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The Unexpected Regulator: Regulation Through Settlement After Vioxx and Bextra

Warren Allen

NOTES

THE UNEXPECTED REGULATOR: REGULATION THROUGH SETTLEMENT AFTER VIOXX AND BEXTRA

INTRODUCTION

In 2003 alone, the prescription pain reliever Vioxx generated $2.5 billion in sales for its creator Merck.[1] It was actively marketed in over eighty countries, and had been taken by more than eighty million people worldwide.[2] By the end of 2004, Vioxx had been pulled off shelves after a study revealed that it nearly doubled the rates of heart attacks in longtime users.[3] Pfizer, with its own chemically similar drug Bextra, soon followed suit.[4] Subsequently, allegations arose that the two pharmaceutical giants had engaged in the inappropriate marketing of unsafe products,[5] producing a flurry of lawsuits.[6] This in turn led two coalitions of state Attorneys General (AGs) to file suits against Merck and Pfizer for violations of state consumer protection laws.[7] The two settlements that resolved these lawsuits not only brought the states considerable sums of monetary damages,[8] but also

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1. Rita Rubin, *How Did Vioxx Debacle Happen?*, USA TODAY, Oct. 12, 2004, http://www.usatoday.com/news/health/2004-10-12-vioxx-cover_x.htm.

2. *Id.*; Eric J. Topol, *Failing the Public Health—Rofecoxib, Merck, and the FDA*, N. ENGL. J. MED. 351;17, 1707 (2004), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp048286.

3. *Merck Withdraws Vioxx; FDA Issues Public Health Advisory*, FDA CONSUMER, Nov.–Dec. 2004, at 11, *available at* http://findarticles.com/p/articles/mi_m1370/is_6_38/ai_n7069493/; Richard Knox, *Merck Pulls Arthritis Drug Vioxx from Market*, NPR (Sept. 30, 2004), http://www.npr.org/templates/story/story.php?storyId=4054991.

4. William C. Sheil, Jr., *COX-2 Inhibitors Dilemma Vioxx, Celebrex, Bextra What Patients Should Do*, MEDICINENET.COM (Apr. 7, 2005), http://www.medicinenet.com/script/main/art.asp?articlekey=41853.

5. *See* Teresa Curtin & Ellen Relkin, *Preamble Preemption and the Challenged Role of Failure to Warn and Defective Design Pharmaceutical Cases in Revealing Scientific Fraud, Marketing Mischief, and Conflicts of Interest*, 35 HOFSTRA L. REV. 1773, 1783 (2007).

6. Micah L. Berman, *Smoking Out the Impact of Tobacco-Related Decisions on Public Health Law*, 75 BROOK. L. REV. 1, 9 (2009). In 2007, approximately 27,000 lawsuits over deaths and injuries caused by Vioxx were settled for $4.85 billion. Alex Berenson, *Merck Agrees to Settle Vioxx Suits for $4.85 Billion*, N.Y. TIMES (Nov. 9, 2007), http://www.nytimes.com/2007/11/09/business/09merck.html.

7. Press Release, Pennsylvania Office of the Attorney General, Attorney General Corbett Announces a Multi-State, $58 Million Settlement with Merck over Deceptive Advertising Concerning the Safety of Vioxx (May 20, 2008), *available at* http://www.attorneygeneral.gov/press.aspx?id=3660; Press Release, The State of New Jersey, Office of the Attorney General, Attorney General Announces $2.1 Million Settlement with Pfizer over Promotion of Celebrex, Bextra (Oct. 22, 2008) [hereinafter N.J. Press Release], *available at* http://www.nj.gov/oag/newsreleases08/pr20081022a.html.

8. *See* Stipulated General Judgment at 11, Oregon *ex rel.* Myers v. Merck & Co. [hereinafter Merck Stip. Judgment], *available at* http://www.merck.com/newsroom/vioxx/pdf/ag_document.pdf (providing a total award of $58 million to the participating states); Stipulated General Judgment at 15, Oregon *ex rel.* Myers v. Pfizer, Inc. [hereinafter Pfizer Stip. Judgment], *available*

contained potentially momentous substantive terms granting the state AGs broad regulatory enforcement power.[9]

Over the past fourteen years, the offices of the state AGs have demonstrated an increased interest in regulating business through litigation.[10] Faced with the failure of legislatures and administrative agencies to impose sufficient limits on corporate action, AGs have turned to litigation as a means of enforcement.[11] Through litigation, state AGs may, in conjunction with state courts, simultaneously reap sizable monetary awards for the state,[12] while also creating substantive terms to dictate the future behavior of an offending corporation.[13] Such terms effectively function as a new system of regulation—placing new requirements on corporate conduct and giving rise to new causes of action if they are violated.[14]

Nowhere does this seem more effective, yet disruptive, than in the context of the settlement of mass tort claims, where a coalition of state AGs may easily have the power to force a lopsided agreement to increase its own regulatory powers over corporations.[15] While the discretion of whether to approve such a settlement ultimately lies with the judge,[16] courts may be hesitant to interfere with the AGs' efforts,[17] particularly where such an agreement will bring tremendous financial benefits to states in need.[18] The results of such an agreement, however, may disrupt the federal regulatory model,[19] while simultaneously raising costs for businesses and consumers alike.[20] Such action therefore raises constitutional concerns with respect to the separation of powers doctrine, as state executives are petitioning courts for regulatory power that is traditionally granted through legislative

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at http://www.doj.state.or.us/releases/pdf/pfizer_stip_judg_complaint.pdf (providing a total award of $60.1 million to the participating states).

9. *See* Christopher R. Page, Comment, *These Statements Have Not Been Approved by the FDA: Improving the Postapproval Regulation of Prescription Drugs*, 88 OR. L. REV. 1189, 1208 (2009); Donald G. Gifford, *Impersonating the Legislature: State Attorneys General and* Parens Patriae *Product Litigation*, 49 B.C. L. REV. 913, 946 (2008).

10. *See* Gifford, *supra* note 9, at 914.

11. Deborah R. Hensler, *The New Social Policy Torts: Litigation as a Legislative Strategy Some Preliminary Thoughts on a New Research Project*, 51 DE PAUL L. REV. 493, 498 (2001).

12. MARTHA A. DERTHICK, UP IN SMOKE FROM LEGISLATION TO LITIGATION IN TOBACCO POLITICS 1 (2d ed. 2005). The estimated award going to the forty-six states involved in the tobacco settlement totals $246 billion over a twenty-five-year period. *Id.*

13. *See, e.g.*, Page, *supra* note 9, at 1208–09.

14. *See, e.g.*, *id.*

15. *See id.* at 1201–02.

16. FED. R. CIV. P. 23(e) ("The claims, issues or defenses of a certified class may be settled . . . only with the court's approval.").

17. Gifford, *supra* note 9, at 945.

18. *Id.*

19. *See, e.g.*, *id.* at 945–46; *see generally* Gregory W. Traylor, Note, *Big Tobacco, Medicaid-Covered Smokers, and the Substance of the Master Settlement Agreement*, 63 VAND. L. REV. 1081 (2010) (arguing that payments from Big Tobacco litigation violated the Social Security Act).

20. *See, e.g.*, Traylor, *supra* note 19, at 1097; Gifford, *supra* note 9, at 951.

processes.[21] Moreover, serious policy issues arise from the increasing control of state AGs over businesses.[22]

The purpose of this note is to illustrate the need for some limitation on state regulation by litigation, as demonstrated by the Vioxx and Bextra settlements, while also proposing an alternative that integrates the state AGs into the federal regulatory structure. Part I will briefly examine these settlements as a logical progression from the AGs' earlier Tobacco Master Settlement Agreement. Part II will analyze justiciability concerns in the approval of such settlements regarding both horizontal and vertical separation of powers. It will conclude with a discussion of recent congressional action to explicitly include state AGs within the federal regulatory scheme. Part III will explore potential negative policy implications of allowing state AGs to bring unchecked suits for the purpose of expanding their own regulatory enforcement power. Finally, in Part IV, this note concludes that Congress must take action to explicitly define the enforcement role of state AGs within controversial areas of the federal regulatory scheme. Such an approach, which has already been employed in some areas of federal regulation,[23] would provide guidance as to both the acceptable and unacceptable limits of the state AGs' regulatory roles, and enable an integrated system to reap the benefits of state AGs as regulators, while avoiding the potential harms of state overreach.

I. INCREASING STATE REGULATION BY LITIGATION: THE VIOXX AND BEXTRA SETTLEMENTS

The template for state AGs actively pursuing a greater regulatory enforcement role grew out of litigation against Big Tobacco in the 1990s.[24] Traditionally, the state AGs have been recognized as the "chief legal officers of the states."[25] In the case of the tobacco litigation, however, the AGs arguably transcended their role to enact considerable policy reform through a Master Settlement Agreement (MSA) with the major cigarette manufacturers.[26] The AGs gained regulatory power as a result of the settlement when, in addition to paying substantial monetary awards,[27] the

21. Gifford, *supra* note 9, at 946–51.

22. *Id.* at 947.

23. Congress has granted state AGs the right to bring suit as *parens patriae* for violations, provided that notice is given to the appropriate regulatory agency. *See, e.g.*, Consumer Product Safety Improvement Act, 15 U.S.C. § 2073(b) (2008); *see also* Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), Pub. L. No. 111-203, §§ 1041–1042, 124 Stat. 1376, 2011–14 (2010) (codified at 12 U.S.C. §§ 5551–5552 (2010)).

24. *See* Page, *supra* note 9, at 1203–04.

25. *About NAAG Information on the Association*, NAT'L ASS'N OF ATTORNEYS GEN., http://www.naag.org/about_naag.php (last visited Nov. 19, 2010) [hereinafter *About NAAG*].

26. DERTHICK, *supra* note 12, at 1–3.

27. *Id.* at 1. The total estimated award to the states is $246 billion, dispersed from 2008 through 2025. *Id.*

tobacco companies also agreed to abide by far reaching limitations on how their products could be marketed, particularly to children.[28] The success of the MSA unlocked vast possibilities for the AGs in terms of expanding their enforcement and regulatory powers via the substantive terms of a settlement.[29] Commentators have noted that the substantive terms of the settlement effectively created the kinds of regulations for which advocacy groups had unsuccessfully lobbied Congress.[30] Attempts to enact policy change by both traditional legislative and administrative routes had proved fruitless when it came to the unusual problem of tobacco.[31] In this way, the tobacco MSA provided states with a game plan when two of the world's largest pharmaceutical companies, Merck and Pfizer, engaged in illicit "off-label" marketing of drugs with harmful side effects.[32]

A. VIOXX (MERCK)

In the case of both Vioxx and Bextra, the perceived ineffectiveness[33] of the Food and Drug Administration's (FDA) pharmaceutical regulation likely encouraged state AGs to pursue the regulatory measures included in the corresponding settlements.[34] A history of the events leading up to the eventual recall of Vioxx illustrates the fact that discontent with the FDA's regulation led other actors to take action.[35] In 2001, as Vioxx's popularity was on the rise, the FDA delivered an extensive warning letter to Merck, detailing explicit misrepresentations that the company had made as to the cardiovascular safety of the drug, while also voicing concerns that the drug actually raised the rate of heart attacks.[36] After the delivery of the letter,

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28. *See, e.g.*, Master Settlement Agreement, Project Tobacco, Nat'l Ass'n of Attorneys Gen., (Nov. 1998), 24–36, http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/MSA%20with%20Sig%20Pages%20and%20Exhibits.pdf/file_view; *see also* DERTHICK, *supra* note 12, at 3–4.

29. *See id.* at 2–4; Page, *supra* note 9, at 1204.

30. *See, e.g.*, Hensler, *supra* note 11, at 498; Page, *supra* note 9, at 1204 ("Antismoking advocates had tried for years to obtain similar restraints on the tobacco industry from Congress, to no avail, presumably due to lobbying efforts.").

31. Hensler, *supra* note 11, at 498. A previous settlement agreement, having national effect, had been reached by the state AGs in 1997, pending Congress' approval. The settlement, however, included terms that the state AGs recognized might not withstand constitutional scrutiny, and required passage by the federal legislative branch. Congress subsequently did not approve the settlement, opening the door for the current tobacco MSA. DERTHICK, *supra* note 12, at 119–29 (chronicling the opposition to, and ultimate failure of, the 1997 settlement). It is worth noting that the proposed 1997 settlement would have imposed greater substantive restrictions on the tobacco industry than the 1998 MSA, but these restrictions also involved the FDA as a regulator. *Id.* at 176.

32. Page, *supra* note 9, at 1189, 1204–14.

33. *See, e.g.*, *id.*

34. *Id.* at 1207–14; MCDERMOTT, WILL & EMERY, MERCK SETTLES VIOXX LITIGATION WITH STATE ATTORNEYS GENERAL: AN ANALYSIS 2 (May 29, 2008), *available at* http://www.mwe.com/info/news/wp0508a.pdf.

35. MCDERMOTT, WILL & EMERY, *supra* note 34, at 2.

36. *See* FDA Warning Letter from Thomas W. Abrams, Dir., Div. of Drug Mktg., Adver., and Comm'ns, to Raymond V. Gilmartin, President & CEO, Merck & Co., Inc. (Sept. 17, 2001),

however, the FDA considered the matter "satisfactorily resolved."[37] They did not require Merck to take any action concerning its misleading press release and did not issue further letters alleging the improper marketing of Vioxx.[38] Nonetheless, significant evidence existed as early as March 2000 that Vioxx increased, and possibly even doubled, the rate of heart problems when compared to other anti-inflammatory drugs.[39] Yet, the FDA failed to require even a warning about cardiovascular risk to be applied to the medication's label until 2002.[40] Meanwhile, the drug remained on the market until September 30, 2004.[41]

Within the Merck settlement agreement, the AGs attempted to give themselves greater power to protect their constituents from agency inactivity.[42] The result is two distinct groups of terms—some of which increased the participating state AGs' enforcement powers in relation to the FDA's regulatory realm, while others created entirely new demands on Merck.[43] In the first category, for instance, Merck agreed not to violate the terms of the Federal Food, Drug, and Cosmetic Act (FDCA) in regard to "any written or oral promotional claims of safety or effectiveness."[44] This, along with other terms,[45] gives the state AGs power to enforce any violations of the Merck settlement by means of a contempt proceeding.[46] Merck also agreed to additional restrictions over the future marketing of their products,[47] including agreeing to delay any proposed Direct to Consumer (DTC) marketing plan if the FDA's Director of the Center for Drug Evaluation recommends such a delay, for however long the Director

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available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166383.pdf.

37. Report of John S. Martin, Jr. to the Special Comm. of the Bd. of Dirs. of Merck & Co., Inc. Concerning the Conduct of Senior Mgmt. in the Dev. and Mktg. of Vioxx, at 96 (Sept. 5, 2006), *available at* http://www.merck.com/newsroom/vioxx/pdf/001_02_report_of_the_honorable_john_s_martin_jr_our_findings.pdf.

38. *Id.*

39. Rubin, *supra* note 1.

40. *Id*.

41. Topol, *supra* note 2, at 1707.

42. *See* Page, *supra* note 9, at 1208.

43. *Id.* at 1208.

44. *See* Merck Stip. Judgment, *supra* note 8, at 5–8.

> Merck shall not make any written or oral promotional claims of safety or effectiveness for any FDA-approved Merck Product in a manner that violates the Food, Drug and Cosmetic Act, . . . accompanying regulations, or voluntary agreements with [the] FDA, as interpreted by the FDA in a writing by the Director of the Center for Drug Evaluation at the FDA.

Id. at 5 (internal citation omitted).

45. *Id.* at 5–8.

46. Page, *supra* note 9, at 1209.

47. *Id*. at 1208.

recommends.[48] Moreover, in paragraph 9 of the settlement agreement, Merck agreed to submit any future DTC television advertising directly to the FDA for review and approval, and to make any changes that the FDA suggests.[49]

These provisions expand the regulatory enforcement power of the state AGs to areas that have previously only fallen within the purview of the FDA.[50] The potential implications of these settlements on the federal regulatory scheme could be profound, as state AGs gain the *de facto* ability to enforce the FDCA and FDA regulations.[51] One commentator on the Merck settlement has noted the following: "[T]he fact that State AGs, individually and collectively, can now march into court under FDA's own regulations effectively means that there is a 'new cop on the beat' ready, willing and able to pursue actions for alleged advertising violations whenever they believe FDA is not doing the job properly."[52]

At the same time, the creation of brand new requirements for Merck to abide by also allows the state AGs to effectively make regulatory decisions on the nature of corporate advertising.[53] It is debatable whether enhancing the state AGs' powers in this way is valid under the constitutional separation of powers doctrine, as it may create a "blank check" for the state AGs to intrude upon the federal or legislative realms.[54]

B. BEXTRA (PFIZER)

The downfall of Bextra closely paralleled that of Vioxx. Bextra was designed to reduce the risk of illness associated with traditional anti-inflammatory drugs; yet, there was no evidence that it was successful as compared to traditional methods.[55] Nevertheless, they marketed the drugs as safer alternatives to other anti-inflammatories, such as Advil and Aleve.[56] When thirty-three states and the District of Columbia launched their 2003 investigation into whether Pfizer had violated state consumer protection laws,[57] concerns arose regarding the AGs' case. The AGs concluded that

48. *See* Merck Stip. Judgment, *supra* note 8, at 6.

49. *Id.*

50. Jennifer Wolsing, *Vioxx Settlement: State AGs' New Rights to Enforce Food & Drug Law*, THE FEDERALIST SOC'Y FOR LAW AND PUB. POL'Y STUDIES (Aug. 15, 2008), http://www.fed-soc.org/publications/pubID.1148/pub_detail.asp.

51. *Id.*; Page, *supra* note 9, at 1208–09.

52. MCDERMOTT, WILL & EMERY, *supra* note 34, at 5. *See also* Page, *supra* note 9, at 1213.

53. *See* Page, *supra* note 9, at 1209. Page notes that certain terms requiring submission of advertising to agencies may also give rise to a constitutionality issue under the First Amendment. *See id.* This issue is not dealt with here. *See also* MCDERMOTT, WILL & EMERY, *supra* note 34, at 4.

54. *See* Gifford, *supra* note 9, at 951.

55. N.J. Press Release, *supra* note 7.

56. *Id.*

57. *Id.*; Page, *supra* note 9, at 1212. Oregon led the litigation. Other states joining the litigation included: Alaska, Arizona, Arkansas, California, Connecticut, Florida, Idaho, Illinois, Iowa,

Pfizer had actively marketed Bextra for off-label uses that had been explicitly rejected by the FDA by means of "an aggressive, deceptive and unlawful campaign."[58] These concerns may have contributed to additional provisions within the settlement, increasing the state AGs' oversight authority over Pfizer.

While both settlements provide for similar expansions of state enforcement authority into the federal regulatory realm,[59] the terms of the Pfizer settlement further expands the state AGs' role in regulation.[60] While both the Merck and Pfizer settlements contain a provision requiring that any future DTC television campaign be submitted to the FDA,[61] the Pfizer settlement provides that, in the event the FDA does not respond within forty-five days, Pfizer may run the advertisement after contacting a "Multistate Executive Committee" of AGs.[62] The company must, however, provide written notice that the FDA has not given Pfizer feedback on its proposed advertising and submit all materials delivered to the FDA directly to the Multistate Executive Committee.[63] Note that this may have actually been preferable for Pfizer, as Merck's settlement required the company to wait until it had received word from the FDA regardless of how much time passed.[64] One commentator has suggested that this variation suggests that the state AGs realized they lacked the means to ensure the actual enforcement of the terms of the settlement.[65] Here then, it seems that the

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Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, Wisconsin, and the District of Columbia. *Id.*

58. *Id.* A regional manager who played a major part in promoting Bextra's off-label marketing stated in court that off-label marketing was part of Pfizer's corporate culture, and that her own success in illicitly promoting Bextra was described as "awesome" by company medical directors. Jim Edwards, *Pfizer Exec: Company Approved of Off-Label Bextra Promotion*, BNET.COM, http://www.bnet.com/blog/drug-business/pfizer-exec-company-approved-of-off-label-bextra-promotion/1934.

59. *See* Pfizer Stip. Judgment, *supra* note 8, at 5; Merck Stip. Judgment, *supra* note 8, at 5.

60. Page, *supra* note 9, at 1212–13 (describing terms in the Pfizer settlement not found in the Merck settlement, including self-reporting).

61. *See, e.g.*, Pfizer Stip. Judgment, *supra* note 8, at 6; Merck Stip. Judgment, *supra* note 8, at 6.

62. *See* Pfizer Stip. Judgment, *supra* note 8, at 2, 6.

63. *See id.*

> . . . Pfizer shall provide written notice to the Multistate Executive Committee that Pfizer is running the advertisement and that the FDA has not provided Pfizer with a pre-review response addressing the substance of the advertising . . . and also provide a copy of all material submitted to FDA for the review of the subject advertisement. . . .

Id.

64. Page, *supra* note 9, at 1212–13; Merck Stip. Judgment, *supra* note 8, at 6.

65. Page, *supra* note 9, at 1212–13 ("The states added an interesting twist to the new settlement's terms that seemed to address a perceived difficulty with enforcing the Merck settlement."); Merck Stip. Judgment, *supra* note 8, at 6.

state AGs preferred to take some oversight into their own hands rather than rely on the FDA to render accurate judgments.[66]

Moreover, the settlement imposes additional requirements not found in the Merck settlement.[67] In total, the Pfizer settlement contains approximately four additional pages of terms, which predominantly address Pfizer's well publicized off-label marketing.[68]

II. THE CONSTITUTIONALITY OF REGULATORY SETTLEMENTS

This part analyzes potential constitutional issues arising out of the approval of regulatory settlements. The first section examines the horizontal separation of powers issue, arguing that the approval of a regulatory settlement inappropriately eschews the legislative branch. The second section looks at recent developments in the vertical separation of powers and attempts to demonstrate both how they shaped the Vioxx and Bextra settlements and how they might affect regulatory settlements in the future. Though these issues may seem like two sides of the same coin, the preemption doctrine has been significantly litigated in recent years in a way that the political question doctrine has not. Nonetheless, both are essential to an understanding of the issues raised by regulatory settlements.

A. HORIZONTAL SEPARATION OF POWERS

1. Horizontal Separation of Powers: The Political Question Doctrine

When a state AG asks a court for the kinds of relief sought within the Vioxx and Bextra settlements, the question arises as to whether the court actually has the power under the Constitution to grant such relief.[69] This issue surfaces because a court's power to grant relief is necessarily limited when a party seeks the court's intervention in a matter that falls within the purview of the legislative or executive branches of government.[70] In *Baker v. Carr*, Justice Brennan recognized the inherent difficulty of creating a strict test for these "nonjusticiable political question[s]."[71] He describes six factors that a court should look for when ascertaining whether such a question exists:

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66. *Id.*

67. *See, e.g.*, Pfizer Stip. Judgment, *supra* note 8, at 13. "Pfizer shall not disseminate samples of a Product with the intent of increasing Off-label prescribing of the Product." *Id.* "Pfizer shall not award prizes or other incentives to its sales force as rewards for specifically increasing the Off-Label use of a Product." *Id.* at 11.

68. *See, e.g.*, *id*. at 11–13.

69. *See* Gifford, *supra* note 9, at 946–48.

70. *See* KATHLEEN M. SULLIVAN & GERALD GUNTHER, CONSTITUTIONAL LAW 49 (16th ed. 2007) (discussing the origins and role of doctrine as a limitation on courts' power).

71. Baker v. Carr, 369 U.S. 186, 209 (1962) (internal quotation marks omitted).

> [1] a textually demonstrable constitutional commitment of the issue to a coordinate political department; or [2] a lack of judicially discoverable and manageable standards for resolving it; or [3] the impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion; or [4] the impossibility of a court's undertaking independent resolution without expressing lack of the respect due coordinate branches of government; or [5] an unusual need for unquestioning adherence to a political decision already made; or [6] the potentiality of embarrassment from multifarious pronouncements by various departments on one question.[72]

The "inextricable" presence of any one of these factors would make it inappropriate for a court to allow such matter to proceed.[73] The rationale for this includes the fact that the "coordinate elected branches" of the government would be better equipped to reach a proper decision than federal judges and would also be held responsible by their electorate for the outcome of such a decision.[74]

In the context of regulatory litigation, the political question doctrine establishes implicit limits on the degree to which a court may grant nonmonetary relief.[75] To wit, a vast scheme of substantive relief, imposed by the court, may result in the creation of a *de facto* regulatory scheme traditionally left to legislative or administrative offices.[76] For instance, some courts have found that state litigation against major polluters, intended to reduce global warming, raised serious nonjusticiable political questions.[77] Such findings were not universal;[78] yet, where they did occur, the courts have consistently demonstrated concern over making detailed policy judgments that could have vast implications for the U.S. economy.[79]

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72. *Id.* at 217.

73. *Id.*

74. James R. May, AEP v. Connecticut *and the Future of the Political Question Doctrine*, 121 YALE L.J. ONLINE 127, 127–28, http://yalelawjournal.org/the-yale-law-journal-pocket-part/supreme-court/aep-v.-connecticut-and-the-future-of-the-political-question-doctrine/.

75. *See* Gifford, *supra* note 9, at 949–50.

76. *See id.* at 950 (discussing the Rhode Island Nuisance Abatement Plan).

77. Amelia Thorpe, *Tort-Based Climate Change Litigation and the Political Question Doctrine*, 24 J. LAND USE & ENVT'L. L. 79, 80–81 (2008); Gifford, *supra* note 9, at 944. These suits arose when, in an effort to regulate global warming, some state AGs attempted to use common law public nuisance suits as a means of regulating major polluters. *Id.* at 948–49. The political question doctrine has also been invoked in other recent disputes, including a claim against the federal government for the destruction of a Sudanese factory thought to have terrorist ties. *D.C. Circuit Rejects Claim for Sudanese Bombing as Political Question*, CONSTITUTIONAL L. PROF. BLOG (June 16, 2010), http://lawprofessors.typepad.com/conlaw/2010/06/dc-circuit-rejects-claim-for-sudanese-bombing-as-political-question.html.

78. *See* Thorpe, *supra* note 77, at 83; Gifford, *supra* note 9, at 948–49.

79. *See* Order Granting Defendants' Motion to Dismiss at 11, 19, Cal. v. Gen. Motors Corp., 2007 WL 2726871 (N.D. Cal. 2007); Native Vill. of Kivalina v. ExxonMobil Corp., 663 F. Supp. 2d 863, 876–77 (N.D. Cal. 2009). *See also* Conn. v. Am. Elec. Power Co., 406 F. Supp. 2d 265 (S.D.N.Y. 2005), *rev'd*, 582 F.3d 309 (2d Cir. 2009), *rev'd*, 131 S. Ct. 2527 (2011); Thorpe, *supra* note 77, at 84 (describing Judge Senter's reasoning in *Comer v. Nationwide Mut. Ins. Co.*). Courts

Notably, the Supreme Court recently heard one such global warming case, where the political question controversy was discussed at length by the lower courts but was unaddressed in the Court's opinion.[80] The Court resolved the dispute, instead, by finding that the Environmental Protection Agency's role and Congress' choice to pass the Clean Air Act prevented state AGs from bringing a federal tort claim.[81]

The scope of relief granted through the Vioxx and Bextra settlements may similarly implicate the factors discussed in *Baker*, particularly the first three. The *de facto* power of state AGs to enforce elements of federal law, for example, likely implicates the first factor because it is a power that has previously been limited by Congress to the FDA.[82] Likewise, virtually any of the substantive terms constitutes a potential "initial policy determination of a kind clearly for nonjudicial discretion,"[83] given that the regulatory scheme created upon approval of one of the settlements discussed above constitute a use of power explicitly granted to "Congress, the state legislature, or federal agencies."[84] For instance, if a federal agency is to enact official and enforceable regulatory rules, it must go through a detailed process of evaluating the effectiveness of its proposed rules, which includes weighing alternatives and considering policy interests.[85] In the context of the substantive terms promulgated by regulatory settlements such as the Vioxx and Bextra settlements, however, there is no evidence that such procedures were followed.[86]

Nevertheless, many settlements that, in practice, serve to regulate major manufacturers or industries have been approved in recent years and have avoided constitutional scrutiny. For example, a settlement over racially discriminatory pricing within the insurance industry did not discuss constitutional concerns.[87] Additionally, the aforementioned tobacco MSA similarly avoided the constitutional inquiry.[88]

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have also considered that legislation dealing with the issues for which redress was sought was, at the time of proceedings, under review by state legislatures. *See id.* at 80–81. *But see In re* Methyl Tertiary Butyl Ether (MTBE) Products Liab. Litig., 438 F. Supp. 2d 291, 302, 304 (S.D.N.Y. 2006); *In re* "Agent Orange" Product Liab. Litig., 373 F. Supp. 2d 7, 64, 69, 70 (E.D.N.Y. 2005) (finding no political question issues raised by certain products liability cases brought by private parties).

80. May, *supra* note 74, at 129–30.

81. Am. Elec. Power Co. v. Conn., No. 10-174, slip op. 1, 10 (U.S. June 20, 2011).

82. Wolsing, *supra* note 50; MCDERMOTT, WILL & EMERY, *supra* note 34, at 3, 5.

83. Baker v. Carr, 369 U.S. 198, 217 (1962).

84. Gifford, *supra* note 9, at 913.

85. W. KIP VISCUSI, SMOKE-FILLED ROOMS 217 (University of Chicago Press 2002).

86. *Id*.

87. *See, e.g.*, Multi-State Regulatory Settlement Agreement, Wash. State Office of Ins. Comm'r, Order D04-188 (June 9, 2004), *available at* http://www.insurance.wa.gov/oicfiles /orders/2004orders/d04-188.pdf (settling claims that insurance companies sold policies at higher premiums based on race).

88. *See, e.g.*, Master Settlement Agreement, Project Tobacco, *supra* note 28, at 18–23.

Though the Tobacco defendants raised the political question doctrine at least once during litigation,[89] the MSA has not been overturned on those (or any) grounds.[90] Yet, courts involved in the litigation have received criticism for their role in approving the MSA with what appeared to be minimal scrutiny of the relief awarded.[91] Martha Derthick, a scholar who has written at length on American governance and policymaking, states:

> A judicial check was . . . largely evaded. Courts were arenas of the fight but rendered few decisions. Courts might have declined to accept the cases on the ground that the issues were political in nature and more appropriately left to legislatures. Recall that the industry tried to make that argument in Mississippi but was rebuffed by Chancellor [William] Myers. The judiciary, which often sits in judgment on what other branches do, here would be the primary arena of decision.[92]

As a result, the lack of judicial oversight suggests a potential "rubber stamp" by the judiciary in the face of legitimate constitutional objections.[93] Perhaps, as has been suggested by many, the states and the tobacco companies had reached a stalemate in a conflict for which both sides needed resolution.[94] Yet, the judiciary's failure to act suggests that courts may be willing to take a passive role in regulatory litigation implicating both large damage awards and potentially transformative effects on industry.[95]

This passivity implicates practical issues that arise when litigation seeks relief for a broad scope of injuries. One tort scholar has argued that the remedies pursued by state AGs inherently ask more from the judiciary than the branch is entitled to give.[96] Yet, few such cases receive adequate consideration,[97] and fewer may even be dismissed.[98] Even when they do, as

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89. DERTHICK, *supra* note 12, at 77.

90. *Id*. at 77, 234.

91. *Id*. at 234.

92. *Id*. Chancellor William Myers rejected the tobacco companies' political question arguments in 1995, providing no rationale for his decision. *Id.* at 77.

93. Arthur B. LaFrance, *Tobacco Litigation: Smoke, Mirrors and Public Policy*, 26 AM. J.L. & MED. 187, 198–99 (2000).

94. DERTHICK, *supra* note 12, at 223; Berman, *supra* note 6, at 7–8.

95. *See* Gifford, *supra* note 9, at 944–45.

96. *Id.* at 949–50 (discussing the regulatory scheme granted by a district court in lead paint litigation). Gifford writes,

> The question is whether this can be accomplished by a court or whether, instead, such a public health situation requires a response from the legislature and appropriate administrative officers. In short, the myriad of policy decisions necessary to remediate lead-based paint hazards throughout the state may be at the core of the issues that the U.S. Supreme Court regards as political questions.

Id. at 950.

97. *See, e.g.*, DERTHICK, *supra* note 12, at 77 (discussing that Chancellor William Myers rejected the tobacco companies' political question claims without explanation).

98. *See* Gifford, *supra* note 9, at 944–45.

the global climate change litigation illustrates, the results are controversial and inconsistent.[99]

This indicates that some judges may be inclined to allow state AGs greater leeway in prominent suits, refusing to dismiss these broad claims even for valid reasons.[100] This behavior may stem from the fact that these suits represent vast potential awards to impecunious state governments and citizens that may have a genuine need for such funds.[101] The practical effect, however, is a failure in the traditional judicial review process that may very well allow state executives to impose intense pressure upon commercial ventures.[102]

2. An Additional Note on Tobacco and Horizontal Separation of Power

While not strictly implicating the political question doctrine, review of the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corporation* is necessary when considering the relation of the court system to the other branches of government in the context of regulatory settlement. In *Brown & Williamson Tobacco Corporation* (decided after the MSA's adoption), the Supreme Court held that efforts undertaken by the FDA to regulate the tobacco industry were precluded since Congress had already undertaken considerable legislation to regulate tobacco.[103] Justice O'Connor, writing for the majority, stated that "[the FDA's attempt to exert] authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA."[104]

Given this ruling, it is curious that no party has questioned why those same statutes cited in the Court's ruling in *Brown & Williamson Tobacco Corporation*—some of which date back to 1965—should not also preclude the judiciary from approving the regulatory terms within the tobacco MSA, or currently preclude state AG enforcement of such terms. If the scope of tobacco regulation has already been strictly delineated by Congress, then the MSA's continued existence is questionable. This rationale might be extrapolated to the state AGs dealing with pharmaceutical companies, as

99. *See id.*, at 948–49 (noting some courts' hesitation to approach the policy interests at play in these cases); Thorpe, *supra* note 77, at 81–84 (contrasting some courts' findings that the political question doctrine is decisive in these cases with others that decline to even mention it).

100. Gifford, *supra* note 9, at 944–45.

101. *Id.*

102. *See id.*

103. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126 (2000).

104. *Id.*

Congress has clearly passed legislation granting broad power to the FDA over prescription drug marketing.[105]

B. VERTICAL SEPARATION OF POWERS: PREEMPTION AND *WYETH V. LEVINE*

A vertical separation of powers problem arises when a state's proposed action would enable the state to occupy an area reserved by Congress for a federal actor.[106] When such a conflict occurs, the federal government must be able to prevent the state from exercising power over that area.[107] Early in its history, the Supreme Court found that the Constitution established that federal law, in order to maintain a stable union, must be able to preempt state actions that conflicted with goals of Congress.[108] In *Pacific Gas & Electric Company v. State Energy Resources Conservation & Development Commission*, the Court expanded on this doctrine: "[w]hen the Federal Government completely occupies a given field or an identifiable portion of it . . . the test of pre-emption is whether 'the matter on which the State asserts the right to act is in any way regulated by the Federal Act.'"[109]

Practically speaking, however, it has become increasingly difficult to identify which fields the federal government has intended to occupy, and to what degree.[110] As federal government has expanded into areas of state welfare,[111] and perceived federal agency inaction has drawn the ire of state officials,[112] fierce battles have been waged over how much state action is precluded by the language of congressional statutes.[113]

The conflict over preemption grew particularly divisive during the presidency of George W. Bush, whose administration pushed the doctrine as a means of limiting tort liability, particularly in the area of pharmaceutical litigation.[114] Though this had previously been an area in which state consumer protection law and the FDA worked in concert,[115]

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105. *See generally* Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1987) (codified as amended in scattered sections of 21 U.S.C.) (amending the FDCA to preserve the integrity of drug marketing).

106. SULLIVAN & GUNTHER, *supra* note 70, at 229–30.

107. *See* M'Culloch v. Maryland, 17 U.S. 316, 405 (1819).

108. *See id.*; SULLIVAN & GUNTHER, *supra* note 70, at 229–30.

109. Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 212–13 (1983) (citing Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 236 (1947)).

110. Anthony C. Coveny & Shelly A. Sanford, *Executive Activism Not Reciprocated with Judicial Activism:* Wyeth v. Levine *and* Cuomo v. Clearing House *Return Preemption to the Legislative Branch*, 22 ST. THOMAS L. REV. 362, 369 (2010).

111. *Id. See also* Catherine M. Sharkey, *Federalism Accountability: "Agency-Forcing" Measures*, 58 DUKE L.J. 2125, 2131–41 (2009) (singling out the FDA for special criticism).

112. *Id.* at 2131–41. *See also* Page, *supra* note 9, at 1190–93 (describing the FDA's difficulties with post-approval drug regulation).

113. Coveny & Sanford, *supra* note 110, at 269–70.

114. *Id.* at 398.

115. Wyeth v. Levine, 555 U.S. 555, 574–77 (2009); Coveny & Sanford, *supra* note 110, at 378–79.

numerous conflicts arose over whether suits brought under existing state consumer protection laws would be preempted.[116] This in turn produced a string of recent decisions that have greatly expanded the range and limits of the preemption doctrine in regard to administrative agencies.[117] At least one legal scholar has described this line of cases as having "crested (at least for now)" in favor of the preemption doctrine with *Riegel v. Medtronic*, before ebbing back in favor of the states with *Wyeth v. Levine*.[118] While there is no way of knowing whether such cases actually influenced the Vioxx and Bextra settlements, it seems likely that similar cases and settlements will raise preemption issues by virtue of the states' interaction with federal law.

1. *Riegel v. Medtronic*

In *Riegel v. Medtronic*, the Supreme Court designated certain state tort actions as incompatible with the explicit wording of federal law.[119] In this case, the plaintiff sought damages under New York tort law for injuries caused by a defective angioplasty balloon.[120] Yet, the majority found that Congress had manifested the clear intent to eliminate state causes of action through the language of a medical devices amendment to the FDCA.[121] Justice Scalia framed the case by first analyzing whether the federal government's statutes placed clear requirements on the device at issue in *Medtronic*,[122] and then by examining the statute under which the plaintiff brought suit.[123] Scalia questioned whether the plaintiff's claims allowed the state to place a requirement on the manufacturer that was "different from, or in addition to" the requirements of federal law.[124] By answering both these questions in the affirmative,[125] the Court found that holding Medtronic liable for breaches of state law would effectively require the company to

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116. Coveny & Sanford, *supra* note 110, at 398–99; Richard L. Cupp, Jr., *Preemption's Rise (and Bit of a Fall) as Products Liability Reform:* Wyeth, Riegel, Altria, *and the* Restatement (Third)*'s Prescription Product Design Defect Standard*, 74 BROOK. L. REV. 727, 729 (2009).

117. Coveny & Sanford, *supra* note 110, at 398; Cupp, *supra* note 116, at 729.

118. Cupp, *supra* note 116, at 728.

119. *Id.* at 740–41.

120. Riegel v. Medtronic, 552 U.S. 312, 316 (2008).

121. *Id.* at 316. The relevant statute reads:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement– (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (2006).

122. *Medtronic*, 552 U.S. at 321.

123. *Id.* at 323.

124. *Id.* (citing 21 U.S.C. § 360k(a) (2006)).

125. *Id.* at 312.

comply with state regulations, in addition to those imposed by federal law.[126]

2. *Wyeth v. Levine*

By contrast, the Court in *Wyeth v. Levine* established that federal drug regulations create a federal "floor" of regulation,[127] but do not preempt the enactment of more stringent requirements by state tort law or other means.[128] This case arose from a doctor's injection of Wyeth's drug, Phenergan, directly into a patient's vein, subsequently requiring the patient's arm to be amputated.[129] Although the drug warned against such practice, the plaintiff's counsel argued that the company should have featured a different kind of warning label explicitly stating that the drug should not be administered by this method.[130] This in turn triggered preemption concerns, as Wyeth argued that allowing the plaintiff's claims to proceed presented an unacceptable conflict with Congress' implied intent as manifested in the federal food and drug laws.[131] In support of this idea, Wyeth argued that the preamble to the FDCA (added by the FDA in 2006)[132] placed full discretion for the revision of drug labels solely within the FDA's purview.[133]

The press called *Wyeth* the "highest profile" and "most important business case of the term,"[134] and there was the perception that the Court would find in favor of Wyeth and a broad preemption scheme.[135] An outcome in favor of the drug manufacturers could have had the effect of negating almost all failure to warn claims, at least within the pharmaceutical industry.[136] Yet, the Court ultimately declined to accept the implicit

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126. *Id.* at 328–30.

127. Wyeth v. Levine, 555 U.S. 555, 577–78, 581 (2009).

128. *Id.* at 578, 581.

129. *Id.* at 559.

130. Levine v. Wyeth, 944 A.2d 179, 183 n.1 (Vt. 2006).

131. *Wyeth*, 555 U.S. at 573. The FDCA does not contain an explicit preemption notice; any claim for preemption would have to be made on an implicit theory. Coveny & Sanford, *supra* note 110, at 376.

132. *Wyeth*, 555 U.S. at 577.

133. *Supreme Court Asked to Consider Congressional Staff Report on Eve of Oral Argument in* Wyeth v. Levine, CROWELL & MORING (Nov. 5, 2008), http://www.crowell.com/newsevents/alertsnewsletters/all/1352087. Just days before the Court heard arguments in *Wyeth*, U.S. Representative Henry Waxman released a lengthy report suggesting that a conflict had arisen over the appropriateness of the preamble within the FDA, between top regulatory officials and agency appointments from within President George W. Bush's administration. *Id.*

134. Michael Doyle, *Supreme Court Appears Poised to Side with Drugmakers*, CHRON.COM (Nov. 3, 2008, 6:30 AM), http://www.chron.com/disp/story.mpl/nation/6092924.html; Adam Liptak, *Drug Label, Maimed Patient and Crucial Test for Justices*, N.Y. TIMES, Sept. 18, 2008, at A1.

135. *See, e.g.*, Doyle, *supra* note 134.

136. Coveny & Sanford, *supra* note 110, at 383; Anthony J. Sebok & Benjamin C. Zipursky, *The Upcoming Supreme Court Case of* Wyeth v. Levine *and the Preemption Temptation: Part*

preemption theory proposed by both the pharmaceutical companies and the FDA.[137]

The majority instead endorsed a more cooperative view of state and federal regulations, establishing that federal regulations generally establish a baseline without limiting regulations imposed by more demanding state laws.[138] In regard to the FDCA's 2006 preamble, the Court was unconvinced that an agency's "mere assertion that state law is an obstacle"[139] justified the kind of broad preemption sought.[140] Pointing to a long-standing presumption against preemption, the Court reiterated that the "powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[141] Here, Justice Stevens, writing for the majority, argued that it was not clear that such a purpose existed.[142] Indeed, the Court noted that, prior to the plaintiff's lawsuit, the FDA itself had actually appeared to be generally in favor of the "floor, not a ceiling"[143] approach, under which a state had the discretion to establish stricter regulatory laws if it so chose.[144] Moreover, Wyeth failed to convince the Court that any sufficient conflict existed that would make it impossible for the company to meet the standards of both federal and state law.[145] *Wyeth*, therefore, stands for the proposition that even areas which have long been the domain of the federal government do not per se preempt state action.[146]

Yet, Justice Breyer's concurrence and Justice Alito's dissent raised concerns over what might happen if state action interferes with the FDA's regulatory goals.[147] Breyer felt the need to emphasize that the instant case did not preclude administrative agency regulations "bearing the force of law"[148] from maintaining preemptive effect.[149] To this end, he suggested that there might sometimes be a need to preempt state regulations that

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One in a Two-Part Series, FINDLAW (Sept. 23, 2008), http://writ.news.findlaw.com/sebok/20080923.html.

137. *Wyeth*, 555 U.S. at 581.

138. *Id.* at 577–78, 581.

139. *Id.* at 576.

140. *Id.* at 576–77.

141. *Id.* at 565 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)) (internal quotation marks omitted).

142. *Id.* at 581.

143. *Wyeth*, 555 U.S. at 563 (quoting *Levine v. Wyeth*, 944 A, 2d 179, 185 (Vt. 2006)).

144. *Id.* at 577–78.

145. *Id.* at 581.

146. *Id.* at 581; Dan Schweitzer, *The Presumption Against Preemption Strikes Back: The Lessons of* Altria Group v. Good *and* Wyeth v. Levine, NAT'L ASS'N OF ATTORNEYS GEN., NAAGAZETTE, http://www.naag.org/the-presumption-against-preemption-strikes-back-the-lessons-of-altria-group-v.-good-and-wyeth-v.-levine.php (last visited Nov. 19, 2010).

147. *Wyeth*, 555 U.S. at 582 (Breyer, J., concurring); *id*. at 605–06 (Alito, J., dissenting).

148. *Id.* at 581 (Breyer, J., concurring) (quoting the majority at 580) (internal quotation marks omitted).

149. *Id.* at 581–82.

generate either excessive interference with the FDA's activities or excessive costs that would make the product inaccessible to people in need.[150] Alito argued more vigorously that the FDA's regulatory efforts over the years sufficed to preempt the action of the state,[151] and that a state jury judging a tort suit would hardly be able to make the same kinds of measured judgments that were demanded of the FDA.[152]

3. Application of the Modern Preemption Doctrine to Regulatory Settlements

Within the context of regulatory settlements, the preemption doctrine places at least some limitations on the substantive relief that a state can ask for and enforce. Given *Medtronic*, for instance, a settlement that attempted to regulate the marketing of certain medical devices governed by the explicit preemption statute would be unenforceable.[153]

Yet, because the Court explicitly rejected the FDA's argument that the FDCA presents both a "floor and a ceiling" for possible regulation,[154] it is harder to argue that the Vioxx and Bextra settlements are themselves preempted by federal regulatory law. As previously discussed, no explicit preemption clause exists within the FDCA,[155] meaning that *Medtronic* likely would not apply. Moreover, the Court's recent ruling in *Cuomo v. Clearinghouse*, granting considerable discretion to state law actions, makes an implied preemption claim more difficult.[156] With regard to Vioxx and Bextra, while the settlements were approved in federal court and take power from (secondarily) enforcing federal terms, they derive directly from state consumer protection law.[157] Since *Cuomo* affirms the state AG's right to pursue enforcement of such laws,[158] it would be difficult to make a preemption case on these facts.

Moreover, one commentator has noted that the terms of the AGs' settlements make clear efforts to avoid falling into the preemption trap.[159] This is evident by the fact that the terms of both settlements explicitly state that the settlement agreements are not intended to conflict with action that

150. *Id.* at 582.
151. *Id.* at 608–09 (Alito, J., dissenting).
152. *Id.* at 626.
153. *See, e.g.*, Riegel v. Medtronic, 552 U.S. 312, 323 (2008).
154. *Wyeth*, 555 U.S. at 573–75.
155. Coveny & Sanford, *supra* note 110, at 376.
156. *See generally* Cuomo v. Clearing House Ass'n, 557 U.S. 519 (2009) (holding that the mere fact that an agency has sole regulatory power to interpret a federal statute does not preempt a state AG's state law enforcement action against banks).
157. *See, e.g.*, Page, *supra* note 9, at 1207–11.
158. *See generally Cuomo*, 557 U.S. 519 (holding that the mere fact that an agency has sole regulatory power to interpret a federal statute does not preempt a state AG's state law enforcement action against banks).
159. MCDERMOTT, WILL & EMERY, *supra* note 34, at 2–3.

was either requested or prohibited by the FDA or the terms of the FDCA.[160] This implies that, should a conflict arise with a federal statute or long-standing FDA rule, the settlement would defer to the federal law.[161] *Wyeth* and *Cuomo*, however, would seem to grant the state considerable discretion in the absence of an explicit statement to the contrary.

Nonetheless, this is not to say that the possibility of preemption can be ruled out,[162] or that even a slight increase in the scope of settlement terms would create an unacceptable state-federal conflict.[163] As noted, both Justice Breyer's concurrence and Justice Alito's dissent in *Wyeth* made a point of indicating that there must still be limits to the realm of state action.[164] Even the majority opinion in *Wyeth* hinges much of its rejection of the preemption theory on the fact that state tort suits will do more good than harm to the federal regulatory scheme.[165] An actual demonstration to the contrary—that the results of litigation significantly interfere with the work of a federal agency, significantly raise costs of essential items for state citizens, or otherwise infringe upon a federal regulatory statute—might well be enough to preempt a regulatory settlement.

It also bears noting that, when reports of injuries caused by Vioxx and Bextra first surfaced, it was unclear whether state tort suits would be wholly preempted given the involvement of the FDA.[166] The feeling existed, particularly given the atmosphere before *Wyeth*, that the agency would attempt to "backdoor" preemption as a means of curtailing excessive tort liability.[167] This, of course, ultimately proved to be a nonissue.[168] In today's environment, however, where concern over corporate ties to the FDA seems to have lessened,[169] the courts might be more inclined than they were in *Wyeth* to grant an agency request to preempt state regulatory action.

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160. *See* Merck Stip. Judgment, *supra* note 8, at 5–6; Pfizer Stip. Judgment, *supra* note 8, at 5–6.

161. MCDERMOTT, WILL & EMERY, *supra* note 34, at 2–3.

162. *See* Gifford, *supra* note 9, at 951 (noting that state regulatory litigation actions raise valid preemption issues).

163. *See id.*

164. *Wyeth*, 555 U.S. at 582 (Breyer, J., concurring); *id*. at 605–06 (Alito, J., dissenting).

165. *See id.* at 574–78 (majority opinion).

166. *See* Jonathan V. O'Steen & Van O'Steen, *The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs*, 48 ARIZ. L. REV. 67, 92 (2006).

167. *Id.* at 92.

168. *See, e.g.*, Merck Stip. Judgment, *supra* note 8, at 11 (illustrating the fact that settling for $58 million was not challenged).

169. *See* Andrew Zajac, *Under Obama, a Reinvigorated FDA*, L.A. TIMES, Oct. 9, 2010, http://articles.latimes.com/2010/oct/09/nation/la-na-fda-enforce-20101010.

C. CONGRESSIONAL DELEGATION TO STATE AGS BY EXPLICIT GRANT

It is significant that in the wake of the intense conflict over preemption, Congress has actively sought to increase the role of the state AGs in the enforcement of federal law.[170] This appears to be a growing trend, and includes passing explicit grants of enforcement authority within new statutes,[171] amendments to existing statutes,[172] and proposed or pending legislation.[173] This authority has enabled state AGs to act as a layer of oversight at the federal level into a diverse array of areas, including enforcement of consumer protection, banking, and telemarketing laws.[174] Such explicit grants, however, allow the legislature to eschew the preemption debate by delineating clear cases where they wish to extend the power of the state AGs. By the same token, it is important to note that even these explicit causes of action contain significant limitations—primarily a notification requirement that state AGs alert the agency whose duty it typically is to enforce the federal statute the AG is considering acting under—and give the agency the opportunity to take over the action.[175]

One worthwhile question might be whether the increased use of congressional enforcement grants to the state AGs might preempt this kind of action. The argument would hinge on demonstrating a clear congressional preference for areas of federal litigation in which the state AGs are allowed to enforce federal law and areas where they are not. Such claims have not been litigated, however, and such an argument might require a broad and intensive analysis, not just of the statutes themselves, but of its relation to the federal regulatory scheme as a whole.

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170. *See, e.g.*, Consumer Product Safety Improvement Act, 15 U.S.C. § 2073(b)(1) (2008); Dodd-Frank Act § 1042, 124 Stat. 2012–14 (codified at 12 U.S.C. § 5552) (granting state AGs enforcement power).

171. *See, e.g.*, Consumer Product Safety Improvement Act § 2073(b)(1); Dodd-Frank Act § 1042, 124 Stat. 2012–14 (codified at 12 U.S.C. § 5552).

172. *See, e.g.*, Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d-5, *amended by* American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 13410(e), 123 Stat. 115, 271 (2009) (codified at 42 U.S.C. § 17938).

173. *See, e.g.*, Data Accountability and Trust Act (DATA Act) H.R. 2221, 111th Cong. § 4(c) (2009); FTC Reauthorization Bill of 2008, S. 2831, 110th Cong. § 11 (2008); American Clean Energy and Security Act of 2009, H.R. 2454, 111th Cong. § 334(b) (2009); Mortgage Reform and Anti-Predatory Lending Act, H.R. 1728, 111th Cong. § 219 (2009); Personal Data Privacy and Security Act, S. 1490, 112th Cong. § 318(a) (2009); Data Breach Notification Act, S. 139, 111th Cong. § 9(a) (2009).

174. *See, e.g.*, Consumer Product Safety Improvement Act § 2073(b)(1); Dodd-Frank Act § 1042, 124 Stat. 2012–14 (codified at 12 U.S.C. § 5552); Telemarketing and Consumer Fraud and Abuse Prevention Act, 15 U.S.C. § 6103(a) (1994).

175. *See, e.g.*, Consumer Product Safety Improvement Act § 2073(b)(1); Dodd-Frank Act § 1042, 124 Stat. 2012–14 (codified at 12 U.S.C. § 5552); Telemarketing and Consumer Fraud and Abuse Prevention Act 15 U.S.C. § 6103(a) (1994).

III. POLICY ISSUES WITH EMPOWERING STATE AGS WITH BROAD REGULATORY POWERS THROUGH SETTLEMENT

Even assuming that these kinds of settlements hold up to judicial scrutiny, the methods by which they are obtained, as well as the potential causes of action they give rise to, raise substantial policy issues. One such issue that may arise in any tort litigation by the states is one of disparate bargaining power within negotiations, which may in turn produce an unfair settlement.[176] Another issue is the political nature of state executives, which may spark the targeting of businesses based on visibility and the probability of a high payout rather than blameworthiness.[177] Finally, the contingency fee relationships formed by state AGs with private counsel in the course of litigation creates the possibility of private parties taking inappropriate control over the shape of public policy.[178]

A. COERCION

Litigation against a business creates a "nuisance value" that goes beyond the merits of a claim to the actual and potential costs of litigating a claim.[179] The business must therefore carefully weigh the costs of litigation against the possible risk-reward of proceeding with such a claim.[180] The magnitude of such risks increases in a class action tort suit.[181] In a products liability case, particularly where a substantial number of people have suffered harm, a manufacturer who elects to go to trial may very well hinge the future of the company on the decision of an unpredictable jury.[182] In instances of multistate litigation, an unfavorable verdict could result in the company being held liable for the injuries of millions of state citizens.[183] Moreover, such a result would inevitably lead to a slew of private plaintiffs' suits that may well bury the company in expenses.[184] Unsurprisingly, such calculations often require the prudent company seeking to meet its duty of care to settle rather than face such risks.[185]

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176. Gifford, *supra* note 9, at 944; Page, *supra* note 9, at 1201.

177. *See* Victor E. Schwartz & Christopher E. Appel, *The Plaintiffs' Bar's Covert Effort to Expand State Attorney General Federal Enforcement Power*, WASH. LEGAL FOUND. LEGAL BACKGROUNDER, July 10, 2009, at 4 (July 10, 2009), *available at* http://www.wlf.org/Upload/legalstudies/legalbackgrounder/071009Schwartz_LB.pdf.

178. *See id.*; Gifford, *supra* note 9, at 964.

179. David Rosenberg, *The Regulatory Advantage of Class Action*, *in* REGULATION THROUGH LITIGATION 244, 300–02 (W. Kip Viscusi ed., 2002).

180. *Id.*

181. *Id*.

182. Gifford, *supra* note 9, at 944.

183. Page, *supra* note 9, at 1201.

184. *Id.*

185. Gifford, *supra* note 9, at 944; Page, *supra* note 9, at 1201.

There is also an additional risk of damage done to the corporation through the court of public opinion.[186] Whether the everyday person will assign fault against a large corporation in favor of sympathetic clients, or whether the public will come to believe that individuals' injuries were the product of their own choices, is largely a matter of public relations.[187] Yet, corporate counsel's natural desire to control as much information as possible in the face of litigation may simultaneously impede public relations personnels' ability to do their jobs.[188] Merck, for its part, appears to have acted proactively in minimizing public opinion damage during its litigations over Vioxx.[189] Part of this strategy has involved fully litigating certain cases initiated before the settlement was reached, with considerable success.[190] Two such cases commenced by individual state AGs ended in resounding victories for Merck.[191]

Particularly within the pharmaceutical context, however, the risk of state settlement coercion cannot be overstated. The reason for this is that a pharmaceutical company's existence depends on continuing to receive payments from the federal healthcare system.[192] In 1998, the Department of Health and Human Services revised a rule to expand the authority of its Office of Inspector General to exclude pharmaceutical companies that have engaged in deceptive practices from the Medicare and Medicaid programs.[193] Given the vast percentage of revenue that pharmaceutical

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186. *See generally* Mark Herrmann & Kim Kumiega, *On Trial in the Courts of Law and Public Opinion: The Tension Between Legal and Public Relations Advice*, 28 LITIG. 29 (2002) (describing various vulnerabilities and strategies of corporate counsel and public relations personnel when faced with media attention sparked by litigation).

187. Larry Smith, *Media Strategies in Product Liability Crises*, 22 No. 9 OF COUNSEL 6 (2003).

188. *See* Hermann & Kumiega, *supra* note 186, at 29–30.

189. *See generally* Larry Smith, *Merck's Powerful Tactical Advantage in the Court of Public Opinion*, 25 No. 11 OF COUNSEL 12 (2006) (examining Merck's public relation strategy in the course of a 2006 Vioxx case).

190. *See* Berenson, *supra* note 6, at C10.

191. Press Release, Merck, Merck Wins Case Filed by Louisiana Attorney General Involving VIOXX® (June 29, 2010), http://www.merck.com/newsroom/news-release-archive/corporate/2010_0629.html. In 2009, a similar case brought by the Texas AG had been dismissed on summary judgment. Press Release, Merck, Merck Wins Summary Judgment in Texas Attorney General's Lawsuit Involving VIOXX® (Nov. 23, 2009), http://www.merck.com/newsroom/news-release-archive/corporate/2009_1123.html [hereinafter Merck Texas Press Release]. Texas took part in the multistate settlement after investigating claims under their Deceptive Trade Practices and Consumer Protection Act. *See* Merck Stip. Judgment, *supra* note 8, at 3. Yet, they continued to pursue claims under their state Medicaid Fraud Protection Act. Merck Texas Press Release, http://www.merck.com/newsroom/news-release-archive/corporate/2009_1123.html. Ten other state AGs' claims remain undecided. *See, e.g.*, *id.*

192. John E. Osborn, *Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information*, 10 YALE J. HEALTH POL'Y, L. & ETHICS 299, 328 (2010).

193. *See* Health Care Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting from Public Law 104-191, 63 Fed. Reg. 46,676, 46,679 (Sept. 2, 1998) (to be codified at 42 C.F.R. pt. 1000, 1001, 1002 & 1005).

companies derive from these federal programs, this rule virtually precludes a pharmaceutical company from taking the risk of setting foot into court in any case against the government.[194] If the offending company is willing to enter into a settlement, however, then that company "can reasonably expect that the [Office of Inspector General] will not exercise its discretion to exclude the company from continuing to receive federal reimbursement funds; [by contrast,] companies that challenge the government's allegations in court clearly put the company at risk of extinction . . . ."[195] For Merck or Pfizer to be cut off from receiving payments from the Medicare and Medicaid programs would likely mean their end.[196] Therefore, such a rule completely undermines any bargaining power that a company might have when trying to reach a settlement with state AGs. Moreover, it seems possible that new causes of action that follow from the settlement may create a circular effect, allowing the state AG to petition the court for more substantive terms to ensure enforcement of the existing settlements.

B. POLITICALLY TINGED LITIGATION

Critics of increasing state AGs' regulatory enforcement power often suggest that such grants lead to selective and politically biased litigation against corporations.[197] The position of a state AG remains, in virtually all states, a political one.[198] The nature of the position also guarantees that the

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> Just as nurses, home health aides, administrators and others who do not bill the programs directly for their services have been excluded over the years, we believe that untrustworthy manufacturers and suppliers of drugs, medical devices and durable medical equipment and other reimbursable items must be treated in a similar fashion.
>
> . . . .
>
> [T]he concern for protecting the programs from those who are untrustworthy applies to all those convicted of health care criminal offenses.

Id.

194. Osborn, *supra* note 192, at 328. "Indeed, it is often said that no sane company would ever challenge in court allegations that, if proven, would result in a felony conviction and certain exclusion." *Id.*

195. *Id.*

196. *See id.* It is interesting to note, however, that cutting a giant company, such as Pfizer, off from Medicaid might have just as devastating an effect on the U.S. healthcare system as it would on the corporation. *See* Drew Griffin & Andy Segal, *Feds Found Pfizer Too Big to Nail*, CNNHEALTH (Apr. 2, 2010), http://articles.cnn.com/2010-04-02/health/pfizer.bextra_1_bextra-pfizer-and-pharmacia-generic-drugs?_s=PM:HEALTH.

197. *See* Schwartz & Appel, *supra* note 177, at 4.

198. *About NAAG*, *supra* note 25.

> The Attorney General is popularly elected in 43 states, as well as in Guam, and is appointed by the governor in five states (Alaska, Hawaii, New Hampshire, New Jersey, and Wyoming) and in the four jurisdictions of American Samoa, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands. In Maine, the Attorney General is selected by secret ballot of the legislature and in Tennessee, by the state Supreme Court. In the

state AG essentially has exclusive say on whether to sue a particular company on behalf of the citizenry.[199] Commentators have noted that this may lead some state AGs to pursue high profile and politically appealing cases for the sake of public appearances and future political gain rather than public welfare.[200] At the same time, this unilateral disparity in prosecution may vastly shape a state's economic outlook by targeting and imposing new burdens on some industries and manufacturers but not others.[201]

C. THE IMPROPRIETY OF INVOLVING OUTSIDE COUNSEL WITH STATE LITIGATION

Critics also argue that increased enforcement authority will allow the plaintiffs' bar to both inappropriately profit from and influence state litigation via contingency fee arrangements with state offices.[202] Such arrangements stipulate that private attorneys will work in conjunction with the state for no charge unless the litigation proves successful.[203] In the event of a monetary award, however, the private counsel receives a predetermined percentage of that award.[204] It is generally accepted that, without such contractual arrangements, the state AGs' offices would generally be unable to litigate against private corporate defendants with any great success.[205]

Yet, the process by which such attorneys are chosen may be quite lax, particularly when weighed against the potential value of fees at stake.[206] In some cases, little to no formal bidding process may occur.[207] Regardless of any process, it also appears that political allies or confidants of the state AG often end up winning the contract.[208] This most famously appeared as an issue in the states' tobacco litigation,[209] where around one hundred firms had primarily worked on a contingency fee basis for rates that came to as much as 33 percent of the eventual award.[210] Most of these firms would reap awards in the millions of dollars,[211] and a select few would even exceed the billion-dollar mark.[212] Recognizing that their constituents and

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District of Columbia, the Mayor appoints the Attorney General whose powers and duties are similar to those of the Attorneys General of the states and jurisdictions.

Id.

199. Gifford, *supra* note 9, at 938–39.
200. *See* Schwartz & Appel, *supra* note 177, at 4.
201. Gifford, *supra* note 9, at 938–39.
202. *See id.* at 964; Schwartz & Appel, *supra* note 177, at 2, 4.
203. *See* DERTHICK, *supra* note 12, at 80.
204. *Id.*
205. Gifford, *supra* note 9, at 964.
206. *See* Schwartz & Appel, *supra* note 177, at 2.
207. *See id.* at 2.
208. *See id.*
209. DERTHICK, *supra* note 12, at 192.
210. *Id.*
211. *Id.*
212. *Id.*

legislature might object to such astronomical numbers, which would eventually be paid by the consumer,[213] the state AGs required the tobacco companies to settle the attorney's fees themselves through either arbitration or direct agreements with the firms.[214] The end result was that no reliable information was ever obtained that would enable calculation of a reliable total for fees,[215] yet some announcements led to harsh criticism from professionals who felt that the figures and contract terms constituted violations of legal ethics.[216]

The more disturbing issue developing from these contracts is the degree to which the state officials' decision to litigate may be influenced by their relationships with these private attorneys.[217] One commentator writes that "private plaintiff's firms routinely . . . lobby state attorneys general and urge them to litigate against one industry or another."[218] This was a facet of the tobacco litigation, where AGs "often" brought in private counsel that had been politically supportive in the past.[219] Such reports reinforce the fear that expanding the ability to bring suit against a given corporation will open up litigation based on local politics and the appealing target of a fat wallet rather than actual blameworthiness.[220]

D. COSTS AND THE DISTINCTION BETWEEN TOBACCO AND PHARMACEUTICAL LITIGATION

Fundamentally, it is undeniable that the proliferation of regulatory settlements grants power to the state AGs to change how companies do business.[221] Certainly, executively constructed regulation places the targeted company at a competitive disadvantage. The ultimate cost to corporations of such regulation, broadly applied, will likely be virtually impossible to quantify, just as it is within the larger federal scheme.[222]

Yet, the end results of such unchecked executive action will be increased economic costs for customers, who will foot the bill for monetary damages, litigation expenses, and the costs of complying with the new settlement regulations.[223] Because tobacco is a product that people are viewed as having the choice of using, there may be fewer qualms about

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213. *Id.*
214. *Id.*
215. *Id.* at 193.
216. *Id.* at 194.
217. *See* Gifford, *supra* note 9, at 966.
218. *See id.*
219. DERTHICK, *supra* note 12, at 198. The author cites the story of Joseph J. Jamail, who "claimed that Attorney General Morales [of Texas] had asked him for $1 million in 1996 to discuss the possibility of his hiring Jamail to head the state's legal team." *Id.*
220. *See* Schwartz & Appel, *supra* note 177, at 4.
221. *See, e.g.*, Traylor, *supra* note 19, at 1100–01.
222. *See, e.g.*, Clyde Wayne Crews, *Ten Thousand Commandments: An Annual Snapshot of the Federal Regulatory State*, COMPETITIVE ENTER. INST. (July 10, 2008), http://cei.org/node/20855.
223. *See, e.g.*, Traylor, *supra* note 19, at 1081.

requiring the buyer to pay a little extra, particularly if some of those buyers will likely later incur high costs to the state taxpayers as a result of tobacco-related illnesses. But this argument is inapplicable to pharmaceutical litigation, where consumers may have no alternative to taking already costly medication.

This distinction between tobacco and the pharmaceutical industries illustrates an important point in thinking about regulatory settlements. The constitutionality of such regulation has—and continues to be[224]—criticized at great length in the context of the tobacco MSA.[225] By contrast, criticism of the Vioxx and Bextra settlements (at least in terms of constitutionality) has been less vociferous.[226] Theoretically, this might be due to the enormous size and scope of the tobacco MSA—a settlement that managed to reshape an entire area of commerce.[227] It may also be on account of what the Supreme Court has recognized as the unique cultural place of tobacco within American society.[228] Yet, the Vioxx and Bextra settlements demonstrate a willingness by state AGs to capitalize on the promise of the tobacco MSA by expanding these kinds of broad, multistate settlements into new areas. Even assuming the legitimacy of the MSA, the dangers presented by such regulation through settlement, combined with unaddressed constitutional issues, illustrate the need for congressional control.

IV. BUILDING A NUANCED ROLE FOR STATE AGS INTO OUR FEDERAL FRAMEWORK

Ultimately, the goal should be to integrate the state AGs into the existing federal regulatory structure, rather than completely marginalize their power. It would be foolish to say that the AGs' success in reaping rewards for their state, even in the face of legislative and agency foot-dragging,[229] should be completely overlooked. Yet, as a free-floating entity targeting corporate actors based on public relations or political bias, it seems clear that the state AGs may do more harm than good. One solution to the problem might be to respond to the growing power of the state

224. On November 8, 2010, the Competitive Enterprise Institute filed a petition for writ of certiorari review with the Supreme Court, challenging the constitutionality of the MSA under the Compact Clause. Christine Hall, *Lawsuit Against Government-Tobacco Cartel Brought to Supreme Court*, COMPETITIVE ENTER. INST. (Nov. 9, 2010), http://cei.org/news-releases/lawsuit-against-government-tobacco-cartel-brought-supreme-court. The Court denied this petition on March 7, 2011. S&M Brands, Inc. v. Caldwell, 614 F.3d 172 (5th Cir. 2010), *cert. denied*, 131 S. Ct. 1601 (2011).

225. *See, e.g.*, DERTHICK, *supra* note 12, at 192; VISCUSI, *supra* note 85, at 217.

226. *See generally* Page, *supra* note 9 (arguing that regulation of off-label marketing would be better addressed through FDA reorganization rather than Vioxx- and Bextra-type litigation).

227. *See, e.g.*, Traylor, *supra* note 19, at 1085.

228. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159–60 (2000).

229. *See, e.g.*, Page, *supra* note 9, at 1204.

executive by encouraging legislatures to constrict the power of the AG's office. While such measures might ultimately restrict unfair regulatory litigation, such proposals would fail to capitalize on the potential of having a nationally engaged state AG's office.

Instead, Congress should address the issue of state enforcement power by means of explicit grants of authority within federal law. This kind of integrated approach would provide a layer of oversight to inactive federal regulatory agencies, while simultaneously placing limitations on the most egregious examples of overreaching by the states through the separation of powers doctrine. An appropriate amendment to the FDCA and other relevant acts, clearly delineating the extent to which the state AGs may pursue enforcement actions under federal law, would eliminate the need for the terms included in the Vioxx and Bextra settlements. At the same time, Congress can reap the benefits of an external check on lackadaisical agencies and negligent manufacturers, while also prescribing limitations to avoid potential policy issues previously described. As discussed earlier, such explicit grants of authority already exist in a vast number of federal statutes.[230] Expanding these grants into new areas of regulatory law would eliminate the horizontal and vertical separation of powers issues, described in Part II of this note, by requiring the federal legislature to devote their full and measured policy judgments in defining the realm of state enforcement authority. Such a judgment would also enable Congress to impose reasonable limits on the state AGs' role, including requiring notice of actions to the appropriate agency and potentially placing conditions on the use of contingency fee arrangements.

Of course, such action will not remedy all the issues inherent with litigation by regulation. But it does place the issue before Congress to review and render its best judgment on how to balance the good and bad of such litigation. An appropriate middle ground could serve to maximize the efficiency of regulation, with a minimal impact on business.

CONCLUSION

In the context of regulation by settlement, a regulatory scheme with potentially drastic implications is crafted away from federal agencies or state legislatures.[231] In many circumstances, there may well be no need to involve such additional parties. There are times, however, when the federalist structure of our government and the policy concerns described in Part III of this note may demand the involvement of others—federal regulators or the elected branches.

While addressed here primarily in the context of public health concerns, the potential scope of settlement-driven regulation is limited only by the

230. *See supra* text accompanying note 23.
231. *See* Gifford, *supra* note 9, at 914.

willingness of courts to bless such agreements. The templates of Vioxx and Bextra, and by proxy the Tobacco MSA, could well expand across a wide range of industries—from environmental offenders to the continuously developing markets of the internet. Most recently, the issue has been implicated by the national settlement reached between major banks, forty-nine state AGs, and the federal government over the home mortgage crisis.[232] This approach allows the states to act as a check against federal inaction, while ensuring that state settlements do not give rise to a convoluted patchwork of regulation. This kind of integration therefore presents the most balanced and desirable outcome.

Warren Allen[*]

232. *National Mortgage Settlement*, http://www.nationalmortgagesettlement.com/ (last visited Mar. 29, 2012).

[*] B.S., Boston University, 2008; J.D. candidate, Brooklyn Law School, 2012. Special thanks to my parents for their love and support. I would also like to thank Amy Craiger and Janine Stanisz, as well as the entire Journal staff, for their remarkable care and patience in editing this note.