry. See, e.g., Borger, supra note 260 (predicting that under Republican president George Bush, the U.S. will return to its role of battering ram for pharmaceutical industry interests). The Court's conservatives have shown a willingness to reverse their normal state-friendly stance when upholding state laws would conflict with competing conservative agendas. See Bush v. Gore, 121 S. Ct. 525, 530 (2000) (holding that the Florida Supreme Court's order of voter recounts in the 2000 election lacked the standards necessary to satisfy the Equal Protection Clause, thereby sealing a Republican victory). 275 See Sara Sachse, Comment, United We Stand—But For How Long? Justice Scalia and the New

to uphold state laws challenged for potential violation of the dormant Commerce Clause.<sup>274</sup> Sara Sachse opined that the dormant Commerce Clause's chief opponent, Justice Scalia, is gaining ground in his desire to abandon the dormant Commerce Clause in the form of exceptions to the rule.<sup>275</sup> Given the important health policy implications of the Maine law, the Court may well find some sort of health and welfare exception to the rule.

The other factor favoring the states is the current political climate. Given the federal government's general failure to implement meaningful healthcare reform, eyes have turned increasingly to the states to help solve the problem.<sup>276</sup> Some state health insurance programs already implemented have been widely viewed as successful,277 and there is increasing acceptance of states as social policy engines, espe-cially in the area of healthcare.<sup>278</sup> In addition, the new presidential administration has promised to shift power from the federal government to the states on a host of domestic policy issues, one of which is health and welfare.<sup>279</sup>

Based on these two factors, there is a good possibility that states will be granted the ability to exert more control over drug costs in the near future, notwithstanding an effect on interstate commerce. We will wait to see what form the state's control will take.

Developments of the Dormant Commerce Clause, 43 ST. LOUIS U. L.J. 695, 720 (1999).

See Pear, supra note 244 (noting recent state efforts to expand health insurance programs though innovative techniques).

See id.

<sup>&</sup>lt;sup>274</sup> See Drahozal, supra note 218, at 263-64 (noting that Rehnquist is a strong supporter of states' rights and voted for upholding the statute in 79% of the cases studied).

See Sachse, supra note 273 at 720.
See SPARER, supra note 193, at 2-4 (discussing the failure of the Clinton national healthcare proposal and the subsequent bipartisan turn to the states to solve the problem).

See, e.g., Pear, supra note 244 (quoting a health law professor as saying that Wisconsin's expanded Medicaid program has been a "stunning success"); FURROW ET AL., supra note 45, at 880 (noting that Arizona's Medicaid managed care program has been given high marks).