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Medicaid and the Unconstitutional Dimensions of Prior Authorization

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NOTE

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INTRODUCTION

If a free society cannot help the many who are poor, it cannot save the few who are rich.

— John Fitzgerald Kennedy[1]

Summum ius summa iniuria.

— Cicero[2]

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* The author wishes to dedicate this Note to the late Dr. David McKillop — a professor, mentor, and friend. His life's work lives on in the deeds of his students.

1. Inaugural address (Jan. 20, 1961) (transcript available in the John Fitzgerald Kennedy Library).

2. M. TULLI CICERONIS, DE OFFICIIS I, 14 (Oxford Univ. Press 1994) ("Extreme justice is extreme injustice.").

The political outcry over prescription drug costs has been one of the most vociferous in recent memory. From tales depicting renegade seniors sneaking cheap prescriptions of Vioxx out of Tijuana across the border,[3] to the promises of reduced prices made by front-runners during the 2000 Presidential election,[4] the calls for lower drug prices have been forceful and demanding. This war for lower-priced pharmaceuticals fought by consumers, interest groups and politicians against the pharmaceutical industry itself has recently developed yet another front. The latest battle is over Medicaid.[5] The new victims are the poor.

Presently, federal statutory provisions in the Medicaid program provide relief from high drug prices through a mandatory rebate mechanism.[6] Federal law requires pharmaceutical manufacturers to rebate their drugs sold to Medicaid recipients at a minimum level of 15.1 percent of the average manufacturer's price of those drugs.[7] In addition to the mandatory rebate, federal law provides for the discretionary provision of prior authorization by which the states may serve the best interests of their Medicaid recipients in a cost-effective manner.[8] The federal Medicaid program allows states to condition prescription of a covered drug on special prior authorization of that drug with a state official.[9] Both the mandatory rebate and prior authorization provisions serve to balance access and cost in an attempt to provide necessary care for the indigent.[10]

In the face of mounting pressure over rising drug prices, several states sought to expand the federal rebate and prior authorization

3. Tim Weiner, *Low Prices for Unregulated Prescription Drugs Lure Americans*, N.Y. TIMES INT'L, Aug. 14, 2001, at A7.

4. Alan Bernstein, *Presidential Election Left Dimples All Over Y2*, HOUSTON CHRONICLE, Dec. 31, 2000, at A1 (noting that Governor Bush and Vice-President Gore narrowly tailored their messages to capture the numerous voters concerned with high prescription drug prices).

5. Congress created the sister programs of Medicaid and Medicare under Title XIX and Title XVIII, respectively, of the Social Security Act of 1965. Medicaid, a federal-state matching program, pays for the medical expenses of low-income persons. In essence, the noble goal of Medicaid is "to ensure access to health care for low income Americans." TEX. HEALTH & HUMAN SERVS. COMM'N, TEXAS MEDICAID IN PERSPECTIVE (4th ed. 2002). See also *infra* Part I for a more detailed description of the nature and political history of the Medicaid program.

6. 42 U.S.C.A. § 1396r-8 (West 2000).

7. 42 U.S.C.A. § 1396r-8(c)(1)(B)(i)(V) (West 2000).

8. 42 U.S.C.A. § 1396r-8(d)(5) (West 2000).

9. For example, a state could declare Rogaine subject to prior authorization. As a consequence of this designation, any time a physician prescribed Rogaine she would have to make a telephone request to a state commission. Only after permission by the commission could the drug be prescribed. The commissioner must respond by telephone or another telecommunication device within 24 hours of the request. *See* 42 U.S.C.A. § 1396r-8(d)(5)(A) (West 2000).

10. *See infra* Section I.B.

provisions in order to further reduce pharmaceutical prices for Medicaid beneficiaries.[11] The most legally controversial of these state programs has been the "Maine Rx Program" ("Maine Program").[12] Under the Maine Program, the Commissioner of the Maine Department of Human Services negotiates to obtain rebates above and beyond those required by federal law with pharmaceutical manufacturers.[13] Although these rebates are voluntary, those non-compliant manufacturers are subject to prior authorization for their particular non-complying drugs.[14] Thus, Maine in effect uses the prior authorization as an incentive or a leverage device for extracting supplemental rebates from manufacturers for its citizens.[15]

With the advent of the Maine Program in May 2000, controversy ensued. The Pharmaceutical Research and Manufacturers of America ("PhRMA") quickly filed suit in the District Court of Maine[16] arguing: (1) the prior authorization provision was preempted by federal Medicaid law; and (2) the mandatory rebate provision was an extraterritorial regulation in violation of the dormant commerce clause of the Constitution.[17] PhRMA asserted that the use of prior authorization as

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11. For example, Vermont, Maine, Florida, and Michigan. *See* Theresa Agovino, *States seek ways to Reduce Cost of Drugs*, WIS. ST. J., Aug. 9, 2001, *available at* 2001 WL 25521619 (describing Florida's, Missouri's, and Maryland's programs as well as the proposal for a multi-state buying consortium); Russell Gold et al., *Pharmaceutical Industry Sues Michigan to Block Attempt to Cut Drug Prices*, WALL ST. J., Dec. 3, 2001, at A2 (describing the Michigan program and the litigation by PhRMA in Michigan, Vermont, Maine and Florida).

12. ME. REV. STAT. ANN. tit. 22 § 2681 (West 2001).

13. *See* Joan Henneberry, *Addendum to State Pharmaceutical Assistance Programs: The Maine Rx Program*, *at* www.nga.org/center/divisions/1,1188,C_ISSUE_BRIEF^D_2287,00.html (Aug. 3, 2001).

14. *Id.*

15. In addition to the rebate and prior authorization provisions, the Maine Program also contained another controversial element. The Maine Program prohibited unconscionable prices and unreasonable profits by manufacturers. ME. REV. STAT. ANN. tit. 22, § 2697(2) (West 2001). This outrageous provision, however, was immediately deemed an unconstitutional regulation of out-of-state manufacturers' revenues in violation of the dormant commerce clause. 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 *4-5 (D. Me. Oct. 26, 2000) [hereinafter *Commissioner*]. This provision is not discussed in the course of this Note for two reasons. First, extraterritoriality will be analyzed extensively in the course of the discussion on the rebate provision. That extraterritorial analysis can be cross-applied to the unreasonable profit provision. Second, the state of Maine never appealed the District Court's ruling on this issue. Pharm. Research & Mfrs. of Am v. Concannon, 249 F.3d 66, 72 n.2 (1st Cir. 2001). Therefore, it is unlikely that other states will use the illegal profiting provision in enacting any similar price reduction Medicaid programs. As a result, the provision does not have the appeal of general application to warrant extensive discussion.

16. *Commissioner*, 2000 U.S. Dist. LEXIS 17363, at *4.

17. U.S. CONST. art. I, § 8, cl. 3: "The Congress shall have Power . . . To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes." The dormant commerce clause is in effect a "negative" Commerce Clause prohibiting states from interfering with interstate commerce in the absence of congressional regulation. *See* Letter from James Madison to J.C. Cabell (Feb. 13, 1829), *in* 3 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, at 478 (M. Farrand ed., 1937) (noting that the Commerce Clause

a leverage device ran contrary to the clear congressional intent limiting the use of prior authorization to curbing over-prescription of unnecessary medication.[18] Therefore, PhRMA contended, federal Medicaid law governing prior authorization and the congressional intent behind that provision should preempt the Maine Program. PhRMA also argued that the supplemental state rebate provision under the Maine Program unconstitutionally regulated transactions between manufacturers and wholesalers that took place wholly out-of-state.[19] As a result, PhRMA asserted that such an extraterritorial regulation violated the dormant commerce clause.[20] In *Pharmaceutical Research & Manufacturers of America v. Commissioner, Maine Department of Human Services*, the District Court of Maine agreed with PhRMA on both the preemption and dormant commerce clause claims.[21] On appeal, however, the First Circuit in *Pharmaceutical Research & Manufacturers of America v. Concannon*[22] reversed on both points of law and upheld the Maine Program. The Supreme Court, realizing the significance of the dispute, granted certiorari in June of 2002.[23]

The Maine Program presents a novel method for dealing with high prescription drug prices for Medicaid recipients and the public at large. Due to the potential of such a programs to cut Medicaid costs, other states have watched and continue to follow closely the litigation over the Maine Program as they attempt to formulate similar statutes.[24] Thus, the legality of the Maine Program may be of great consequence for many states and their strategies in combating escalating pharmaceutical prices.[25] Since the Maine Program and other similar

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"was intended as a negative and preventive provision against injustice among the States themselves, rather than as a power to be used for the positive purpose of the General Government . . . ."). For an example of the Supreme Court's first major encounter in developing the doctrine, see *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824).

18. *Commissioner*, 2000 U.S. Dist. LEXIS 17363, at *20.

19. *Id.* at *13-17.

20. *Id.*

21. *Id.* at *4-5.

22. *Concannon*, 249 F.3d 66 (1st Cir. 2001).

23. Pharm. Research & Mfrs. of Am. v. Concannon, 122 S.Ct. 2657 (2002).

24. For example, in 2001 Florida passed the State Medicaid Formulary Law ("Florida Program"). FLA. STAT. ANN. § 409.912 (West 1998). The Florida Program requires drug manufacturers to provide rebates as a condition to get their products onto the state Medicaid formulary. *PhRMA Goes to Court Over Florida Rebates*, MARKETLETTER, Aug. 20, 2001, *available at* 2001 WL 9080194. Those non-complying manufacturers will have their non-complying drugs subject to prior authorization. *Id.* PhRMA is currently in the midst of challenging this statute as well. The District Court judge recently ruled against PhRMA and upheld the program. *See* Pharm. Research & Mfrs. of Am. v. Medows, 184 F. Supp. 2d 1186 (N.D. Fla. 2001). PhRMA is preparing an appeal to the Eleventh Circuit. *See* Jan Faiks, Press Release, Jan. 2, 2002, *at* www.phrma.org/mediaroom/press/releases///02.01.2002.320.cfm.

25. In fact, Michigan most recently enacted a prior authorization statute patterned after the Maine Program. *See* 2001 Mich. Pub. Acts 60; *see also* Jan Faiks, Press Release, Nov. 30,

programs that tie supplemental rebates to prior authorization may serve as revolutionary statutory models for the rest of the nation,[26] assessing the constitutionality of such statutes and the litigation arising under the Maine Program is of tremendous importance.[27] In particular, the most salient legal issues regarding preemption and the dormant commerce clause require attention.

The Supremacy Clause of the Constitution[28] provides the doctrinal basis for preemption claims. Pursuant to the Supremacy Clause, any state law running contrary to Acts of Congress must yield to those federal acts.[29] Preemption claims normally fit into one of three categories: express,[30] implied field,[31] and implied conflict preemption.[32] Implied conflict preemption is the relevant preemption claim in the case of a Medicaid dispute over a prior authorization state statute.[33]

2001, *at* www.phrma.org/mediaroom/press/releases///30.11.2002.316.cfm. PhRMA challenged the Michigan law in state court in Michigan. *See* Pharm. Research & Mfrs. of Am. v. Mich. Dep't of Cmty. Health, No. 01-94627-AZ, 2002 WL 27746 (Mich. Cir. Ct. 2002); *see also PhRMA v. Michigan Dep't of Cmty. Health*, *at* www.phrma.org/publications/quickfacts/30.11.2001.317.cfm (last visited Aug. 23, 2002). The court there struck down the law and ruled that the state agency went beyond its statutory authority in creating the program, and that the program also violated the Michigan state constitution. Jan Faiks, Press Release, Jan. 7, 2002, *at* www.phrma.org/mediaroom/press/releases///07.01.2002.321.cfm. The Michigan litigation provides a unique approach in challenging state prior authorization statutes: as violations of state statutory and constitutional provisions. The analysis in this Note dealing with the federal constitutional issues of the Maine statute can also be applied to the Michigan program, which similarly ties voluntary rebates to prior authorization.

26. *See* Daniel B. Moskowitz, *Maine's Threat of Drug Price Controls Is a Model for Other States' Lawmakers*, MEDICINE & HEALTH, June 28, 2001, at 2S1 (" 'As Maine goes, so goes the nation.' "); *see also Maine Appeals Halt on its Rx Plan: Hopes for Expedited Review to Meet Jan 1 Start*, MARKETLETTER, Nov. 20, 2000, *available at* 2000 WL 7544245 (stating that roughly twenty-eight other states are planning to introduce legislation similar to Maine's).

27. Although discussion will focus primarily on the Maine Program, this Note refers to "prior authorization statutes" generally — those statutes that tie rebates to prior authorization — with the hope of broadening the applicability of the analysis.

28. U.S. CONST. art. VI, cl. 2: "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land."

29. *See* Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1 (1824).

30. Express preemption occurs where there is explicit preemptive language by Congress to take exclusive control of a certain field. Gade v. Nat'l Solid Waste Mgmt. Ass'n, 505 U.S. 88, 98 (1992).

31. Implied field preemption occurs where the entire federal regulatory framework is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

32. Implied conflict preemption takes place, in the absence of express preemptive language, either where congressional intent dictates that "compliance with both federal and state regulations is a physical impossibility," Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963), or where such intent demonstrates that the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

33. Federal law does not expressly prohibit states from enacting prior authorization and additional rebate laws. *See* 42 U.S.C.A. § 1396r-8 (West 2000). Therefore, express preemp-

Since the conflict is implicit in implied conflict cases, ascertainment of congressional intent is of paramount importance in assessing these claims.[34] A mere fragment or a strained inference depicting congressional intent is not enough to preempt a state law.[35] The presumption is against preemption,[36] and only when congressional intent is shown to be "clear and manifest" will that presumption be rebutted and preemption found.[37]

Due to the integral role of congressional intent in implied conflict preemption cases, the interpretive devices used to ascertain intent may be crucial to the discovery of Congress's clear and manifest purposes. Consequently, whether a judge is committed to a textualist or a purposive paradigmatic framework[38] may result in the use of widely varying legislative materials and ultimately result in different findings regarding preemption.[39] Similarly, the nature of the statute involved may lend guidance as to the discovery of true congressional intent and a finding for preemption.[40] For example, in the case of Medicaid, the statute embodies a delicate balance of compromises between medical professionals, patients, manufacturers, federal legislators, and state interests.[41] Therefore, identifying the inherent nature of the statute at

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tion does not apply. Additionally, Medicaid is a joint federal-state program. *See* MARK R. DANIELS, *Introduction: The Inconsistency and Paradox of American Health Care, in* MEDICAID REFORM AND THE AMERICAN STATES 3 (Mark R. Daniels ed., 1998). Therefore field preemption is not the appropriate category as the states occupy a very large part of the Medicaid regulatory scheme. Thus, the relevant preemption category is one of implied conflict — whether the state prior authorization statutes stand as obstacles to the accomplishment and execution of the full congressional purposes and objectives behind Medicaid. The First Circuit also recognized that only implied conflict preemption was at stake in assessing the Maine Program. The court stated: "There is no explicit language in the Medicaid statute that forbids the Maine Rx Program. Nor is the doctrine of 'field' preemption relevant, as Medicaid is a cooperative federal and state program . . . . Therefore, we consider only implied conflict preemption as a basis for PhRMA's argument." Pharm. Research & Mfrs. of Am v. Concannon, 249 F.3d 66, 74 n.6 (1st Cir. 2001).

34. *See Gade*, 505 U.S. at 96 ("The question of whether a certain state action is preempted by federal law is one of congressional intent."); *see also* Retail Clerks Int'l Ass'n v. Schermerhorn, 375 U.S. 96, 103 (1963) (noting that "the purpose of Congress is the ultimate touchstone" in preemption cases).

35. Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 715 (1985).

36. *Id.*

37. *Id.*

38. See *infra* Section I.A for a discussion of the textualist and purposive interpretive approaches.

39. *See* Boggs v. Boggs, 520 U.S. 853 (1997); *see also* Karen A. Jordan, *The Shifting Preemption Paradigm: Conceptual and Interpretive Issues*, 51 VAND. L. REV. 1149, 1153 (1998) (characterizing *Boggs* as dealing with the outcome-determinative interpretive debate over textual and purposive approaches in an implied preemption context).

40. *See, e.g.*, Int'l Paper Co. v. Ouellette, 479 U.S. 481 (1987) (recognizing the balanced nature of the Clean Water Act in its preemption analysis); Florida Lime & Avocado Growers v. Paul, 373 U.S. 132 (1963) (taking into account the nature of the avocado quality regulation in its preemption inquiry).

41. *See infra* Section I.B.

hand may provide guidance to a judge seeking to interpret that statute in a manner consonant to the underlying nature and the corresponding purpose behind the various legislative compromises.

In addition to the preemption issue, programs like Maine's come under constitutional attack as violations of the dormant commerce clause. The dormant commerce clause forbids states from unduly burdening interstate commerce even in the absence of specific congressional regulation.[42] Courts analyze state statutes under varying levels of scrutiny corresponding to the degree a statute facially discriminates against out-of-staters.[43] Of pertinence to this Note are two specific categories of laws: laws that regulate extraterritorially[44] and laws that are facially neutral.[45]

The preemption and dormant commerce clause issues serve as the largest stumbling blocks in the passage of statutes like the Maine Program. Clearing these constitutional hurdles is necessary before such programs can become a reality and a long-lasting solution to high prescription drug prices. This Note contends that these constitutional hurdles cannot be cleared. Part I argues that the state prior authorization statutes are preempted by federal Medicaid law. Part II then contends that the state prior authorization statutes violate the dormant commerce clause of the Constitution because they regulate extraterritorially and alternatively fail under a dormant commerce clause bal-

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42. *See* FELIX FRANKFURTER, THE COMMERCE CLAUSE UNDER MARSHALL, TANEY & WAITE (1937). *See generally* Noel T. Dowling, *Interstate Commerce and State Power*, 27 VA. L. REV. 1 (1940); Noel T. Dowling, *Interstate Commerce and State Power — Revised Version*, 47 COLUM. L. REV. 547 (1947); Julian N. Eule, *Laying the Dormant Commerce Clause to Rest*, 91 YALE L.J. 425 (1982); Donald H. Regan, *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, 84 MICH. L. REV. 1091 (1986).

43. *See* Eule, *supra* note 42.

44. The Supreme Court has held that state laws that extraterritorially regulate out-of-state conduct of business are per se unconstitutional. *See* Healy v. Beer Inst., 491 U.S. 324 (1989); CTS Corp v. Dynamics Corp., 481 U.S. 69 (1987); Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573 (1986); Edgar v. MITE Corp., 457 U.S. 624 (1982). Such statutes project legislation onto other states and therefore burden interstate commerce by undermining state sovereignty. *See Brown-Foreman*, 476 U.S. at 582-83. As a result, extraterritorial laws are subject to strict scrutiny.

45. Laws that regulate commerce by facially treating in-staters and out-of-staters alike are held to the lowest level of scrutiny — the balancing test. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970). Under the balancing test, the burdens imposed by the state law on commerce are weighed against its benefits. *Id.* If those burdens are clearly excessive in contrast to the putative local benefits, then the law is struck down in violation of the dormant commerce clause. *Id.*

In applying a balancing test to a state statute, due to the broad discretion of the test, it is crucial to place the appropriate items in the balance. In addition to traditional items regarding effects on commerce, judicial concerns and ideals behind dormant commerce clause theory may serve to tip the balance. Such judicial concerns vary, but include, among other things, interpreting statutes to guard against protectionism, or to encourage national uniformity, or to advance the interests of vulnerable minorities. *See generally* Regan, *supra* note 42 (discussing judicial concerns within the rubric of the dormant commerce clause). These concerns may be as weighty as the effects on commerce.

ancing test.[46] This Note concludes that state prior authorization statutes, such as the Maine Program, are unconstitutional devices that also fail to provide an appropriate remedy for high prescription drug prices.

I. THE STRONG MEDICINE OF PREEMPTION

In examining prior authorization statutes, such as the Maine Program, the key issue in the preemption context is ascertaining congressional intent. If the state statutes "stand[ ] as . . . obstacle[s]" in the accomplishment of federal objectives, then courts must find such statutes preempted under implied conflict preemption standards.[47] Determining congressional intent is not, however, an easy task. Moreover, seemingly multiple expressions of congressional intent confound and confuse the inquiry in light of varying interpretive theories.[48] This Part argues that, subsequent to a court adopting a more paradigmatic and politically contextual approach in searching for congressional intent, the prior authorization statutes will be deemed to run contrary to that congressional intent and preempted by federal law. Section I.A argues that adopting a purposive interpretive theory in examining the relationship between the federal Medicaid statute and the state laws properly fulfills the judiciary's role within the legislative process and leads to the conclusion of preemption. Section I.B argues that Medicaid is a delicate balance of compromises and that courts must find preemption in order to preserve the series of compromises that embody the federal legislation.

A. *A Purposive Framework: The Search for Intent*

The two major statutory interpretive theories that battle within the juridical theatre are textualism and intentionalism.[49] A court adopting

46. The Supreme Court has, however, in the past balanced an extraterritorial statute rather than automatically deem it per se unconstitutional. *See Edgar*, 457 U.S. 624. Therefore, it may be inappropriate to consider balancing and extraterritoriality as alternative standards. Nonetheless, many of the extraterritorial cases dispense with balancing altogether. *See supra* note 44 (listing cases). Moreover, there may be a presumption against balancing developing on the Court. *See CTS Corp.*, 481 U.S. at 95 (Scalia, J., concurring) (positing that a balancing test is "ill suited to the judicial function and should be undertaken rarely if at all").

47. Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

48. *See generally* T. Alexander Aleinikoff, Patterson v. McLean: *Updating Statutory Interpretation*, 87 MICH. L. REV. 20 (1988) (discussing the numerous models of statutory interpretation).

49. *Id.* at 22. For excellent discussion on the competing views on textualism, see Antonin Scalia, *Common-Law Courts in a Civil-Law System: The Role of United States Federal Courts in Interpreting the Constitution and Laws*, *in* A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW 3 (Amy Gutmann ed., 1997), and HENRY M. HART, JR. & ALBERT

a textualist approach to statutory interpretation looks to the plain meaning of the statute — usually exclusively and at the expense of the legislative history — in order to determine the legislature's intent in enacting the statute.[50] Intentionalism, on the other hand, posits that contextual analysis is necessary to discern the full meaning of the statute's terms.[51] One intentionalist model, known as purposivism, uses the context of the statute's text, legislative history, and circumstances surrounding enactment in order to discover the broad purposes embodied in the legislation and to fit those purposes into the entire fabric of the law.[52] The purposive judge operates from the premise — sometimes troubling to textualists and public choice scholars — that the legislature acted with a purpose.[53] This Section first argues that purposivism is the more jurisprudentially sound interpretive theory *within the preemption setting*[54] in that it allows the judiciary to fulfill its role within the legislative process. Only by focusing on the interpretive debate first can a court confidently venture into the ambiguities of the Medicaid statute armed with the most appropriate and powerful weapons from its paradigmatic arsenal. That is, the arguments advancing purposivism must be firmly established before a court can grapple with the heart of the legal controversy over prior authorization.

From this interpretive starting point, this Section then directly confronts the difficulties of the prior authorization statutes and argues that federal law preempts the Maine Program and similar prior authorization state statutes. A critical analysis, in light of a purposive framework, of the Maine Program and the two related judicial opinions concludes that the First Circuit used a myopic textual approach and failed to take into account the legislative history dealing with prior

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M. SACKS, THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW (William N. Eskridge, Jr. & Philip P. Frickey eds., 1994) on purposivism.

50. Aleinikoff, *supra* note 48, at 23.

51. *Id.*

52. Jordan, *supra* note 39, at 1202-05; *see also* HART & SACKS, *supra* note 49, at 1124-25.

53. Aleinikoff, *supra* note 48, at 26; *see also* HART & SACKS, *supra* note 49, at 1125; Jodan, *supra* note 39, at 1204. For a discussion on public choice theory and the possible inconsistencies with the doctrine of purposivism, see generally William N. Eskridge, Jr., *Politics Without Romance: Implications of Public Choice Theory for Statutory Interpretation*, 74 VA. L. REV. 275 (1988); Jonathan R. Macey, *Promoting Public-Regarding Legislation Through Statutory Interpretation: An Interest Group Model*, 86 COLUM. L. REV. 223 (1986); Richard A. Posner, *Economics, Politics, and the Reading of Statutes and the Constitution*, 49 U. CHI. L. REV. 263 (1982); Martin H. Redish & Theodore T. Chung, *Democratic Theory and the Legislative Process: Mourning the Death of Originalism in Statutory Interpretation*, 68 TUL. L. REV. 803 (1994).

54. Whether or not purposivism is the better interpretive approach *in general* is an issue that falls outside of the purview of this Note. This Note argues that, within the limited setting of implied conflict preemption cases involving Medicaid disputes, purposivism serves as the stronger interpretive paradigm.

authorization and the context of other states' implementation of prior authorization in accordance with this legislative history.

1. *The Doctrinal Formulation*

Purposivism provides the strongest interpretive foundation for assessing preemption disputes. A court's adoption of a purposive approach is better than the utilization of a textual one in examining preemption questions in general and Medicaid disputes in particular.[55] Purposivism allows the judiciary to fulfill its role as an active participant in the lawmaking process — a role especially important in the context of preemption.[56] This view is based upon the Founders' belief that each branch of government is interdependent in its contribution to the deliberative and lawmaking processes.[57] This judicial role becomes of supreme importance in the preemption setting because courts are the only bodies that can properly manage federalism concerns — the very concerns at the foundation of preemption conflicts.[58] Because Congress "cannot, *ex ante*, draft meaningful preemption provisions . . . [and] Congress has demonstrated an inability to modify the language of preemption provisions even in light of judicial decisions pointing out textual inadequacies," then it logically follows that "Congress is even less likely to manage federalism in the implied preemption context."[59]

Purposivism, furthermore, provides judges with the ability to go outside of the inadequacies of the text in finding legislative intent, thus better managing federalism concerns. Congress is simply unable to imagine every undesirable application of its statutory provisions in order to evince an explicit preemptive intent.[60] A purposive judge can seek guidance from legislative history and the overall context of the

55. Jordan, *supra* note 39, at 1192 ("[A]lthough a textual approach to statutory interpretation may be sound in many contexts, the approach is unsatisfactory in the context of preemption.").

56. *Id.* at 1219; *see also* William N. Eskridge, Jr., *Spinning Legislative Supremacy*, 78 GEO. L.J. 319 (1989); Cass R. Sunstein, *Interpreting Statutes in the Regulatory State*, 103 HARV. L. REV. 405, 426 (1989) (noting that "resort to purpose was an effort to maintain the role of the courts as agents of the legislature while at the same time acknowledging the inadequacy of textualism").

57. *See* ROBERT A. KATZMANN, COURTS AND CONGRESS 1 (1997); JOHN E. NOWAK ET AL., CONSTITUTIONAL LAW § 3.5 (5th ed. 1995) (explaining the interdependence and intermingling between the branches and refuting the notion that the three branches operate separately in compartmentalized spheres — all in culinary terms: "While people sometimes refer to the three branches of the federal government as a three-layer cake, it is more accurate to think of it as a marble cake"); Jordan, *supra* note 39, at 1220.

58. Jordan, *supra* note 39, at 1218-19.

59. *Id.*; *see also* Catherine L. Fisk, *The Last Article About the Language of ERISA Preemption? A Case Study of the Failure of Textualism*, 33 HARV. J. ON LEGIS. 35, 96 (1996).

60. Jordan, *supra* note 39, at 1220.

legislation within the grand legal setting in order to determine Congress's purposes. A textualist judge, on the other hand, would be forced to abandon her role in adjudicating federalism disputes in the absence of textually explicit intent.[61] Purposivism is the superior interpretive framework in implied preemption cases generally because its enhanced interpretive devices better accommodate Congress's limitations in statutory creation and amendment.

In addition, in the particular implied preemption case involving a Medicaid dispute, purposivism provides the superior paradigm. Often the degree of judicial activism in preemption cases will depend on the federal law at issue.[62] Medicaid requires an especially heightened judicial role because of the pervasive and inherent federalism concerns found within the administration, nature, and history of the program.[63] In describing the nature of the Medicaid program, one political theorist notes:

> Federalism, a fundamental feature of American governance, profoundly shapes Medicaid. The joint responsibility of the national and state governments for funding and implementing the program has enmeshed it in perennial debates about the appropriate division of labor, or balance of power, between levels of government in the federal system.[64]

In addition, the political history of Medicaid has been a tumultuous one with the federal-state relationship constantly changing.[65] An understanding of the greater legal fabric and historical context of the Medicaid program allows for a more involved judicial search focusing on the true spirit and meaning of the law.[66] Medicaid, due to its history

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61. *See* Karen M. Gebbia-Pinetti, *Statutory Interpretation, Democratic Legitimacy and Legal-System Values*, 21 SETON HALL LEGIS. J. 233, 280 (1997) ("[T]extualism may actually frustrate the legislature's design, particularly when a statute is applied in circumstances not expressly contemplated by the legislature, because the statute's words will not always convey the full import of the legislature's policy choices.").

62. Jordan, *supra* note 39, at 1220.

63. Michael H. Armacost, *Foreword*, *in* MEDICAID AND DEVOLUTION: A VIEW FROM THE STATES, at vii (Frank J. Thompson & John J. DiIulio Jr. eds., 1998).

64. *Id.*

65. *See, e.g.*, John D. Blum, *Overcoming Managed Care Regulatory Chaos Through a Restructured Federalism*, 11 HEALTH MATRIX 327, 329-30 (2001):

> While Medicaid affords states' discretion concerning the scope of benefits and administration of their respective programs, the program operates under federal oversight, and the history of this dually administered enterprise has been one of contention between the respective levels of government. In particular, federal and state regulators most often disagree about funding, and over the years they have had a series of intergovernmental disputes related to joint financing responsibilities which have accelerated with heightened federal mandates being placed on state Medicaid programs.

See generally JEAN DONOVAN GILMAN, MEDICAID AND THE COSTS OF FEDERALISM, 1984-1992 (1998) (describing the changing federal-state relationship within Medicaid).

66. See *Holy Trinity Church v. United States*, 143 U.S. 457, 459 (1892), for the purposivist motto that a "thing may be within the letter of the statute and yet not within the statute, because not within its spirit, nor within the intention of its makers."

and nature, demands a more searching judicial inquiry designed to uphold the spirit of the law and maintain the federalism issues found therein.

While the textualist judge would argue that the purposive approach only leads to judicial over-reaching and impermissible legislating,[67] such concerns are exaggerated and unwarranted in the preemption context. The textualist judge contends that her purposivist colleague can easily abandon the statutory text in order to impute a purpose that could easily be a judicial one not envisioned by the legislature.[68] The textual approach, on the other hand, serves the ideals of judicial restraint by keeping the legislative role in the hands of Congress and not the court.[69] The textual approach purports to harness the dangers of judicial lawmaking by preventing judicial consultation of legislative materials and the social context of the statute.[70] Although the concern over judicial over-reaching is noteworthy, it can be eased and refuted — at least in the preemption context — in three different ways.

First, a purposivist judge does not abandon the text, but rather looks to extra-textual materials only after finding that the text is ambiguous as to the statute's purpose.[71] Judicial restraint in the form of deference to the text still remains in a purposive world. Those "purposivist" judges who seek to manipulate the text through the expansion of interpretive factors grossly misapply purposive theory.[72] These same manipulators could just as easily manipulate under the guise of

67. *See* Aleinikoff, *supra* note 48, at 28; Frank H. Easterbrook, *The Role of Original Intent in Statutory Construction*, 11 HARV. J.L. & PUB. POL'Y 59, 62-3 (1988) (the search for intent "greatly increases the discretion, and therefore the power, of the court"); *cf.* Orrin Hatch, *Legislative History: Tool of Construction or Destruction*, 11 HARV. J.L. & PUB. POL'Y 43, 47 (1988) (positing that in constitutional adjudication the legislative history "often provide[s] the only restraint upon an expansive and inaccurate interpretation of what [the constitutional] clauses were originally drafted to accomplish").

68. *See* Aleinikoff, *supra* note 48, at 28; A. Michael Froomkin, *Climbing the Most Dangerous Branch: Legisprudence and the New Legal Process*, 66 TEXAS L. REV. 1071, 1083 (1988) (stating that "[a]rmed with an attribution of the statute's general purpose, the court can adapt the text of the statute to changing circumstances without, one assumes, too much concern for the embarrassments of specific language."); Redish & Chung, *supra* note 53, at 817 ("Because a purposivist judge willingly posits a *reasonable* legislature — an assumption that is not necessarily valid in all instances — she can hardly guarantee that the purposes she discerns represent the actual purposes of the enacting body.").

69. Aleinikoff, *supra* note 48, at 23.

70. *Id.* ("By restricting courts to the language of the statute, textualism attempts to prevent the creative judicial lawmaking that can occur when judges consult legislative materials and the social context of the statute.").

71. *See* Aleinikoff, *supra* note 48, at 28-29 (arguing that "Hart and Sacks advocated contextual analysis as the way to resolve the ambiguities inherent in language"); Gebbia-Pinetti, *supra* note 61, at 284-85 (noting that a purposivist judge "first examines the statutory language, because the text is the best evidence of the legislature's intent or the statute's purpose").

72. *See* Aleinikoff, *supra* note 48, at 28-29.

the textualist framework — albeit with fewer tools — in order to meet their purposes.[73] Thus, the textualist's concerns for the primacy of the text and the prohibition against manipulation and de facto judicial legislating are still safeguarded under a purposive approach.

Second, grasping onto the face of the text without regard to the depth of congressional intent can lead to strained interpretations that are wholly inaccurate.[74] It is the search for accuracy that requires increased judicial involvement through a purposive framework. If the text is ambiguous, the purposivist judge uses legislative history and other extra-textual materials in order to interpret the statute.[75] The textualist would argue against the use of such materials and would accept a "substantial margin of error in identifying legislative will" for the sake of restraint.[76] Under the purposivist framework, "an increase in accuracy is purchased at the price of greater opportunities for judicial policymaking."[77] The trade-off between restraint and accuracy, however, is far from equal.

The inaccuracies of textualism can produce contrived interpretations that lack coherence and are based on unnatural inferences.[78] Moreover, the benefits of restraint found through the abandonment of extra-textual devices are illusory. As one legal scholar notes:

> We should not insulate ourselves from the context in which legally significant words were uttered if we care about ascertaining what the speaker intended to convey. Whether we see this upon our initial reading of the document (intrinsic ambiguity), or only later after we have conducted adequate investigation (extrinsic ambiguity) is ultimately of little significance.[79]

The reason that such distinctions between intrinsic and extrinsic ambiguities become seemingly irrelevant is that the introduction of context into the interpretive melting pot does not eliminate or create new interpretations; rather context makes some interpretations "more salient

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73. In fact, some scholars argue that textualism needs restraint from a different form of manipulation. *See* A. Michael Aleinikoff & Theodore M. Shaw, *The Costs of Incoherence: A Comment on Plain Meaning,* West Virginia University Hospitals, Inc. v. Casey, *and Due Process of Statutory Interpretation*, 45 VAND. L. REV. 687, 689 n.8 (1992) ("[J]udicial restraint should prevent the Court from elevating its affinity for linguistic simplicity and consistency across the statutory landscape over Congressional intent.").

74. *See* Lawrence M. Solan, *Learning Our Limits: The Decline of Textualism in Statutory Cases*, 1997 WIS. L. REV. 235, 258.

75. *See* Redish & Chung, *supra* note 53, at 816.

76. *See* Aleinikoff, *supra* note 48, at 27.

77. *Id.*

78. Solan, *supra* note 74, at 258.

79. *Id.* at 256; *see also* RICHARD A. POSNER, THE PROBLEMS OF JURISPRUDENCE 263-64 (1990) (describing the failure to examine context in evaluating textual clarity as the "plain meaning fallacy"). For an example of Posner's "plain meaning fallacy," see Federal Deposit Ins. Corp. v. W.R. Grace & Co., 877 F.2d 614 (7th Cir. 1989).

and others less salient."[80] Therefore, the benefits of restraint derived from abandoning extra-textual devices are limited and yet serve to undermine the ascertainment of accurate results.

Finally, the concern over excess judicial involvement is misplaced in the preemption setting. Preemption calls for more judicial involvement because preemption disputes can be characterized as judicial in nature insofar as they involve the allocation of authority.[81] As opposed to the creation of laws for the regulation of conduct, preemption deals with federal-state relations and the potential invalidation of laws.[82] Such a topic is one for judicial eyes; therefore, textualism hampers the judiciary from becoming involved in a realm that demands heightened judicial responsibility.

Thus, purposivism is a superior interpretive theory to textualism in preemption disputes because it allows the court to manage federalism concerns in an area of law — Medicaid — that desperately needs such management. Although the textualist judge argues for a more restrained approach in order to keep the judiciary in check, ultimately her concerns are overstated relative to purposivist theory. Moreover, the textualist judge sacrifices accuracy for limited checks on judicial over-reaching, and undermines the inherently judicial task of assessing preemption disputes.

2. *Purposive Application: The Maine Rx Program*

Application of the purposive approach to the conflict between the Maine Program and federal Medicaid law clearly demonstrates that the Maine Program must be preempted. A critical analysis of the First Circuit decision in *Concannon*[83] demonstrates that the First Circuit ignored the clear legislative history, the subsequent state statutes, and the proposed regulations by the Health Care Financing Administration ("HCFA") evincing the purpose of prior authorization embodied in that history. By taking these three important factors into account, the Maine law stands as an obstacle to the execution and accomplishment of the full purposes and objectives of Congress.

The statutory text of the federal Medicaid program is silent as to the situations in which prior authorization may be implemented. Federal Medicaid law explicitly provides for prior authorization under limited circumstances.[84] The statutory language alone, however, fails

80. Solan, *supra* note 74, at 256-57.

81. Jordan, *supra* note 39, at 1220.

82. *Id.*

83. Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66 (1st Cir. 2001).

84. Federal law states: "A state plan under this title . . . may require . . . the approval of the drug before its dispensing . . . only if the system providing for such approval . . . provides response by telephone or other telecommunication device within 24 hours of a request for

to provide Congress's intentions as to the limitations on the use of prior authorization. Standing alone, the text might stand for the ideal that prior authorization may be implemented for any purpose.

An examination of the legislative history, however, shows that Congress had a specific and limited scope for prior authorization. The House Reports illuminate that Congress intended states only to have the option of imposing prior authorization in order to safeguard against unnecessary over-prescription of drugs and to provide for a proper balance of quality and economy.[85] As the District Court of Maine noted, "It may have never occurred to Congress that the Medicaid program could be hijacked to provide leverage for other purposes . . . . Maine's Rx rebate program has nothing to do with these concerns of unnecessary use of prescription drugs or safeguarding Medicaid payments."[86]

In addition to the legislative history, the circumstances surrounding enactment shed insight into congressional purpose and serve to place the statute in its appropriate legal context.[87] In assessing the legal landscape, an important factor to consider is how prior authorization was most commonly implemented by the states immediately after the provision was enacted in 1990. In a paper published in the early 1990s, Drs. Robert Buchanan and Scott Smith found that the "most common method used by the Medicaid programs to enforce their poli-

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prior authorization; and . . . provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation." 42 U.S.C.A. § 1396r-8(d)(5)(A)-(B) (West 2001).

85. *See* H.R. REP. NO. 101-881, at 98 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2110 ("As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care. However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment."); H.R. REP. NO. 101-964 Part B (1990) ("Except in the first year following approval of a new drug, States are permitted to subject any covered outpatient drug to prior authorization. States may limit quantities of drugs, provided the limitations are necessary to discourage waste.").

86. 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 *20 n.12 (D. Me. Oct. 26, 2000).

87. The purposivist judge need not limit herself only to the text and legislative history in ascertaining the statute's purpose. Redish & Chung, *supra* note 53, at 816. The purposivist judge must also examine the entire "legal landscape" in order to properly interpret the statute in a manner consonant with the greater legal context. *Id.* While the text and legislative history inform the more immediate purposes of the statute by allowing glimpses into the enacting Congress's mind, the legal landscape involves assessing the dynamic legal, social and political forces that change and shape the statute into one that fits into the legal system as a whole as it develops throughout time. *See* HART & SACKS, *supra* note 49, at 1124 ("The purpose of a statute must always be treated as including not only an immediate purpose or group of related purposes but a larger and more subtle purpose as to how the particular statute is to be fitted into the legal system as a whole.").

cies against off-label use is prior authorization."[88] Off-label use is the practice of physicians prescribing approved medications for other than their intended indications.[89] Thus, interpreting the prior authorization provision to apply only to the prevention of off-label use serves to further the statute's purpose within the existing legal landscape of the early 1990s. Moreover, the use of prior authorization in the context of limiting off-label prescription — a practice that can lead to unnecessary over-prescription — fits harmoniously with the legislative history.[90] This legal landscape created by the states in the early 1990s provides a greater context in ascertaining the statute's true purposes. This contextual framework, coupled with the legislative history, suggests the purpose behind the prior authorization was to reduce unnecessary and inefficient over-prescription by curbing off-label use.

Finally, proposed regulations by the HCFA, the agency that once administered Medicaid,[91] further paint a picture of the legislative landscape in conformity with the prior state enactments and legislative history. The HCFA failed to issue formal regulations regarding prior authorization.[92] Yet the proposed regulations that the HFCA promulgated indicate that prior authorization should only be used to curb unnecessary prescription, not to limit coverage.[93] As such, the proposed regulations by the HFCA support the idea that the Maine Program should be preempted as it conflicts with federal law.[94]

In light of this legislative history and legal landscape, the First Circuit failed to recognize the intent underlying prior authorization. The First Circuit, in assessing the Maine Rx Program, argued that the

88. Robert J. Buchanan & Scott R. Smith, *Medicaid Policies for HIV-Related Prescription Drugs*, HEALTH CARE FIN. REV., Spring 1994, at 43, 57.

89. MEDICINENET, INC., MEDTERMS DICTIONARY (2002), *at* http://www.medterms.com (last visited Aug. 23, 2002); *see, e.g., infra* note 90.

90. An example of the use of prior authorization as a method for controlling unnecessary prescription of off-label drugs is as follows: "state X" places minoxidil on its Medicaid formulary for the treatment of hypertension. Doctors in "state X" begin prescribing minoxidil off-label in order to treat hair loss. "State X" subjects minoxidil to prior authorization in order to curb this off-label prescription which it believes to be unnecessary and uneconomical in light of the allocation of funds for the most important drugs.

91. *See* Abigail B. Pancoast, Comment, *A Test Case for Re-evaluation of the Dormant Commerce Clause: The Maine Rx Program*, 4 U. PA. J. CONST. L. 184, 190 (2001). HCFA, as of July 1, 2001, no longer exists. HCFA is now the Centers for Medicare and Medicaid Services. *See* Centers for Medicare and Medicaid Services, *at* http://cms.hhs.gov/about/default.asp (last visited July 31, 2002).

92. 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 *20 n.12 (D. Me. Oct. 26, 2000); Pancoast, *supra* note 91, at 190.

93. *See* Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, 60 Fed. Reg. 48,442, 48,454 (Sept. 19, 1995) (to be codified at 42 C.F.R. pts. 441 and 447) (noting that states should be prevented from "using a prior authorization program as a proxy for a closed formulary").

94. *See* Pancoast, *supra* note 91, at 190.

Maine statute permissibly utilized prior authorization by noting that the federal text explicitly allowed for prior authorization and that, absent any textual proof to the contrary, deference must be given to the Maine Department of Human Services' application of the provision.[95] The First Circuit's decision is flawed in two respects.

First, that court used a strictly textual approach in examining the preemption question and therefore ignored Congress's true purposes. As noted above, the legislative history, the proposed HCFA regulations, and state laws established post-enactment demonstrate the narrow intentions that Congress had for prior authorization.[96] The First Circuit, however, ignored the legal context and instead used the silence of the text to make the bold conclusion that it was "not convinced that the Medicaid statute is concerned with the motivation behind imposing prior authorization."[97] The implication of this statement is potentially disastrous. As the District Court below argued, "If Maine can use its authority over Medicaid authorization to leverage drug manufacturer rebates for the benefit of uninsured citizens, then it can just as easily put the rebates into a state program for highway and bridge construction or school funding."[98] The First Circuit briefly, but insufficiently, responded to this argument, noting that highway construction and school funding are unrelated to providing medical services and, therefore, could not be justified.[99] This response is insufficient because the crux of the District Court's argument deals not with the latter part of its statement — the use of funds for highways and schools — but the former — the use of prior authorization as a leverage device. Because the First Circuit already indicated that the motivations behind prior authorization are not of concern,[100] presumably a state could implement a program as a leverage device against doctors, or as a tool to reduce Medicaid spending at the expense of the poor, or for any other purpose it so desired. Moreover, in addressing the latter part of the District Court's argument, if the First Circuit only limited the use of the rebate monies to providing medical services to the needy, states still could potentially leverage drug manufacturers and use the funds not for highways but for the construction of county hospitals or other medically-related self-dealing. This certainly was not the vision that Congress had for prior authorization.[101]

95. Pharm. Research & Mfrs. of Am v. Concannon, 249 F.3d 66, 75 (1st Cir. 2001).

96. *See supra* notes 85-90 and accompanying text.

97. *Concannon*, 249 F.3d at 76.

98. *Commissioner*, 2000 U.S. Dist. LEXIS 17363, at *20.

99. *Concannon*, 249 F.3d at 77.

100. *See supra* note 97 and accompanying text.

101. *See supra* notes 85-86 and accompanying text.

Second, the First Circuit's decision is incomplete in that it failed to find preemption of the state statute based on the law's conflict with Medicaid's requirement that health care be in the "best interests" of the program.[102] Prior authorization as implemented by Maine runs contrary to the Medicaid provision that any state restriction on drug distribution "provide such safeguards as may be necessary to assure that . . . care and services . . . will be provided, in a manner consistent with . . . the best interests of [Medicaid] requirements."[103] The Maine Program harms Maine recipients by impeding their access to their doctors' first-choice medications and, therefore, runs opposite to the best interests of providing medically necessary services to the poor.[104] The First Circuit did not reject this argument and only ruled against PhRMA on this point because of PhRMA's inability to sustain its burden on this facial challenge.[105] Rather, the First Circuit voiced its concern in stating: "Since both sides agree that the prior authorization requirement is the 'hammer' or 'force' that coerces manufacturers to enter into the Program, the possibility that first-choice drugs will not be readily approved where second-choice inferior alternatives exist concerns us."[106] The District Court stated that the best interests of the patient would be hurt by prior authorization and it would therefore defeat the fundamental purposes of Medicaid law.[107] There was testimony on the record that when prior authorization is used inappropriately, patients are hurt by increased delays, anxiety and confusion, and by the potential prescription of less safe and efficacious drugs.[108] Furthermore, although little empirical study has been done on the effects of prior authorization, existing empirical data strongly support PhRMA's argument.[109] Taken together, all these factors demonstrate the high likelihood that the Maine statute's use of prior authorization

102. *Concannon*, 249 F.3d at 78.

103. 42 U.S.C.A. 1396c(a)(19) (West 2000).

104. *Concannon*, 249 F.3d at 77. In addition to the obstacles in receiving first-choice medication, the state prior authorization statutes harm Medicaid recipients in the long run in the form of research and development losses incurred by pharmaceutical companies. This further compounds the state statutes' conflict with the Medicaid program's "best interests" requirement. *See infra* Section II.B.

105. *Concannon*, 249 F.3d at 78.

106. *Id.*

107. 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 *19-20 (D. Me. Oct. 26, 2000).

108. *Concannon*, 249 F.3d at 77-78 (quoting the testimony of Dr. Scott Howell).

109. *See* Walter E. Smalley et al., *Effect of a Prior-Authorization Requirement on the Use of Nonsteroidal Antiinflammatory Drugs by Medicaid Patients*, 332 NEW ENG. J. MED. 1612, 1614 (1995). The study examined NSAIDs that did not have a generic equivalent and were subject to prior authorization. *Id.* The study found that during the two years after prior authorization began, total expenditures for NSAIDs fell by $12.8 million compared to projections. *Id.* In addition, the study found no evidence of an increase in other related services and drugs. *Id.*

undermines Congress's explicit purposes of safeguarding the best interests of the Medicaid program and its patients.[110]

This Section has demonstrated that under a purposive paradigm, with a view of the legislative history and circumstances in the states subsequent to enactment, Congress meant prior authorization to be used only in limited circumstances.[111] The First Circuit, using a textual approach, failed to identify the limited purposes of the prior authorization statute, and also failed to interpret the statute properly in order to harmonize it with the best interest requirement which undergirds the federal statute.[112] Taking these factors into account, the Maine Program stands as an obstacle to the accomplishment of the aforementioned congressional purposes and therefore must be preempted.

This Section has shown that the purposive approach is superior to the textual framework in the context of Medicaid preemption because of the increased role of the judiciary in safeguarding the federalism concerns inherent in the statute. Under this purposive paradigm, the Maine Program must be preempted in light of the legislative history and subsequent state enactment reflecting the narrow purposes found in that legislative history. Pursuant to the congressional purposes, prior authorization does not stand as a leverage device used to extract rebates from pharmaceutical companies. Therefore, its misapplication stands as an obstacle to Congress's purposes and Medicaid's best interest purposes.

B. *A Delicate Balance Undone: The Impermissibility of Cost Over Access*

"All interpretive theories must ultimately be grounded in a political theory and a theory of law."[113] The notion of a purposivist framework operating in a political vacuum is therefore both unrealistic and impossible. The appropriate political theory often depends on the nature of the law at stake. In analyzing Medicaid, courts should adopt a delicate balance political theory because of the nature of the Medicaid program and because such a theory creates appropriate outer boundaries to the purposive paradigm. Further, under a delicate balance theory of law, the state prior authorization statutes must be preempted because they effectively unravel careful compromises over cost and access embodied in the legislation.

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110. *See* H.R. REP. NO.101-881 (1992), *reprinted in* 1990 U.S.C.A.N. 2017 ("[T]he Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment.").

111. *See supra* notes 85-86 and accompanying text.

112. *See supra* notes 101-109 and accompanying text.

113. Aleinikoff, *supra* note 48, at 31.

The delicate balance theory rests upon the idea that legislation is a package of compromises between various groups, and states should not be allowed to upset the political decisions made by Congress in accommodating competing interests and interest groups.[114] The case of *International Paper Co. v. Ouellette*[115] illustrates this theory. The Court in *Ouellette* first noted that a "state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach this goal."[116] The Clean Water Act, the law at issue in *Ouellette*, carefully balanced public and private interests in attempting to eliminate water pollution.[117] The Court held that the Vermont law allowing common-law suits would upset this carefully crafted balance of interests at the federal level and therefore must be preempted.[118] Thus, the Court recognized the balanced nature of the statute and deferred accordingly to that balance.

Three reasons demonstrate why this political theory is so attractive in the present case. First, Medicaid, much like the Clean Water Act, is a program that balances interests of different groups — doctors, recipients, and pharmaceutical manufacturers — and balances competing goals — accessibility and cost-effectiveness.[119] For example, the federal rebate requirement serves as a quid pro quo to balance the pharmaceutical manufacturers' open access to state formularies, i.e., states' lists of covered drugs — an arrangement that protects and preserves the interests of manufacturers, patients, and both federal and

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114. Paul Wolfson, *Preemption and Federalism: The Missing Link*, 16 HASTINGS CONST. L.Q. 69, 77-79 (1988).

115. 479 U.S. 481 (1987). For other examples of delicate balance theory, see City of Burbank v. Lockheed Air Terminal, Inc., 411 U.S. 624 (1973); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 169 (1963) (White, J., dissenting); Paul W. Kahn, *The Court, the Community and the Judicial Balance: The Jurisprudence of Justice Powell*, 97 YALE L.J. 1 (1987). For an example of the theory in the food and drug setting, see Schering Corp. v. Food & Drug Admin., 51 F.3d 390, 396 (3d Cir. 1995).

116. *Ouellette*, 479 U.S. at 494.

117. *Id.* at 494.

118. *Id.* at 497 ("The CWA carefully defines the role of both the source and affected States, and specifically provides for a process whereby their interests will be considered and balanced by the source State and the EPA. This delineation of authority represents Congress' considered judgment as to the best method of serving the public interest and reconciling the often-competing concerns of those affected by the pollution. It would be extraordinary for Congress, after devising an elaborate permit system that sets clear standards, to tolerate common-law suits that have the potential to undermine this regulatory structure.").

119. *See generally* GILMAN, *supra* note 65 (discussing the twin goals of controlling expenditures and providing the best care); MEDICAID REFORM AND THE AMERICAN STATES (Mark R. Daniels ed., 1998) (same); REMAKING MEDICAID: MANAGED CARE FOR THE PUBLIC GOOD, at xiv (Stephen M. Davidson & Stephen A. Somers eds., 1998) (same). For a description of the competing interests inherent in Medicaid's comparable sister program, Medicare, see Massachusetts Medical Society v. Dukakis, 815 F.2d 790 (1st Cir. 1987).

state governments.[120] Medicaid epitomizes the delicate balance theory of legislation.

Second, delicate balance theory guides courts in dealing with difficult issues of federalism in an area of complex federal/state relations. For example, in the case of Medicaid, the political history of the program demonstrates the federal government's controlling position vis-à-vis the states, thereby providing courts with the clear message that the federal balance of interests should be upheld.[121] In the late 1980s and early 1990s, the federal government began to exert greater control in Medicaid and treat the states not as co-equals, but as subordinates to be commanded.[122] In describing the Medicaid program as an example of this new change in federal/state relations, one scholar notes: "Instead of relying upon the carrot of federal grants and conditions-of-aid to gain state cooperation, the federal government has relied increasingly upon sticks of various sorts, including legislative regulation, preemption, and judicial decrees."[123] Even when Congress did give discretion to the states during this time, it did so in many cases with instructions of great specificity.[124] If Congress demanded to be in the driver's seat in the promulgation of Medicaid requirements, then presumably it would also not want those provisions reflecting a delicate balance to be subverted by the states. Deference to federal interests via the delicate balance theory therefore recognizes Congress's intent to retain greater control in the realm of Medicaid.

Third, the delicate balance theory provides outer limits to protect against judicial lawmaking. The theory is based on the idea of law that the legislature forms legislation as a package of compromises and that the judiciary cannot interfere to destroy the package.[125] Thus, the delicate balance theory used in conjunction with purposivism serves as a balance within the jurisprudence. The purposivist judge proactively searches for statutory intent, yet the limits of the delicate balance theory prevent excessive judicial overreaching and the destruction of legislative will.[126] The purposivist court looks to the purposes of the law, and if it sees legislation that seems to be indicative of a delicate balance, then it defers to that balance. Therefore, a delicate balance

120. Complaint for Declaratory, Injunctive and Other Relief at para. 17, Pharm. Research & Mfrs. of Am. v. Meadows (N.D. Fla. 2001) (4:01CV356-ws).

121. GILMAN, *supra* note 65, at 105.

122. *Id.*

123. *Id.*

124. *Id.* at 115.

125. Wolfson, *supra* note 114, at 77.

126. *See* Aleinikoff, *supra* note 48, at 27 (noting that the objective of archeological models of interpretation is legislative supremacy); Jordan, *supra* note 39, at 1216-17 (recognizing that purposivism, as well as textualism, is wholly committed to the idea of legislative supremacy).

theory may provide sound guidance for the purposivist judge who seeks to fulfill her role in safeguarding federalism while stopping short of legislating from the bench. Thus, the nature of the Medicaid program, the creation of outer limits to prevent against judicial lawmaking, and a recognition of Congress's purposeful superiority over the states in Medicaid all support the utilization of a delicate balance theory in assessing a Medicaid preemption conflict.

Some opponents of the delicate balance theory, however, argue that it overlooks the fundamental premise of federalism that holds that there are two levels of legislative activity: federal and state.[127] These critics continue by noting that a delicate balance theory does not necessarily evince an intent by Congress to preclude the states from altering the balance at their legislative level.[128] If states were precluded from acting, the opponents argue, then "there would seem to be little if any room for state regulatory authority."[129] The slippery slope is wet with the fear that the delicate balance theory may lead to the extreme centralization of government. Although a valid concern in the field of Medicaid, there are two responses to this contention.

First, the delicate balance theory would only preclude states from acting and upsetting federal interests where the legislation demonstrates a multi-interest, compromise nature. If states were allowed to subvert the balance in these types of laws, then there would be no reason for Congress to strike the balance in the first place.[130] One could easily envision Congress washing its hands of formulating any legislation that involved a complex network of interests. Programs like Medicaid and the Clean Water Act would be subject to a patchwork of varying state visions, and the uniformity found within these programs would be lost.

In addition, the theory would only amount to "minifield" preemption where Congress marks out a small part of a piece of legislation that represents a delicate balance and cannot be upset.[131] For example, a court could conclude in the case of Medicaid that the provisions relating to rebates and prior authorization[132] represent a minifield that Congress completely occupies due to the balance of interests found in those subsections. Thus the states would be preempted from entering that field and changing those provisions. States would not be precluded from the whole field of Medicaid and the delicate balance con-

127. Wolfson, *supra* note 114, at 81-82.

128. *Id.*

129. KENNETH STARR ET AL., THE LAW OF PREEMPTION: A REPORT OF THE APPELLATE JUDGES CONFERENCE OF THE AMERICAN BAR ASSOCIATION 36 (1991).

130. Wolfson, *supra* note 114, at 82.

131. *Id.*

132. 42 U.S.C.A. §§ 1396r-8(c)-(d) (West 2000).

sequently would work hand-in-hand with the management of federalism.

In applying the delicate balance theory to the state prior authorization statutes at issue, it becomes clear that the state laws upset the balance struck by Congress between accessibility of drugs provided by pharmaceutical manufacturers and cost-effectiveness realized by the states. By linking prior authorization to extracting supplemental rebates from pharmaceutical companies, states impermissibly decrease access to drugs and subvert the balance between access and expense mandated to the states in 1990. The mandatory rebates in the Medicaid statute were originally part of private voluntary pharmaceutical programs between pharmaceutical manufacturers and states.[133] After many, but not all, states adopted the private program, Congress mandated in its Medicaid legislation that all fifty states adopt this program and thereby increase access to medicines through these rebates.[134] Congress's incorporation of an originally voluntary state program into its federal law as a required program makes one thing clear: the method of rebating in order to improve access to prescription drugs is not optional.

When states leverage supplemental rebates out of drug companies by utilizing the threat of prior authorization, these states effectively turn a congressional mandate into something entirely discretionary. States could require exorbitant supplemental rebate amounts for certain drugs in order to limit access purposefully through the deterrent of prior authorization and thereby cut costs. The delicate balance between cost and access, consequently, would be destroyed. In order to maintain the delicate balance of interests in the federal legislation, the state prior authorization statutes must be preempted as running contrary to the purpose of Congress in tempering cost and open access to necessary prescription drugs for the poor.

Medicaid embodies a delicate balance of interests, and the state prior authorization statutes must be preempted in order to preserve that balance. As the First Circuit noted, "federal preemption of a state law is strong medicine, and is not casually to be dispensed."[135] Although the medicine is strong, it is clearly warranted in the present case. By using a purposive interpretive paradigm that is founded upon a delicate balance political theory, these state statutes must be deemed to be in implied conflict with Congress's purposes, and consequently preempted. Maine and several other states turned the rebate and prior authorization provisions in the federal law on their head. Congress,

133. R. Roy Vagelos, *Are Prescription Drug Prices High?*, 252 SCIENCE, 1080, 1083-1084 (1991) (describing Merck's "Equal Access to Medicines Program").

134. 42 U.S.C.A. § 1396r-8(a)-(c) (West 2000); *see* Vagelos, *supra* note 133, at 1084.

135. Concannon, *supra* note 15, at 75 (internal quotations omitted).

however, never intended prior authorization to be used as a bargaining device to subvert the balanced interests in the legislation.

II. A SLEEPING GIANT AWAKENS: THE DORMANT COMMERCE CLAUSE AND THE PRACTICAL EFFECTS OF PRIOR AUTHORIZATION STATUTES

Resolution of the preemption question does not foreclose the constitutional dilemma associated with prior authorization. Although preemption remains dispositive, alternative grounds of attack remain in the form of the dormant commerce clause. A court managing to squirm around the preemptive qualities of the prior authorization statutes must still cross through the constitutional quagmire of the dormant commerce clause. This Part argues that such a task is impossible because the state statutes clearly run afoul of the dormant commerce clause. Section II.A paves the way for the dormant commerce clause analysis by dismissing market participation as a viable defense for a state seeking refuge from a barrage of Commerce Clause attacks. Section II.B proceeds to argue that the state prior authorization statutes are per se unconstitutional because they have an extraterritorial reach. Section II.C then argues in the alternative that even if the statutes are upheld under an extraterritoriality test, they must be struck down under a balancing test since the burdens on interstate commerce outweigh the local benefits of the statutes.

A. *A Word on Market Participation: The Easy Case*

If a state is acting as a participant in the market and not as a regulator, it may discriminate against out-of-state interests and be free from the constraints of the dormant commerce clause.[136] The distinction between a regulator and a participant is often unclear;[137] nevertheless, it is imperative to understand those differences in the present case to fully address the salient dormant commerce clause attacks. The case of the state prior authorization statutes, however, is an easy one. With regard to these statutes, the distinction is clear: the states' regulation of drug prices through rebate provisions is an act of market regulation and not market participation. Therefore, the states are not exempt from dormant commerce clause violation.

Both the District Court of Maine's and the First Circuit's analysis on this point is instructive. Both courts held that under the Maine statute, Maine was acting as a market regulator. The market partici-

136. *See* Hughes v. Alexandria Scrap Corp., 426 U.S. 794, 810 (1976); *see also* ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 336 (1997).

137. CHEMERINSKY, *supra* note 136, at 337-38.

pant doctrine governs the specific transaction.[138] Under the Maine Program, it is the citizen who transacts and is considered the "payor" for the pharmaceuticals — the state of Maine never buys the prescription drugs.[139] The state is merely using its regulatory power in order to achieve the specific social goal of price reduction for its citizens.[140] This is market regulation and not participation.[141] Consequently, any defense a state may raise through the invocation of the market participant doctrine must necessarily fail. The state prior authorization statutes — Maine's being most illustrative — are a clear exercise of states' regulatory power. The dormant commerce clause's restrictions still apply and therefore extraterritoriality and balancing must still be addressed in turn.

B. *Extraterritoriality and the Prohibition Against Legislative Projection*

"For the most part, states may not legislate extraterritorially, whatever exactly that means."[142] This purposefully ambiguous statement, according to Professor Donald Regan, defines the principle of extraterritoriality.[143] The opaque gloss of Regan's definition perhaps most vividly reflects the confusion both in the constitutional grounding of the principle and its line of jurisprudence.[144] Nonetheless, the Supreme Court has considered extraterritoriality a subject of dormant

138. 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 *11 (D. Me. Oct. 26, 2000).

139. Pharm. Research & Mfrs. of Am v. Concannon, 249 F.3d 66, 80 (1st Cir. 2001).

140. *Commissioner*, 2000 U.S. Dist. LEXIS 17363, at *11.

141. In fact, Maine looked into becoming a bulk purchaser of pharmaceuticals, but decided against it presumably due to budgetary constraints. *See* OFFICE OF POLICY AND LEGAL ANALYSIS, FINAL REPORT OF THE COMM'N TO STUDY BULK PURCHASING FOR PRESCRIPTION DRUGS AND MEDICAL SUPPLIES TO THE JOINT STANDING COMM. ON HEALTH AND HUMAN SERVICES, 199th Leg. 1st Sess., at 3, 19 (Me. 1999); Whitney M. Phelps, Comment, *Maine's Prescription Drug Plan, A Look into The Controversy*, 65 ALB. L. REV. 243, 260 (2001). Thus, Maine's consideration of bulk purchasing is telling insofar as it demonstrates the conscious decision of the state to forgo participation in favor of regulation.

142. Donald H. Regan, *Siamese Essays: (I)* CTS Corp. v. Dynamics Corp. of America *and Dormant Commerce Clause Doctrine; (II) Extraterritorial State Legislation*, 85 MICH. L. REV. 1865, 1896 (1987) [hereinafter Regan, *Siamese Essays*].

143. *Id.*

144. The confusion abounds: whether or not extraterritoriality is a subject of Commerce Clause jurisprudence, *see* Regan, *supra* note 42, at 1280; Regan, *Siamese Essays*, *supra* note 142, at 1894, whether or not balancing and extraterritoriality are mutually exclusive, *see* Edgar v. MITE Corp., 457 U.S. 624, 640-46 (1982); *supra* note 44 (listing cases), and whether or not extraterritoriality is grounded in due process, *see, e.g.*, Robert H. Abrams & Paul R. Dimond, *Toward a Constitutional Framework for the Control of Court Jurisdiction*, 69 MINN. L. REV. 75, 76-83 (1984).

commerce clause jurisprudence[145] and has declared that a state may not regulate commerce "that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State."[146] Thus, if a state projects its own legislation onto the regulatory schemes of other states, the statute is extraterritorial and per se unconstitutional.[147]

The principle of extraterritoriality comes to the forefront in the issue of state prior authorization statutes. PhRMA argued and lost its extraterritorial challenge to the Maine Program before the First Circuit.[148] Under closer inspection of the First Circuit's analysis, however, the court misapplied the principles of extraterritorialism. This Section critically examines the First Circuit's opinion and concludes that the Maine Program is unconstitutional under an extraterritorial Commerce Clause query. This Section begins by advancing the principal argument that the Maine Program impermissibly regulates conduct between pharmaceutical manufacturers and out-of-state wholesalers. Once the foundational argument is established, this Section then recognizes three justifications for upholding the Maine Program on extraterritorial grounds and in turn refutes each of these justifications as being a misapplication of constitutional principles.

The state prior authorization statutes are unconstitutionally extraterritorial because they regulate transactions that occur between out-of-state manufacturers and out-of-state wholesalers. The state of Maine houses no drug manufacturers.[149] Similarly, the vast majority of wholesalers — with only three exceptions — are located out-of-state.[150] The Maine Program, by "forcing" rebates upon manufacturers through the threat of prior authorization, in effect regulates the prices that these complying manufacturers charge their out-of-state whole-

145. *See* CTS Corp. v. Dynamics Corp. of Am., 481 U.S. 69, 86-88 (1987). *But see* Regan, *supra* note 42, at 1280 (arguing that the extraterritorial principle is not a Commerce Clause principle).

146. *Edgar*, 457 U.S. at 642-43.

147. ALA v. Pataki, 969 F. Supp. 160, 174 (1997) (stating that a state cannot enact "legislation that has the practical effect of exporting that state's domestic policies").

148. Pharm. Research & Mfrs. of Am v. Concannon, 249 F.3d 66, 82 (1st Cir. 2001) ("Because the regulation only applies to in-state activities, there is no extraterritorial reach and the Act is not per se invalid under the Commerce Clause.").

149. 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 *13 (D. Me. Oct. 26, 2000).

150. *Id.* at *5-6. ("There are limited exceptions. Hannaford Bros. Co., located in Maine, buys directly from Roxane Laboratories, Inc. and Boehringer Ingleheim Pharmaceuticals, Inc.; Bindley Western Drug Company, a distributor, has a subsidiary, J.E. Goold, that is located in Maine; and Progressive Distributors, Inc., another distributor, has a facility in Maine . . . . Under the contracts with these companies, however, the sale from the manufacturer always occurs at the place of business outside Maine — with the exception of Hannaford Bros. Co. In other words, Bindley Western and Progressive Distributors go to other states to buy their products, then import them into Maine.").

sale buyers.[151] As the District Court declared, "Maine may have power over what pharmacists later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the prices paid earlier in transactions in other states."[152] The "practical effect"[153] of the rebate is clear: manufacturers must sell their drugs at lower prices to wholesalers in order for those wholesalers to sell the prescription drugs in Maine at the rebated price level.[154] Because these wholesalers and manufacturers all reside outside of Maine's borders, the Maine Program is entirely extraterritorial in its reach and therefore unconstitutional.[155]

Three major counter-arguments, however, can be raised in an attempt to uphold the statute on extraterritorial grounds. First, the Maine Program constitutionally regulates extraterritorial conduct because it does so by indirect means. Second, one can distinguish the primary extraterritorial cases as dealing with price control statutes, whereas the Maine Program is not a price control. Third, the rebate agreement in the Maine Program is voluntary and therefore the manufacturers are free to not participate and not be bound extraterritoriarally. The First Circuit upheld the statute on extraterritorial grounds under these three justifications.[156] Although all valid arguments, they are ultimately unpersuasive and will be refuted in turn.

First, the First Circuit argued that an indirect regulation of out-of-state transactions does not violate the constitutional principle of extraterritoriality. The First Circuit upheld the Maine Program because the Maine Program regulated out-of-state transactions in an indirect manner. The court stated: "[T]he Maine Act does not impose direct con-

151. *Concannon*, 249 F.3d at 78 ("[T]he prior authorization requirement is the 'hammer' or 'force' that coerces manufacturers to enter into the Program . . . .").

152. *Commissioner*, 2000 U.S. Dist. LEXIS 17363, at *14.

153. Healy v. Beer Inst., 491 U.S. 324, 332 (1989) (stating that a "state law that has the 'practical effect' of regulating commerce occurring wholly outside that State's borders is invalid under the Commerce Clause").

154. This practical effect becomes more apparent given the fact that the rebate prices are below the pre-rebate wholesale prices, and thus manufacturers necessarily lose profits due to the adjustment of wholesale prices. *See infra* note 172 and accompanying text (discussing Maine's coercive tactics leading to lost profits).

155. The extraterritorial reach of the statute only applies to those transactions between out-of-state manufacturers and out-of-state wholesalers. Therefore, Maine still can constitutionally regulate the limited number of transactions that involve one or more of the state's few wholesalers. Of course, Part I of this Note argues that such regulations would be invalidated on preemption grounds.

If Maine had any in-state manufacturers, the analysis potentially becomes a bit more complex. The physical location of the transaction — whether the sale occurred in the state of Maine or out-of-state — would determine constitutionality under the dormant commerce clause. The complexity arises in determining the exact location of transaction. *See* CTS Corp. v. Dynamics Corp. of Am., 481 U.S. 69 (1987); Regan, *Siamese Essays*, *supra* note 142, at 1874.

156. *Concannon*, 249 F.3d at 81-82.

trols on a transaction that occurs wholly out-of-state."[157] The direct/indirect rule states that a direct regulation is generally held to be per se unconstitutional whereas an indirect regulation is subject to a lower level of scrutiny via a balancing test.[158] Because the Maine Program only regulates the out-of-state transactions between manufacturers and wholesalers indirectly via the rebate provision, the law is not per se invalid. Although this probably was the First Circuit's strongest ground for upholding the statute, two arguments refute the primacy of the indirect/direct distinction.

Indirectness is not dispositive of extraterritorial scrutiny as it is only one of three major principles that govern extraterritorial analysis.[159] Only the second principle — "a statute that directly controls commerce occurring wholly outside the boundaries of a State . . . is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature"[160] — makes reference to a direct control. The second principle also seems mostly to address motive review and the fact that a direct control would be subject to strict scrutiny even if legislative motive was pure. Furthermore, the first principle dealing with price scales (and not mentioning directness) seems most relevant to the Maine rebate statute at hand. Directness maintains a small place in the jurisprudence, but its primacy over the other principles and its use as a criterion for heightened scrutiny is unclear.[161] From the explication of the other principles making no reference to directness, the inference is drawn that the strict scrutiny of extraterritorially does not depend upon the directness of the regulation, and alternative grounds exist to justify an indirect regulation.

Additionally, any direct/indirect test is mechanical and often results in inconsequential and arbitrary results.[162] The key in extraterri-

157. *Id.* at 82.

158. Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573, 579 (1986).

159. As the Court in *Healy* posited, the extraterritorial cases stand for three principles: "First, the Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside the State's borders . . . specifically, a State may not adopt legislation that has the practical effect of establishing a scale of prices for use in other states . . . . Second, a statute that directly controls commerce occurring wholly outside the boundaries of a State . . . is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature . . . . Third, the practical effect of the statute must be evaluated . . . by considering how the challenged statute may interact with the regulatory regimes of other States . . . ." Healy v. Beer Inst., 491 U.S. 324, 336 (1989) (internal citations omitted).

160. *Id.*

161. *See* Daniel M. Forman, Comment, *The Dormant Commerce Clause and the Massachusetts Landfill Moratorium: Are National Market Principles Adequately Served?*, 24 B.C. ENVTL. AFF. L. REV. 425, 435 (1997).

162. Mark P. Gergen, *Territoriality and the Perils of Formalism*, 86 MICH. L. REV. 1735, 1737-38 (1988).

torial cases is the fact that the state is projecting its regulatory scheme onto transactions outside of its boundaries. The direct/indirect distinction misses the point. In the case of the Maine Program, Maine does not deny that the practical effect of the statute is to reduce the prices of the drugs that out-of-state manufacturers sell to out-of-state distributors. The means of doing this — whether through direct regulation of that transaction or through an indirect rebate affecting the eventual prices of the Medicaid drugs sold in Maine — are irrelevant. The means are irrelevant because the state will reach its end regardless of the directness of the means.[163] In fact, subverting principles of state interest for a mechanical directness test may undermine the very ideals of state sovereignty that extraterritorialism seeks to protect.[164] The bottom line of extraterritorialism is not directness, but practical effects. As the Supreme Court has reasoned, "the critical consideration in determining whether the extraterritorial reach of a statute violates the Commerce Clause is the overall effect of the statute on both local and interstate commerce."[165] The effects of a statute on state sovereignty and national economy[166] must have primacy over the mechanics and perversities of directness.

The second major justification for upholding the Maine Program is that the case law governing extraterritoriality deals with the impermissibility of price controls and price affirmations.[167] The First Circuit justified the statute by distinguishing the three cases that PhRMA relied upon[168] as being cases about price affirmation and control and therefore unrelated to the Maine statute which "does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect."[169] As opposed to the price control cases, Maine does not fix the prices of goods sold out-of-state and therefore does not affect the commerce of its sister states.[170]

The problem with the First Circuit's treatment of the cases cited by PhRMA is that the distinction that the court drew is irrelevant. The First Circuit stressed that the Maine Program does not regulate the

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163. *Id.* at 1737.

164. *Id.* at 1740.

165. Healy v. Beer Inst., 491 U.S. 324, 337 n.14 (1989).

166. *Id.* at 335-36 (recognizing the special concerns governing extraterritoriality of national economic union and state autonomy).

167. For an excellent discussion of the economics of price controls, see JOHN KENNETH GALBRAITH, A THEORY OF PRICE CONTROL (1980).

168. PhRMA relied upon *Healy*, 491 U.S. at 324, *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573 (1986), and *Baldwin v. G.A.F. Seelig*, 294 U.S. 511 (1935).

169. Pharm. Research & Mfrs. of Am v. Concannon, 249 F.3d 66, 81 (1st Cir. 2001).

170. *See* Phelps, *supra* note 141, at 265.

sale of drugs by manufacturers to wholesalers at a certain price.[171] The crux of the argument is that in the case of explicit price affirmation and price controls, prices are pre-determined either at a fixed amount or against a fixed benchmark. This is not the case with regard to the Maine Program. Nonetheless, the First Circuit never elaborated why such a distinction is relevant, or why the price needs to be benchmarked to a specific price in order to be extraterritorial.

In fact, the Maine rebate operates exactly as a price control. For example, if a manufacturer agrees to rebate its drug by ten percent, the inevitable effect is a ten percent reduction in the price paid to the manufacturer by the out-of-state wholesaler given the reasonable assumption that the wholesaler wants to maintain its profit margin.[172] The First Circuit noted that the Maine law, unlike the affirmation and control statutes, does not tie the price of its in-state products to out-of-state prices.[173] But that is exactly what the statute does — it makes out-of-state prices dependent on the in-state rebated sales. The First Circuit began its analysis by stating that the Maine Program does not regulate prices "either by its express terms or by its inevitable effect."[174] Yet the court glossed over the fact that the Maine Program, in effect, is a price control. Thus, its treatment of the price affirmation and control cases vis-à-vis the Maine Program was misguided.

The third major justification for upholding the statute deals with the voluntary and non-mutual nature of the rebate agreement. The First Circuit disposed of the extraterritorial challenge on the grounds that the rebate agreement is voluntary and a decision to be bound by it is made freely by the manufacturer.[175] The court went on to note that a manufacturer's choice to engage in the rebates and lose profits is not an extraterritorial regulation of profits, but rather a decision made by the manufacturer itself.[176] The court did, however, recognize that the manufacturer's freedom of choice may become coercive depending upon the negotiation tactics used by the commissioner in extracting

171. *Concannon*, 249 F.3d at 81-82.

172. In other words, regulation of the final price in the sale by the wholesaler to the retailer/recipients (a rebate under the Maine Program) will affect the price in the prior transaction between manufacturer and wholesaler given the assumption that the wholesaler seeks to maintain present profit margin. In this way there is a relationship between both transactions. *See generally* RONALD S. BURT, CORPORATE PROFITS AND COOPTATION: NETWORKS OF MARKET CONSTRAINTS AND DIRECTORATE TIES IN THE AMERICAN ECONOMY 9 (1983) (describing the relational patterns and interdependencies of transactions and pricing in the market).

173. *Concannon*, 249 F.3d at 82.

174. *Id.* at 81.

175. *Id.* at 82 ("The rebate program is voluntary and either the manufacturer or the State may withdraw at any time with sixty days' notice.").

176. *Id.*

rebates and therefore the issue could be revisited subsequent to implementation.[177]

This "voluntary rationale" once again is a misapplication of constitutional principle. Whether the choice to be bound to the statute is entirely voluntary is not of consequence in assessing extraterritoriality. The freedom of choice or lack thereof to be bound by extraterritorial legislation does not in itself provide independent grounds for the conferral of extraterritorial jurisdiction.[178] Thus, something is impermissibly extraterritorial regardless of the mutuality of the party of concern.[179] The First Circuit failed to realize this point.[180]

In addition, the First Circuit's voluntary rationale — specifically its language concerning the voluntary aspects of a manufacturer's decision to forgo profits — is both overly formalistic and arbitrary. First, the court stated that the Maine law in no way regulated profits and that such a decision was strictly based on the manufacturer's own volition.[181] This argument is overly formalistic in that it fails to take into account the effect of the rebate — the reduction of the manufacturer's profit margin. The court, in this same vein of formalism, attempted to justify its position by stating that the statutory language calls for "negotiating rebates" and not "regulating prices."[182] The statute does in fact regulate profits, but it does so indirectly through the mechanism of the rebate.

Second, the court's discussion of the regulation of profits reflects an arbitrariness and a possible prejudice that drives the entire opinion.

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177. *Id.*

178. Regan, *Siamese Essays*, *supra* note 142, at 1903. Professor Regan's discussion of *Brown-Forman* is instructive. *Id.* In *Brown-Forman*, the distiller cooperated in the creation of the New York law to be bound extraterritorially and affirm a set price as a *quid pro quo* for being able to do business in New York. Brown-Forman Distillers Corp. v. New York State Liquor Authority, 476 U.S. 573, 575-76 (1986). The distiller, much like the drug manufacturer in the present instance, remained "free" to abide by the price cap or simply to do no business in New York. Regan, *Siamese Essays*, *supra* note 142, at 1903. Regan compares *Brown-Forman* to the hypothetical of "Jones," an Illinois resident, who irrationally swears out an affidavit to be bound extraterritorially by Georgia's sodomy law; commits sodomy in Illinois in violation of the Georgia law; and then travels to Georgia. *Id.* at 1904. Georgia would not be able to prosecute Jones for something he did in Illinois. *Id.* Regan, comparing "Jones" and *Brown-Forman*, reaches the quite logical conclusion that "[i]f a free undertaking to be bound by extraterritorial legislation, whether by Jones or by a distiller, does not confer extraterritorial jurisdiction, then it seems even clearer that the distiller's actual affirmation, which was to some degree compelled by the New York licensing agreements, should not grant extraterritorial jurisdiction." *Id.*

179. Presumably this would also render the First Circuit's concern for coercion by the state commissioner moot. If a law is extraterritorial regardless of the free choice of the challenging party, then the presence or absence of coercive tactics in no way changes the fact of its extraterritoriality.

180. Pharm. Research & Mfrs. of Am v. Concannon, 249 F.3d 66, 82 (1st Cir. 2001).

181. *Id.*

182. *Id.*

The court noted that the Commissioner's negotiation may become coercive, and at that point in time, a challenge should be brought.[183] Yet the court never addressed exactly at what point in time negotiation would equal coercion. The court's failure to set an objective standard of fairness to measure the level of coercion is potential for an arbitrary normative judgment.

The First Circuit's analysis in its totality perhaps reflects that such a standard of fairness will be biased against the pharmaceutical manufacturers.[184] The court initially glossed over the "inevitable effect" principle of the extraterritorial inquiry most likely because it considered a loss of profits as being a voluntary action completely unrelated to the rebates.[185] The court then created a formalistic and counterintuitive distinction between "negotiating rebates" and "regulating profits."[186] Finally, the court declared that, at the nebulous point of coercion, the issue of extraterritoriality may be reconsidered again; yet, the court never articulated what constitutes such a breaking point.[187] These aspects of the opinion taken together lead to the inference of a possible prejudice that the court may have held against pharmaceutical companies and the perception that such companies make excessive and unwarranted profits.

The Maine Program extraterritorially projects its regulation onto out-of-state transactions. Such a practice runs afoul of fundamental dormant commerce clause values. The First Circuit attempted to validate the statute in light of its apparent deficiency by distinguishing away the relevant price control cases, focusing upon the voluntariness of the statute, and utilizing the indirectness of the regulation as its savings clause. The First Circuit's analysis, however, was misguided. The statute is extraterritorial and per se unconstitutional.

C. *Medicaid in the Balance: An Examination of Burdens and Benefits*

The present dormant commerce clause inquiry should begin and end with extraterritoriality. Nevertheless, for the unpersuaded court that upholds the prior authorization statutes under an extraterritoriality analysis, a lower level of scrutiny will still suffice to demonstrate a

183. *Id.*

184. The First Circuit's prejudice becomes even more apparent in the context of its balancing test analysis. *See infra* notes 237-254 and accompanying text.

185. Pharm. Research & Mfrs. of Am v. Concannon, 249 F.3d 66, 82 (1st Cir. 2001).

186. *Id.*

187. *See id.*

Commerce Clause violation in the present case.[188] Traditionally, a court refusing an extraterritorial challenge applies a balancing test to the statute at hand.[189] Under the balancing test, the statute will be upheld "unless the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits."[190] In the present case, even under the lower level of scrutiny of the balancing test, the state statutes impose burdens on commerce that outweigh their benefits and are therefore unconstitutional. By first evaluating the perceived benefits of lower prescription drug prices for Medicaid recipients, such benefits become exposed as de minimus. Moreover, understanding that courts must weigh in the balance the loss of profits incurred by pharmaceutical manufacturers imposes a significant burden on interstate commerce. Finally, under a *Carolene Products* analysis,[191] the balance must tip in favor of PhRMA because of its potential characterization as a group discriminated against in the political process.

The benefit of lower prices to Medicaid recipients through the supplemental state rebates is small and should be given little weight in the balance. The First Circuit considered lower prices of prescription drugs and the consequent increased access to prescription drugs by the poor a "substantial" benefit.[192] Two primary reasons cut against the value of lower prices as a putative local benefit. First, prescription drugs account for only ten percent of Medicaid spending.[193] Thus, targeting prescription drugs really will not provide substantial benefits relative to Medicaid spending in total.[194] The degree of the benefit is

188. Because state prior authorization statutes clearly do not discriminate facially against out-of-staters, a balancing test, rather than strict scrutiny, applies. *See Concannon*, 249 F.3d at 83; Phelps, *supra* note 141, at 262.

189. Pike v. Bruce Church, 397 U.S. 137, 142 (1970).

190. *Id.* The language "clearly excessive" implies more than a mere mathematical formula, but rather a legal standard conditional on degree. *See id.* ("If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.").

191. United States v. Carolene Prods. Co., 304 U.S. 144 (1938).

192. *Concannon*, 249 F.3d at 84.

193. *Regional Report*, WALL ST. J., Feb. 13, 2002, *available at* 2002 WL-WSJ 3385796.

194. Jonathan L. Mezrich, *International Tax Issues of the U.S. Pharmaceutical Industry*, 10 AKRON TAX J. 127, 135 n.29 (1993) ("Curiously, many Congressmen fail to appreciate the relative insignificance of pharmaceuticals to health care costs . . . .While a 10% cost (if accurate) is a little more significant, it is still a small puddle in the pond."). It should be noted that, although only ten percent of Medicaid spending, pharmaceutical costs still account for a considerable amount of money. *See Regional Report, supra* note 193 ("Collectively states spent $21 billion on drugs in the outpatient and managed-care portions of their Medicaid programs [in 2000]."). Yet, to reiterate, $21 billion is but a small puddle in the pond of a program with gigantic total expenditures. *See* Leighton Ku & Jocelyn Guyer, *Medicaid Spending: Rising Again, But Not to Crisis Levels*, Apr. 20, 2001, *at* http://www.cbpp.org ("Estimates

small if one examines the small place of prescription drugs in the gigantic landscape of Medicaid.

Second, the benefits of lower prices for the poor in the short-run may be a burden to these recipients and to consumers at large in the long-run. The current federal rebate program is structured to make sure manufacturers sell their Medicaid drugs at a minimum of 15.1% off of the manufacturer's average price — with many of the discounts exceeding the 15.1% level.[195] This ensures that the manufacturers are not overcharging, but rather selling at below-market prices.[196] Working under this assumption that drug companies are selling their products to Medicaid recipients at below-market levels already, by further increasing that discount via state supplemental rebates, drug companies will have greater incentive to both decrease sales[197] to Medicaid recipients and slow research and development of life-saving pipeline drugs.[198] Thus, the price benefit to Medicaid recipients today may prevent them from obtaining the necessary medications of tomorrow. In this light, the substantial benefit of lower drug prices loses its value.

Proponents of state statutes like the Maine's contend that lower prices will be off-set by volume increases and thus the effects on research and development are exaggerated and illusory. As a Merrill

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that CBO issued in 1993 projected that the federal government and the states together would spend $1.6 trillion on Medicaid from 1994 to 2000.").

195. Statement of Eli Lilly Spokesperson Gerianne Hap, Aug. 8, 2001 (on file with author); *see also*, 42 U.S.C.A. § 1396r-8(c) (West 2000).

196. Pharm. Research & Mfgs. of Am. v. Thompson, 251 F.3d 219, 225 (D.C. Cir. 2001) (indicating that the rationale for the federal rebate is one of cost-reduction and the prevention of above-market prices charged by manufacturers).

197. A reduction in pharmaceutical sales has a wide-spread adverse effect on both government health care costs as well as costs to consumers. *See* Mitchell E. Daniels, Jr., *Perspective on Pharmaceuticals: A Health-Care Scapegoat Responds; Blaming Drug Companies For All Our Ills Harms Research and Ignores the Cost-effectiveness of the Industry*, L.A. TIMES, Mar. 9, 1993, at B7; Mezrich, *supra* note 194, at 135 n.30 (quoting Gerald J. Mossinghoff, *Pharmaceutical Manufacturers Association President Testifies on International Competitiveness*, TAX ANALYSTS TAX NOTES INT'L, July 24, 1991) ("Medicines not only save lives — they save money. Medicines are the most cost-effective form of medical therapy because they help to reduce the cost of alternative, more expensive forms of medical care, such as surgery or hospitalization."); Mezrich, *supra* note 194, at 135 ("[H]igh pharmaceutical costs still actually save money, because a good medicine tends to keep patients out of hospitals or eliminate the need for surgery or other therapies which may cost much more than even the most expensive drug.").

198. *See* John E. Calfee, *Why Pharmaceutical Price Controls Are Bad for Patients*, AMERICAN ENTERPRISE INSTITUTE: ON THE ISSUES, Mar. 1999, *available at* http://www.aei.org/oti/oti10198.htm ("But prices reflect other costs as well, in particular, the costs of research and advertising. Fixing prices at lower levels would inevitably curtail development and distribution of new products that improve and extend life."); Peter Ferrera, *Poor Prescriptions for Health Prospects*, WASH. TIMES, Aug. 29, 2002, at A20, *available at* 2002 WL 2916888 (noting that price controls and other market interventions delay research and limit access to new drugs and therapies); Leigh Page, *Maine Poised to Set Nation's First Price Controls on Drugs*, Amednews.com, May 8, 2000, *at* http://www.ama-assn.org/sci-pubs/amnews/pick_00/bisc0508.html ("Many doctors worry that clamping down on drug prices will cut back on funding for pharmaceutical research and development . . . .").

Lynch report indicated, "Volume increases could overwhelm negative pricing impact . . . . On a worst-case basis we believe the top-line impact could be negative 6 percent if all Medicare recipients had access to drugs at a 40 percent discount to the manufacturer's price."[199] At only a negative six percent clip, drug manufacturers would not have to dip into their research and development funds in order to finance rebated sales.[200]

This argument, although reassuring in part, fails to recognize that the drug industry is a risky, long-term business. Volume increases on existing drugs may keep the industry alive, but continuous annual loss projections must be accounted for now and affect the development of drugs that could potentially reach market years from now.[201] By limiting profits of the successful drugs, research and development will necessarily decline.[202] The limitation by state rebate statutes, of course, is added to the already 15.1% minimum federal rebate to create an unmanageable obstacle to research and development.[203] One health care

199. Derrick Z. Jackson, *Drug Price Cuts Won't Kill Industry*, BOSTON GLOBE, Sept. 22, 2000, *available at* http://www.commondreams.org/views/092300-101.htm (quoting Merril Lynch Report, June 23, 1999); *see also* Jerry Stanton, Comment, *Lessons for the United States From Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 151-152 (2000) ("[T]he question remains whether Congress should impose those price controls. Consumers would enjoy the immediate benefit of reduced prices while pharmaceutical firms would suffer similar reduced profit margins, although sales volume may increase.").

200. *See* Jackson, *supra* note 199.

201. C. Daniel Mullins et al., *The Impact of Pipeline Drugs on Pharmaceutical Spending*, CENTER ON DRUGS AND PUBLIC POLICY, U. MD. SCHOOL OF PHARMACY, Apr. 13-14, 2000, *at* http://membership.hiaa.org/pdfs/drugsymposium.pdf (noting that consideration of pipeline drugs is imperative for understanding and projecting future drug trends and pricing).

202. JAMES FROGUE, THE HERITAGE FOUNDATION, WHY PRICE CONTROLS ON PRESCRIPTION DRUGS WOULD HARM SENIORS, Executive Memorandum, May 14, 1999, *available at* http://www.heritage.org/library/execmemo/em595.html; HENRY GRABOWSKI, HEALTH REFORM AND PHARMACEUTICAL INNOVATION 19 (1994) (noting that research is funded by profits from current sales of those drugs already in the marketplace); Julio Nogues, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries*, 502 World Bank WPS Paper 18 (Sept. 1990) (indicating that in the United States the pharmaceutical industry invests between 16% and 20.8% of its revenue in research and development); *Pharmaceutical Industry Profile* (Phrma), *at* http://www.phrma.org/publications/industry/pro-file00/chap8nf.html (last visited Sept. 13, 2000) (same); *see also* Elisabeth Rosenthal, *Research, Promotion and Profits: Spotlight is on the Drug Industry*, N.Y. TIMES, Feb. 21, 1993, at 1 ("Drug companies undertake these massive searches knowing there will be a big payoff if they hit a winner. . . . We can have lower drug prices if we accept less of that searching. That's the choice we face.").

203. The obstacle is unmanageable in spite of claims that pharmaceutical profits are excessive and can thus overcome price control. *See* Michael B. Moore, *"Open Wide" (Your Pocketbook That Is!) — A Call For The Establishment In The United States Of A Prescription Drug Price Regulatory Agency*, 1 S.W. J. L. & TRADE AM. 149, 149 n.2 (1994) (citing EARNING A FAILING GRADE: A REPORT CARD ON 1992 DRUG MANUFACTURER PRICE INFLATION, STAFF OF SENATE SPECIAL COMMITTEE ON AGING, 103rd Cong., 1st Sess., at 3 (Comm. Print 1993)). In fact, due to the large fixed sunk costs incurred by pharmaceutical manufacturers, their profits are by no means excessive. One commentator analyzed the pharmaceutical industry's profitability relative to the industry's fixed costs and found quite

policy analyst, in discussing a comparable price rebate scheme for Medicare,[204] characterized the nature of the drug industry and the effect of such a rebate as follows:

> Pharmaceutical research is a very risky business. A number of independent studies have found that between 5,000 and 10,000 compounds are tried on average for every 1 that makes it into a neighborhood pharmacy. And that one may be for a very tiny niche market. The incentive to engage in such intense research and development is the potential for large profits on the few drugs that are successful. If the government limited profits on the successes, then there would be fewer resources devoted to research and development. This would translate into a reduced likelihood that tomorrow's cures will be developed. Last year, U.S. pharmaceutical manufacturers invested $24 billion of their revenues to research new drugs. Jeopardizing such massive expenditures in the search for new medications quite literally would threaten the health of America's seniors.[205]

The argument that present-day volume increases mitigate price impact does not fully take into account the long-term and risk-based nature of the drug industry. Any excessive price impact — no matter how seemingly minimal — must be founded on an understanding of

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the opposite: the industry's profitability is within 1% of its real cost of capital. Stanton, *supra* note 199, at 156 ("The common denominator by which to compare profit levels among disparate industries is to measure their internal rate of return (IRR). In a study comparing internal rates of return from 1959 to 1973 among major industries, pharmaceuticals averaged 12.9% IRR, while chemicals averaged 9.1%, petroleum averaged 10.8%, and the average across all industries was 9.6%. More contemporary analyses have been done on the pharmaceutical industry alone, finding an IRR of 11.1% against the industry's average real cost of capital of 10.5%. Thus the pharmaceutical industry's profitability is within 1% of its real cost of capital, clearly not an excessive level of profitability."). Thus, a supplemental state rebate compounded with the federal rebate will hinder research and development insofar as high profitability cannot cover those losses.

204. *See* Gail B. Agrawal, *Resuscitating Professionalism: Self-Regulation in the Medical Marketplace*, 66 MO. L. REV. 341, 346 (2001) ("In 1965, the federal government created the Medicare program to provide public insurance to individuals from the age of sixty-five and to those with certain disabilities, and joined with the states under the auspices of the Medicaid program to extend health care coverage to those considered categorically or medically needy.").

205. FROGUE, *supra* note 202; *see also* Henry G. Grabowski & John M. Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 J. HEALTH ECON. 383 (1994) (finding in their 1994 study that between 1980 and 1984, only 30% of pharmaceuticals generated returns higher than their average after-tax research and development expenditures, and that the 20% of products with the highest revenues generated only 70% of returns during the study time period.); F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 106 (1993) (finding in his study that 55% of industry profits came from only 10% of pharmaceuticals); Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical* Industry, 26 BROOK. J. INT'L L. 363, 373-74 (2000) ("Thus, given the high costs and risks associated with drug research, companies must rely on a limited number of highly successful products to finance their continuing R&D.").

the long-term projections[206] that manufacturers make and the potentially resultant billion dollar decreases in research and development that could ensue.[207] This is a detriment to the consumer, to society in general, and to the Medicaid recipient which militates against the value of lower prices. Lower prices may be a benefit to Medicaid recipients at first glance. The benefit, however, is severely undermined by taking note of prescription drugs' small role in Medicaid vis-à-vis the long-term repercussions on research and development.[208] In this light, the benefit must therefore be tempered when weighing it against the burdens on interstate commerce.

In relation to the small benefits behind the statute, the burdens on interstate commerce are significant. The most significant burden on interstate commerce by the state prior authorization statutes is the economic devastation in the form of lost profits to manufacturers.[209] Consequently, any balancing test must take into account the profits that manufacturers will lose due to the state regulation because of the burdensome effects of such losses on the interstate prescription drug market. The First Circuit in balancing the effects of the Maine statute, however, refused to place these lost profits in the balance.[210] The First Circuit justified its refusal by citing to the Third Circuit case of *Ford Motor Company v. Insurance Commissioner*[211] as standing for the proposition that "devastating economic consequences on a particular interstate firm is not sufficient to rise to a Commerce Clause burden."[212] Although a valid justification, after a closer reading of *Ford*

206. Pharmaceutical Research & Mfrs. Ass'n of America, *Why Are Patents So Crucial?*, *at* http://innovation.phrma.org (last visited Aug. 23, 2002) ("[I]t often takes more than 15 years and more than $500 million to bring a new medicine to consumers.").

207. *See* Daniels, *supra* note 197, at B7 ("Drug research is probably the riskiest economic venture we know; only one of 5,000 possibilities researched ever becomes a marketed product."); *see also* Mezrich, *supra* note 194, at 136 n.37 (noting the "inherent risk and expense of R&D" and recounting the real possibility of a U.S. pharmaceutical corporation "expending billions on R&D [and failing] to recoup their investment and end[ing] up bankrupt").

208. *See supra* notes 193-207 and accompanying text.

209. Pharm. Research & Mfrs. of Am v. Concannon, 249 F.3d 66, 84 (1st Cir. 2001) (discussing the effect of lost profits on interstate commerce).

210. *Id.*

211. 874 F.2d 926 (3rd Cir. 1989).

212. *Concannon*, 249 F.3d at 84 (internal quotations omitted). In addition, the First Circuit noted the difficulty of weighing the *possible* effects — including the potential loss of profits — instead of the *actual* effects of the statute. This seems to be more of a criticism of the use of a balancing test in general rather than a separate justification for the court's failure to consider lost profits (actual or possible). The court's recognition of the difficulties in foreseeing the future is understandable. Nonetheless, the court's task requires such a prognosticative role under the balancing test employed in dormant commerce clause jurisprudence for effects are not always visible and quantifiable upon first inspection. In any event, this Note treats the First Circuit's complaint as separate from its refusal to balance lost profits and therefore does not consider it in the discussion of devastating economic consequences. For a general criticism of balancing, see Regan, *supra* note 42.

Motor, the Third Circuit's rule does not apply in the present case for two reasons.

First, *Ford Motor* invalidated the use of lost profits in the balance because of the plaintiffs' impure motives in that case — an impurity missing in the state prior authorization statutes. The Third Circuit stated that the plaintiff companies[213] in that case could not "hope to invoke the Constitution at every turn to circumvent state regulation and insure unrestricted expansion and protection of their opportunity to obtain the greatest margin of profit."[214] The court, in effect, utilized a type of motive review[215] and saw evidence of greedy corporate plaintiffs who were seeking to break and circumvent the law for their own gain.[216] Consequently, this sort of "unclean hands" analysis must be seen as driving the Third Circuit's rationale in excluding profits.[217]

Regardless of the validity of such analysis, in the case of state prior authorization laws, manufacturers do not have this same impure motive. The manufacturers already rebate their drugs below market-level pursuant to the federal rebate provisions.[218] Furthermore, as aforementioned, the federal rebate program started on the manufacturers'

213. The two plaintiffs were Ford Motor Company and United States Automobile Association. Each plaintiff had a wholly independent and separate case, but the cases were consolidated on appeal because of the factual and legal commonalities. *Ford Motor Co.*, 874 F.2d at 929.

214. *Id.* at 944.

215. This should not be confused with the traditional meaning of motive review — a review of the legislative motives behind the passage of legislation — which is quite coincidentally employed frequently in assessing dormant commerce clause cases. *See* Regan, *supra* note 42, at 1143-1160; *see, e.g.*, Lochner v. New York, 198 U.S. 45 (1905); Wilson v. Black Bird Creek Marsh Co., 27 U.S. (2 Pet.) 245 (1829); McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316 (1819). Motive review in the present context is more akin to an unclean hands analysis — an examination of the *party's* actions and motives.

216. Plaintiffs were holding companies who acquired numerous savings and loan companies and their subsidiaries. Plaintiffs already owned various subsidiaries that were in the business of selling insurance. Through the expansion of their corporate endeavors into the realm of savings and loans, plaintiffs — with malice aforethought — were in clear violation of a Pennsylvania statute prohibiting savings and loan companies from providing insurance in that state. *Ford Motor Co.*, 874 F.2d at 929-31. Thus, from the facts of the case, the court may have inferred that plaintiffs' widespread expansion, with the knowledge that such expansion would place them in violation of Pennsylvania law, was an attempt to have their cake and eat it too.

217. In fact, the Third Circuit began its analysis with a caveat that rather than drawing attention away from the normative judgment it was making, simply placed a purposefully thin veil over what was quite apparent. The court initially cautioned: "[The plaintiffs' corporate] strategy is their own choosing and we express no value judgments concerning it." *Ford Motor Co.*, 874 F.2d at 943. Yet the court then proceeded to make those very value judgments by characterizing the companies as ones engaged in "unrestricted expansion" and seeking "the greatest margin of profit." *Id.* Whether or not the court intended to poorly mask the value judgments it later made is uncertain. Nonetheless, a close reading of *Ford Motor* reveals motive review of plaintiffs' actions.

218. 42 U.S.C.A. § 1396r-8 (West 2000).

own initiative.[219] This is strong evidence that the pharmaceutical manufacturers' motive is not entirely profit-seeking in nature. The concern manufacturers have with state rebate statutes is that they are excessive and may compromise the companies' abilities to research and to develop new drugs — the lifeline of the drug industry.[220] Because *Ford Motor* employs an "unclean hands" analysis as a criterion for disregarding lost profits, the rule of *Ford Motor* should not apply to the pharmaceutical companies whose motives in the context of Medicaid are more self-preserving than self-serving.[221]

The second distinction between *Ford Motor* and the present case is the difference between interstate insurance and interstate pharmaceutical markets. The Third Circuit relied upon *Exxon Corporation v. Governor of Maryland*[222] in its analysis of the use of lost profits.[223] The Supreme Court in *Exxon* reasoned that because the Commerce Clause protects the interstate market and not particular interstate firms from burdensome regulations, the central inquiry is into the effects upon the market.[224] This is not to say that lost profits cannot affect the interstate market and therefore gain relevancy. The Third Circuit recognized this salient point and characterized the Maryland market in *Exxon* as one rich with an availability of substitutes; if refiners withdrew from the market, other interstate refiners would easily replace them and thus the regulation would place no burden upon interstate commerce.[225] Similarly, the Third Circuit found in *Ford Motor* that if the plaintiffs decided to leave the Pennsylvania market due to a decrease in profits caused by the regulation, other interstate insurers would take their place in the Pennsylvania market, and the burden would be placed not on the interstate market, but only on the exiting firms.[226] Conversely, it follows that an absence of replacements for the

219. *See supra* notes 133-134 and accompanying text.

220. *See supra* notes 195-207 and accompanying text.

221. In examining the key differences between plaintiffs' motives in *Ford Motor* and the present case, two additional points are noteworthy. First, in *Ford Motor*, 874 F.2d at 921-31, the plaintiffs expanded their corporate endeavors into a completely new realm. *See supra* note 216. The pharmaceutical manufacturers never altered their course of dealing. Second, in *Ford Motor*, the statute was on the books and plaintiffs, with knowledge of the law, made conscious business decisions to violate the statute. *Id.* The Maine Program was enacted long after the pharmaceutical manufacturers had entered the Maine market. *See supra* note 16 and accompanying text. Thus, in the case of PhRMA, the manufacturers never engaged in the same "unrestricted expansion" (change in business) designed to "circumvent state regulation" (with prior knowledge of the state statute) that the Third Circuit abhorred and considered unclean. *See supra* notes 214-216 and accompanying text.

222. 437 U.S. 117 (1978).

223. *Ford Motor Co.*, 874 F.2d at 944.

224. *Exxon*, 437 U.S. at 127-28.

225. *Ford Motor Co.*, 874 F.2d at 944 (construing *Exxon*, 437 U.S. at 127).

226. *Id.*

exiting firms would burden interstate commerce, thereby making the lost profits — and their effects on the market — a relevant item to be balanced.

The pharmaceutical market operates with much less opportunity for substitute goods than the insurance market found in *Ford Motor*, and the lack of replacements in the pharmaceutical market thus forces a court to balance lost profits. Research-based drug manufacturers have patent protection over their innovative prescription drugs for a number of years.[227] Thus, if a manufacturer were to leave the Maine market because of Maine's rebate provision and take its drug with it, then presumably no one could replace that drug on the market due to its patent protection. Although generic manufacturers may manufacture such drugs once the patents expire,[228] generic manufacturers do not serve as adequate replacements as far as Medicaid is concerned. The most highly-sought after drugs by Medicaid recipients are the newer, cutting-edge medications — drugs presumably not yet off patent.[229] Due to patent protection,[230] the pharmaceutical market for each prescription drug not off patent is monopolistic and therefore not re-

227. *See* U.S. CONST. art I, § 8 ("The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."); 21 U.S.C.A. § 355 (West 2000); *Innovation, Intellectual Property and Patents* (2001), *at* http://www.innovation.phrma.org/policy/2001-04-29.38.pdf (last visited Aug. 23, 2002) ("*For new medicines*, the effective patent life for pharmaceuticals is actually closer to *11 or 12 years*."); *Prescription Drug Costs: Federal Regulation of the Industry* (2002), *at* http://www.bcbshealthissues.com/proactive/newsroom/release.html?id=17521 (last visited Dec. 4, 2002) (discussing the Hatch-Waxman Act, Orphan Drug Act, and other relevant patent laws).

228. *Hatch-Waxman Act: The Basics*, *at* http://innovation.phrma.org/studyguides/hwbasics.phtml (last visited Dec. 4, 2002) ("Once a brand name drug's patent expires, a copy of the brand name drug can be manufactured and marketed, so long as it meets FDA requirements.").

229. Statement of Gerianne Hap, *supra* note 195 ("While spending for prescription drugs under Medicaid has been rising, that is a result of more people using more and newer medicines . . . ."). In addition to the newer research-drugs being hot commodities, these drugs are the most expensive and consequently most targeted for rebates and other price controls. *See* Stanton, *supra* note 199, at 150 ("The segment of the pharmaceutical market most in need of price controls are those medicines under patent protection, since the patent effectively limits or at least delays competition. Thus to be effective, government price controls must target patented drugs.").

230. *See* U.S. CONST. art. I, § 8; Drug Price Competition and Patent Term Restoration Act, 21 U.S.C.A. 335 (West 2000).

placeable by other interstate firms.[231] This lack of substitution in the pharmaceutical market distinguishes it from the *Ford Motor* market.[232]

Lost profits by pharmaceutical manufacturers and those profits' effects upon the interstate market must be weighed in a dormant commerce clause balancing test. Lost profits from the state rebate laws can produce potentially devastating economic damage to the prescription drug market by forcing manufacturers out of the market and leaving no adequate replacement products.[233] Medicaid patients would be left without necessary drugs, or manufacturers would remain and sell rebated drugs at a significant loss, eating away at research and development and future drug development.[234] Both scenarios are unacceptable and reflect the significant burden of lost profits that the prior authorization statutes impose upon interstate commerce.[235] These losses represent a serious burden to interstate commerce and tip the balance against the state statutes.[236]

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231. *Quick Guide to Intellectual Property*, *at* http://innovation.phrma.org/studyguides/intellpropertyguide.phtml (last visited Dec. 4, 2002) ("Patents are the legal protection for inventions, including new medicines discovered by research-based pharmaceutical companies. A patent in the United States, as in most developed nations and many developing countries, is a grant from the government to the inventor that essentially gives him or her the exclusive right to use and sell the invention for a defined number of years. At the heart of the patent is the corresponding right to exclude others from making, using and selling the invention.").

232. This analysis is more relevant for those pharmaceuticals without therapeutic substitutes and, as aforementioned, generally inapplicable to those drugs off-patent. *See supra* notes 227-231 and accompanying text. Yet regulation — whether in the form of rebates or other price controls — could serve to undermine the competition that does exist between therapeutic substitutes/off-patent drugs and patented pharmaceuticals. *See* Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition In Pharmaceutical Markets?* 43 J. L. & ECON. 311, 312 (2000) ("Generic market shares of off-patent products are significantly higher in countries that permit (relatively) free pricing, such as the United States, the United Kingdom, and Germany, than in countries with strict price or reimbursement regulation, such as France, Italy, and Japan.").

233. *See supra* notes 227-232 and accompanying text.

234. *See supra* notes 201-207 and accompanying text.

235. In fact, the first scenario — Medicaid patients left without necessary drugs — is already a reality. In response to the Michigan prior authorization statute, six of the world's largest drug companies entered into a collusive boycott by refusing to rebate their drugs under the Michigan statute. Gold et al., *supra* note 11 (reporting that the six boycotting companies are "Eli Lilly & Co., Indianapolis; Johnson & Johnson, New Brunswick, N.J.; Merck; Pfizer; Pharmacia Corp., Peapack, N.J.; and Wyeth-Ayerst Laboratories, the prescription drug unit of American Home Products Corp., Madison, N.J."). Boycotts such as these illustrate the long-term ramifications of prior authorization insofar as manufacturers are willing to give up present market share presumably in order to curb a long-term economically devastating scheme. *Id.* Further, consider the potential for similar boycotts in light of the fact that numerous other states and even private health insurance companies plan on implementing similar prior authorization programs. *Id.*; *see also Maine Appeals Halt on its Rx Plan*, *supra* note 26 (stating that roughly twenty-eight other states are planning to introduce legislation similar to Maine's).

236. A critical inquiry in dormant commerce clause cases — specifically in the case of extraterritorial statutes — is "what effect would arise if not one, but many or every, State adopted similar legislation." Healy v. Beer Inst., 491 U.S. 324, 336 (1998). Presumably if lost

Finally, the state prior authorization statutes fail under a balancing test because the burdens on interstate commerce are magnified when one recognizes PhRMA as a politically discriminated against group that deserves judicial protection.[237] This argument is a variation on a theme[238] first expressed in famous footnote four of *United States v. Carolene Products Company*.[239] At first glance, considering PhRMA — a group that accounts for more than 75 percent of brand-name drug sales in the United States[240] — a "discrete and insular"[241] group seems counterintuitive. Yet rather than focusing upon the "discrete and in-

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profits are considered in light of this principle, then the burden greatly increases in degree, and any "possible effects" become much more real and even inevitable.

237. Courts in general should consider the political processes in a dormant commerce clause query. Although political concerns are not traditionally an item to be placed into the burden/benefit balance, a court's concern with preserving political processes shows the motivating factor behind the inquiry and consequently serves as the primary justification to balance in the first place. *See* Regan, *supra* note 42, at 1166 (noting the traditional *Carolene Products* scholar's argument that the *Carolene Products* dormant commerce clause theory provides the justification for balancing). For example, if a court were to determine that the purpose of the dormant commerce clause is to prohibit protectionism, then the decision to balance and everything within the balance would be viewed through anti-protectionist glasses. Regan advocates the primacy of protectionism (yet by no means endorses balancing). *Id.* Similarly, if a court were to consider protecting the politically under-represented as a principal dormant commerce clause concern, a court would use its discretion in weighing the balance in order to tip in favor of the under-represented. Thus, the glasses that the court wears will help give meaning to the items already placed on the scales. To put it another way, it may be much more important to choose the right balance than to choose the right items of measure. (Of course, the added meaning of a political theory is also pertinent in an extraterritorial analysis. Due to the large discretion in a balancing test, however, a court may be able to better serve its purposes in this context rather than in an extraterritorial setting — a reason why the political analysis is discussed here and not earlier).

The political process balance is one of great significance as far as the dormant commerce clause is concerned mainly because it is a political theory that can solve the federal-state and separation-of-powers problems inherent in dormant commerce clause cases. *See* Mark Tushnet, *Rethinking The Dormant Commerce Clause*, 1979 WIS. L. REV. 125, 164-65. This becomes especially pertinent in the present case because of federalism's special role in Medicaid. *See supra* notes 62-63 and accompanying text. Thus, in choosing the appropriate balance, the political process balance must be given strong consideration.

238. The variation is based on Professor Bruce Ackerman's view of *Carolene Products*. Professor Ackerman eschews the "discrete and insular" language of *Carolene Products* and argues that the true focus in examining political dysfunction should be on those groups that are prejudiced, regardless of their discreteness or insularity. Bruce Ackerman, *Beyond* Carolene Products, 98 HARV. L. REV. 713 (1985).

239. 304 U.S. 144, 152 n.4 (1938) ("[P]rejudice against discrete and insular minorities may be a special condition . . . curtail[ing] the operation of those political processes ordinarily to be relied upon to protect minorities, and [so] may call for a correspondingly more searching judicial inquiry.").

240. Complaint for Declaratory, Injunctive and other Relief at para. 8, Pharm. Research & Mfrs. of Am. v. Meadows, 184 F.Supp.2d 1186 (N.D. Fl. 2001) (No. 4:01cv356-ws).

241. The terms "discrete" and "insular" are probably open to differing and controversial meanings. This Note, however, adopts the sensible sociological definitions advanced by Professor Ackerman. Thus, "insularity" describes the "tendency of group members to interact with great frequency in a variety of social contexts." Ackerman, *supra* note 238, at 726. A group is considered "discrete" "when its members are marked out in ways that make it relatively easy for others to identify them." *Id.* at 729.

sular" language of *Carolene Products*, PhRMA deserves protection as justified by the language in the footnote protecting those who languish under the burden of prejudice. PhRMA is a group prejudiced against in the political processes and therefore should be judicially protected.[242] Rather than attempt to suggest that PhRMA possesses the characteristics of either a discrete or insular group, this Note argues that the reasoning behind *Carolene Products* does not stand for the protection only of the discrete and insular, but also of "politically ineffective majorities." As PhRMA is one such ineffective group, it deserves the special attention of the court.[243]

The "prejudice" language of *Carolene Products* is sometimes ignored to the detriment of the under-represented.[244] Therefore, politically ineffective majorities that feel the impact of society's prejudice and are ineffective because of this prejudice, often find themselves without a voice in the formulation of laws that affect them.[245] If *Carolene Products* is truly concerned with political dysfunction, then it is the disdain for prejudice which should serve to protect both the "diffuse and anonymous" as well as the "insular and discrete."[246] As one scholar queries, "Why should the concern with 'prejudice' justify *Carolene*'s narrow fixation upon 'discrete and insular' minorities?"[247] Simply put, it should not.[248] If a group is ineffective in the legislative

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242. *See infra* notes 249-250, 254.

243. *See generally* JOHN HART ELY, DEMOCRACY AND DISTRUST (1980) (arguing for special judicial attention for prejudiced groups); Ackerman, *supra* note 238.

244. Ackerman, *supra* note 238, at 731 ("*Carolene*'s empirical inadequacy stems from its underinclusive conception of the impact of prejudice upon American society.").

245. *See* Ackerman, *supra* note 238, at 722-23.

246. *Id.* at 724.

247. *Id.* at 732.

248. *See* ELY, *supra* note 243, at 153 (noting that prejudice properly addresses the unconstitutional motivations of the legislature, whereas discreteness and insularity do not).

Insularity and discreteness may even be advantageous in the political arena, especially relative to those prejudiced against. As Professor Ackerman posits, the problem with the language of *Carolene Products* is that it "disdains the easy case in its eagerness to pronounce on harder ones." Ackerman, *supra* note 238, at 722-23. Insular and discrete groups normally have tremendous bargaining advantages, *id.* at 723-24, and thus to offer protection to such groups was a bold and broad stroke by the Court. The bargaining advantages of an insular and discrete group come in the form of increased political resources and lower organizational costs relative to an anonymous and diffuse group. *Id.* at 726. As Professor Ackerman explains, insularity "will help breed sentiments of group solidarity." *Id.* at 725. Thus, a group that possesses solidarity is more likely to make symbolic contributions for political purposes. *Id.* Moreover, a group's insularity can easily lead to the exposure of non-contributing free-riders and thereby increase resources by curbing free-riding. *Id.* In way of organizational costs, insular groups have pre-existing channels of communication and therefore find it cheaper to organize. *Id.* at 726. Similarly, a discrete group — due to the ease of recognition of members — will find it cheaper and easier to organize. *Id.* at 730-31; *see also* ELY, *supra* note 243, at 157-60.

The absence of language supporting "the easy cases," however, does not foreclose application of the principle to those cases. An observation of the case law concludes that *Carolene Products* is more concerned with political weakness propagated by attacks on egalitarianism

forum due to widespread and systematic prejudice, then that group — more than any other — must be protected under the spirit of *Carolene Products.*

PhRMA is a victim of prejudice and should thus be protected in the political processes. The portrayal of drug companies as "evil" and "profit-seeking" by members of the media and even high-ranking political leaders[249] has seemingly undermined their political power.[250] Although it is difficult to examine the motives of and influences upon the enacting state legislatures,[251] the mere evidence of widespread societal prejudice against drug companies gives rise to the inference of unconstitutional, prejudicial motivations behind the state prior authorization statutes.[252] Moreover, a mere inference would be ample to justify a more searching judicial inquiry under *Carolene Products.*[253] The inference is further strengthened by PhRMA's ineffectiveness in preventing the passage of the Maine Program in spite of its strenuous

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than with the weakness of the single insular group. Ackerman, *supra* note 238, at 723. The opportunity for all to equally participate in the political processes, and not the nature of the group denied participation, is at the core of *Carolene Products. See* ELY, *supra* note 243, at 77 (arguing that the focus of *Carolene Products* is "whether the opportunity to participate either in the political processes by which values are appropriately identified and accommodated, or in the accommodation those processes have reached, has been unduly constricted").

249. *See* Robert Pear, *U.S. Backs Florida Plan to Cut Drug Costs*, N.Y. TIMES, Sept. 19, 2001, at A14 ("Governor Bush, a Republican, denounced the lawsuit. 'Protecting the large profit margins of multibillion [dollar] pharmaceutical companies is not a priority,' he said."); Maggie Gallagher, *Goring My Health and Yours*, TOWNHALL.COM, Sept. 15, 2000, *at* http://www.townhall.com/columnists/maggiegallagher/mg2000915/shtml (discussing former Vice-president Al Gore's characterization of drug companies as "evil" during his 2000 presidential campaign); Michael Fumento, *Goring Drug Companies: A Plan That Doesn't Help the Elderly*, NAT'L REV. ONLINE, Sept. 25, 2000, *at* http://www.fumento.com/gorecampaign.html (discussing Gore's negative depiction of drug companies).

250. *See Philip Morrising the Drug Companies — Part 3*, para. 11, *at* http://www.yourdoctorinthefamily.com/commentary/comm017.htm (last visited Aug. 23, 2002) ("[W]hat we are actually seeing is yet another escalation of the war against drug companies, a war that will follow the model of the war recently waged against big tobacco. And the first step of such a war (as in any war) is to dehumanize the enemy so that it's okay to slaughter them."); Stephanie Stapleton, *AMA: Science must be key in off-label drug information*, AMEDNEWS.COM, Aug. 18, 1997, *at* http://www.ama-assn.org/sci-pubs/amnews/pick_97/pick0818.htm (" 'The FDA has felt that drug companies are evil monsters out there to dupe the physicians,' said John Seigfried, MD, deputy vice president for scientific and regulatory affairs for the Pharmaceutical Research and Manufacturers of America."); Key Martin, *"Medications For Every Nation"/ Pills Cost Pennies, Greed Costs Lives*, *at* http://www.peoplesvideo.org/hiv_dc.htm (last visited Aug. 23, 2002) (discussing the view that drug companies seek profits at the expense of human lives).

251. *See* ELY, *supra* note 243, at 138 ("[D]etermining whether an illegitimate motivation influenced a decision can be very difficult.").

252. *Id.* (noting that there will be situations where a "responsible inference that the action was unconstitutionally motivated will be possible").

253. *Id.* ("[I]t often will not be possible responsibly to conclude that the challenged action was the product of an unconstitutional motivation, [but that does not mean] . . . that the inquiry should not be undertaken.").

lobbying efforts and organizational advantages.[254] Ultimately, the inference of prejudice — an inference based on vociferous anti-PhRMA statements by political leaders and a war-like rhetoric by media and grass-roots groups against the drug industry[255] — seems strong enough to be of concern to a *Carolene Products* court. Therefore, at the very least, the prejudice factor should be considered in a balancing test and should tip in favor of PhRMA in order to preserve the talismanic political processes.

Under a balancing test that measures the burdens and benefits of a state law on interstate commerce, the state statutes must be struck down as unconstitutional. The perceived local benefits of lower prices for Medicaid recipients are not of great significance. In fact, these benefits may actually serve to undermine pharmaceutical research and development and thus hurt these same consumers in the future. Moreover, the burdens of potential lost profits by manufacturers on the interstate market militate against upholding the statutes. Finally, the more searching judicial inquiry of a revised *Carolene Products* theory suggests protection of PhRMA as an ineffective and persecuted interest group within the political processes. This protection is the final constitutional determinate in tipping the balance and demonstrating the excessive burden of the state statutes relative to the statutes' minimal benefits.

CONCLUSION

This Note concludes that state prior authorization statutes run contrary to the congressional intent behind prior authorization — an intent that clearly calls for the use of prior authorization to curb unnecessary over-prescription. By utilizing a purposive interpretive theory,

254. PhRMA, for example, waged a vociferous advertising campaign in Maine protesting the Maine Program, yet the law passed quite easily. *See* Page, *supra* note 198. In general, PhRMA has been unsuccessful in its lobbying efforts recently despite the expenditure of vast sums of money. For example, in 1999, the pharmaceutical industry was Washington's top lobbying spender, yet it failed to achieve its primary goal of obtaining a tax credit for research and development. *See Pharma lobbying figures from the Center for Responsive Politics*, *at* http://lists.essential.org/pipermail/pharm-policy/2001-June/ 001110.htm (last visited June 4, 2001).

Moreover, PhRMA's localized lobbying losses — as exemplified in Maine — are more indicative of a prejudice at the state level. The inference of prejudice within state legislatures is in part based on the fact that state budgetary pressures serve as incentives for states to act upon public hostility towards pharmaceutical companies. *See* John Sanko, *Medicaid Costs Threaten Budget; Legislators Struggle with Runaway Costs for State Health Insurance*, ROCKY MOUNTAIN NEWS, Dec. 13, 2001, *available at* 2001 WL 7391966 (" 'Medicaid was driving most states' budgets into the red, even before the additional economic downturn that resulted from the Sept. 11 attack,' analyst Alexis Senger told lawmakers." Moreover, according to Senger, 36 states reported Medicaid over-expenditures in fiscal 2001 of up to 19.7 percent). Although PhRMA's lobbying losses are hardly conclusive in demonstrating any prejudicial effect, they may have some probative value in drawing an inference of prejudice.

255. *See supra* notes 249-250 and accompanying text.

congressional intent becomes more apparent in light of the greater legal context of Medicaid. Therefore, federal law must preempt such statutes.

Moreover, this Note demonstrates that state prior authorization statutes violate the dormant commerce clause as being extraterritorial regulations, as well as failing under a balancing test where the burdens on commerce are excessive in relation to the local benefits. Although not a traditional *Carolene Products* group, PhRMA never received a fair shake in the hostile and prejudiced political arena which gave birth to the Maine Program. With the judicial concern for advancing fair representation of prejudiced and ineffective groups in the political fora in mind, the excessiveness of the burdens upon interstate commerce becomes evident. Due to the constitutional limitations upon state prior authorization statutes, they cannot serve as appropriate legislative means to further the interests of Medicaid and its recipients.

The Maine Program is a regulatory scheme with a noble ideal. Yet in its efforts to further the interests of its Medicaid recipients, Maine undermines the interests of all. Maine's program is not only unconstitutional, but it also hinders health care and restricts long-term pharmaceutical research and development. The Supreme Court now awaits to settle this dispute. At stake could be the future of health care in this country as we know it.