

NFIB V. SEBELIUS AND THE RIGHT TO HEALTH CARE: GOVERNMENT’S OBLIGATION TO PROVIDE FOR THE HEALTH, SAFETY, AND WELFARE OF ITS CITIZENS

*Jack M. Beermann**

INTRODUCTION	277
I. POSITIVE CONSTITUTIONAL RIGHTS AND <i>DeSHANEY</i> ...	280
II. AFFORDABLE CARE AND POSITIVE CONSTITUTIONAL RIGHTS	283
III. THE PROXIMITY AMENDMENT AND INTEREST-GROUP EXCEPTIONS TO HEALTH AND SAFETY REGULATION	290
A. Social-Welfare Programs and Safety Regulation...	290
B. Regulation of Vitamins and Supplements	293
C. Health and Safety Exceptionalism and the Constitution	297
CONCLUSION	303

INTRODUCTION

Among the most important roles played by government in contemporary society is ensuring that all people have access to health care and are protected from unsafe products and environmental conditions. The average person encounters numerous potentially dangerous situations each and every day, involving food, water, medications, vehicles, traffic, electronic equipment, machinery, clothing, and, of course, the air. In recent decades, pervasive government regulation in all of these areas and others has created an expectation of a minimal level of safety, provided or at least ensured by the government. Everyone needs health care, and government plays a significant role in making sure that even those who cannot afford to pay for it have access to at least the bare minimum necessary care.

* Professor of Law and Harry Elwood Warren Scholar, Boston University School of Law. Thanks to Bill Marshall, David Seipp, Wendy Gordon, Ken Simons, Gary Lawson, Jim Fleming, Abby Moncrieff, Paul Gugliuzza, Linda McClain, Colin Diver, Pnina Lahav, and Kathy Zeiler for comments and suggestions.

Despite government's pervasive role in ensuring public safety and access to health care, the U.S. Supreme Court has firmly rejected government liability under the federal Constitution for failing to keep safety-related promises, in language that rejects a constitutional basis for any supposed right to health care.¹ The Court explained that the Constitution "forbids the State itself to deprive individuals of life, liberty, or property without 'due process of law,' but its language cannot fairly be extended to impose an affirmative obligation on the State to ensure that those interests do not come to harm through other means."² Thus, as the law currently stands, any government liability for failing to provide access to health care or to protect people from danger would have to arise from state law or from sub-constitutional law such as tort-claims legislation or other statutes.

Although there is no reason to believe that the Supreme Court would retreat from its hesitancy to recognize positive rights under the Constitution, the Court's reasoning in the portion of its opinion in *National Federation of Independent Business v. Sebelius*³ rejecting the Patient Protection and Affordable Care Act's⁴ (PPACA's) expansion of state Medicaid programs is in strong tension with the absence of positive rights under the Constitution. This may seem odd, since in that decision the Court rejected an effort by the other branches of the federal government to provide health care to a greater number of people, but the decision's reasoning makes no sense if it does not recognize a right to health care against the states.⁵ The Court invalidated the PPACA's expansion of Medicaid because it found that the law's requirement that states expand Medicaid coverage or lose all of their federal Medicaid funding was coercive, and thus that Congress could not condition continued funding on compliance with the PPACA.⁶ In other words, it was unrealistic to expect states to repeal their Medicaid programs in order to avoid additional obligations imposed by the PPACA. Government provision of health care for those unable to afford it on their own is so central to the current role of government that placing a new burdensome condition on continued receipt of vital federal support for the program is inherently coercive.

1. See *DeShaney v. Winnebago Cnty. Dep't. of Soc. Servs.*, 489 U.S. 189 (1989). This decision is discussed in Part I below. See *infra* notes 14–15 and accompanying text.

2. *DeShaney*, 489 U.S. at 195.

3. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012).

4. Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010) (codified as amended in scattered sections of the U.S. Code).

5. See *infra* notes 40–55 and accompanying text.

6. See *infra* notes 40–55 and accompanying text.

In addition to government's felt obligation to ensure access to health care, pervasive health and safety regulation indicates that government feels a similar obligation to protect people from danger through safety and environmental laws. However, the proliferation of legislation procured by special-interest groups, which irrationally shields these groups from regulatory control, threatens this obligation. By "irrationally," I mean that no sound public policy basis justifies the exemption, but rather the exemption arises from raw political favoritism due to lobbying, campaign support, etc. The principal example of this sort of legislation used in this article is the 1976 Proxmire Amendment, which prohibits the U.S. Food and Drug Administration (FDA) from limiting the potency of vitamins and restrains the agency from regulating vitamins and food supplements generally.⁷

Under current constitutional standards, statutes such as the Proxmire Amendment are viewed as economic regulation and are reviewed under the very deferential "rational basis" standard.⁸ Statutes like this are almost always upheld because Congress provides the public with a rational-sounding, public-interest justification for its legislation, even if the true reasons for drafting such legislation have more to do with providing benefits to key political supporters.⁹ Regardless of whether a court would ever hold a statute like the Proxmire Amendment unconstitutional, in today's environment—in which the average person is fundamentally dependent on government intervention in order to maintain his or her health, safety, and welfare—such statutes are an abdication of Congress's responsibility to the public and a betrayal of those who depend on government in myriad ways every day.

Part I of this Article contains a general discussion of positive constitutional rights doctrine. Part II discusses how the logic of the decision in *National Federation of Independent Business v. Sebelius*

7. See W. Steven Pray, *The FDA, Vitamins, and the Dietary Supplement Industry*, U.S. PHARMACIST (2008), <http://www.uspharmacist.com/content/d/consult%20your%20pharmacist/c/11002/>. The Act was sponsored by Senator William Proxmire, who "became the standard bearer for the supplement industry." *Id.*

8. See *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313 (1993); *Nebbia v. New York*, 291 U.S. 502, 516 (1934). Two members of the U.S. Court of Appeals for the D.C. Circuit recently argued that scrutiny of economic regulation should be heightened on the ground that such regulation is often a barely disguised transfer of resources between competing interests. See *Hettinga v. United States*, 677 F.3d 471, 480–83 (D.C. Cir. 2012) (Sentelle, C.J., and Brown, J., concurring).

9. Cf. Jonathan Macey, *Promoting Public-Regarding Legislation Through Statutory Interpretation: An Interest Group Model*, 86 COLUM. L. REV. 223 (1986). Macey's article explains very clearly and succinctly the way interest groups procure legislation and undercut the public interest. He acknowledges that courts are unlikely to hold such statutes unconstitutional and thus suggests using statutory construction to protect the public interest.

assumes an affirmative government duty to ensuring access to health care. Part III addresses how statutes like the Proxmire Amendment and other interest-group exceptions to health and safety regulation are inconsistent with government's obligation to provide for the health, safety, and welfare of the public.

I.

POSITIVE CONSTITUTIONAL RIGHTS AND *DESHANEY*

Much ink has been spilled on the question whether government has or should have a constitutional duty to provide for people's basic needs, such as food, clothing, shelter, medical care, and education.¹⁰ While positive rights in a few important areas such as education, environmental regulation, and labor law have been enshrined in state constitutions,¹¹ more general positive rights to health, safety, and welfare have not been recognized in the United States.¹² By and large, the

10. A good starting point for considering positive constitutional rights in U.S. federal constitutional law is the work of Frank Michelman. See Frank I. Michelman, *In Pursuit of Constitutional Welfare Rights: One View of Rawls' Theory of Justice*, 121 U. PA. L. REV. 962 (1973); Frank I. Michelman, *The Supreme Court, 1968 Term—Foreword: On Protecting the Poor Through the Fourteenth Amendment*, 83 HARV. L. REV. 7 (1969). For a more comprehensive, globally focused view, see KATHARINE G. YOUNG, *CONSTITUTING ECONOMIC AND SOCIAL RIGHTS* (2012). Discussion of positive rights in other countries is beyond the scope of this Article.

11. See EMILY J. ZACKIN, *LOOKING FOR RIGHTS IN ALL THE WRONG PLACES: WHY STATE CONSTITUTIONS CONTAIN AMERICA'S POSITIVE RIGHTS* (2013) (discussing educational and environmental provisions in state constitutions); see also, e.g., ILL. CONST. art. X, § 1 ("The State shall provide for an efficient system of high quality public educational institutions and services. Education in public schools through the secondary level shall be free. There may be such other free education as the General Assembly provides by law. The State has the primary responsibility for financing the system of public education."); MONT. CONST. art. XII, § 2, cl. 2 ("A maximum period of 8 hours is a regular day's work in all industries and employment except agriculture and stock raising. The legislature may change this maximum period to promote the general welfare."); PA. CONST. art. I, § 27 ("The people have a right to clean air, pure water, and to the preservation of the natural, scenic, historic and esthetic values of the environment. Pennsylvania's public natural resources are the common property of all the people, including generations yet to come. As trustee of these resources, the Commonwealth shall conserve and maintain them for the benefit of all the people."). But see ZACKIN, *supra*, at 131 (discussing how the Montana provision originally allowed only reductions in the number of hours constituting a "regular day's work"). This Article's focus on the federal constitutional implications of the Court's reasons for striking down the PPACA's expansion of Medicaid is not meant to minimize the importance of state constitutions and state programs to comprehending government's role in the United States.

12. Interestingly, Ed Rubin has claimed that vehement opposition to the PPACA has been inspired at least in part by the fear that the law's passage is a step toward the recognition of positive constitutional rights in the United States. See Edward Rubin, *The Affordable Care Act, the Constitutional Meaning of Statutes, and the Emerging Doctrine of Positive Constitutional Rights*, 53 WM. & MARY L. REV. 1639, 1643

expansion of the welfare and regulatory state in the developed world is viewed in the United States as a matter of legislative largesse rather than constitutional right.¹³

The U.S. Supreme Court has rejected the notion of a federal positive right to government protection or services. In the well-known *DeShaney* decision, the Court came down firmly against reading the federal Constitution to create positive rights. Young Joshua DeShaney was severely injured by his custodial father despite active monitoring for child abuse by the Winnebago County Department of Social Services. In ruling on a substantive due process claim brought against the department, the Court stated that “nothing in the language of the Due Process Clause itself requires the State to protect the life, liberty, and property of its citizens against invasion by private actors. The Clause is phrased as a limitation on the State’s power to act, not as a guarantee of certain minimal levels of safety and security.”¹⁴ Although *DeShaney* could be read narrowly to apply only to protection from private violence, the opinion is widely understood to foreclose the recognition of positive constitutional rights under the Constitution.¹⁵

Of course, an absence of positive rights under the Constitution does not mean that legislatures in the United States have not created extensive social welfare and public-safety programs. These programs are a testament to a widely shared conception of the role of government. Social welfare programs demonstrate the understanding that government has an important role to play in providing for basic human needs, whether motivated by an equality norm¹⁶ or a justice norm.¹⁷

(2012). I do not necessarily disagree with him, but the lesson I draw from the Supreme Court’s invalidation of the Act’s Medicaid expansion is somewhat different from Rubin’s point.

13. Ed Rubin’s article offers the tantalizing thesis that legislators engage in constitutional interpretation when they create social welfare programs, and that statutes like the PPACA are best understood as legislative recognition of a constitutional duty to provide the services included in such programs. *Id.* at 1694–1701.

14. *DeShaney v. Winnebago Cnty. Dep’t of Soc. Servs.*, 489 U.S. 189, 195 (1989).

15. See Susan Bandes, *The Negative Constitution: A Critique*, 88 MICH. L. REV. 2271, 2272–73 (1990). In addition to *DeShaney*, Professor Bandes discusses *Webster v. Reproductive Health Services*, 492 U.S. 490 (1989). In *Webster*, the Supreme Court cited *DeShaney* as support for its decision to uphold restrictions on public provision of abortion services. The *Webster* Court quoted *DeShaney*’s key language: “our cases have recognized that the Due Process Clauses generally confer no affirmative right to governmental aid, even where such aid may be necessary to secure life, liberty, or property interests of which the government itself may not deprive the individual.” *Webster*, 492 U.S. at 507 (quoting *DeShaney*, 489 U.S. at 196).

16. See JOHN RAWLS, A THEORY OF JUSTICE 14–15 (1971) (“[S]ocial and economic inequalities, for example inequalities of wealth and authority, are just only if they result in compensating benefits for everyone, and in particular for the least advantaged members of society.”).

Public-safety programs, such as food-safety regulation and prescription drug testing, demonstrate government's role in ensuring public safety, whether driven by humanitarian values or the importance of product safety assurances to the functioning of the market. In developed democracies, governments that fail to provide sufficient social welfare programs or adequate public safety regulation would have difficulty staying in power.

A country's "constitution" is not simply a piece of paper that spells out its governmental structure and grants rights to the public. Rather, an evaluation of the "Constitution" of the United States should mean examining the entire apparatus of governance, and certainly should not be confined to the text of the document adopted in 1789 (with amendments) and court decisions that purport to interpret that text.¹⁸ A holistic understanding of government in the United States reveals that, as is the case in many other developed countries, providing for the health, safety, and welfare of citizens is among the primary obligations of government. These obligations are so well established that they should be thought of as constitutional in character.

One further point of limitation is in order. The positive right to governmental protection discussed in this Article may not apply to all governments at all times. The rights discussed here are most common in comparatively wealthy, relatively developed democracies where governments have the resources to provide for their citizens' health, safety, and welfare, and in which the people demand such protection. At lesser stages of economic or political development, or in radically different social arrangements, a different conception of the role of government may exist, and it would not be appropriate to measure those societies by the standards developed here.¹⁹ Although it is hard to imagine a society with a government that has the capacity to implement these standards but which nonetheless takes no responsibility for providing health care, or where irrational interest group objections to health and safety programs were deemed appropriate by some cognizable standard, absent a positive right to health and safety programs in their own right, the reasons that could justify condemning these alter-

17. See J. Donald Moon, *The Moral Basis of the Democratic Welfare State* (discussing non-equality-based arguments in support of state provision of welfare), in *DEMOCRACY AND THE WELFARE STATE* 27, 27–52 (Amy Gutmann ed., 1988).

18. For discussion of a similar theory, see ROBERT A. DAHL, *HOW DEMOCRATIC IS THE AMERICAN CONSTITUTION?* 41–73 (2d ed. 2003) (analyzing the structures that comprise the American constitutional system).

19. Cf. JOHN RAWLS, *POLITICAL LIBERALISM* (1993) (explaining that his theory of justice applies in some, but not all, societies).

native situations would necessarily be different from those advocated here.

II.

AFFORDABLE CARE AND POSITIVE CONSTITUTIONAL RIGHTS

The more than eleven million words of the PPACA can be portrayed as instituting, among many others, three major reforms related to the provision of health care. First, to encourage everyone who can afford health insurance to purchase it, the Act imposes a tax penalty on individuals without health insurance.²⁰ Second, the Act facilitates the creation of health-insurance markets with subsidies for lower-income individuals and families.²¹ Third, the Act requires states to substantially expand eligibility for Medicaid, the state-administered, federally subsidized government health-insurance program people for with incomes below 130% of the federal poverty level.²² Opponents of the Act challenged many of its provisions.²³ Although before *National Federation of Independent Business* was decided, most public attention was focused on the requirement that individuals purchase health insurance,²⁴ the Supreme Court upheld the individual mandate but struck down the mandatory expansion of Medicaid eligibility.²⁵

Whether Congress exceeded its power under the Commerce Clause when it required millions of Americans to purchase health insurance, and whether this mandate was nonetheless sustainable under Congress's power to tax and spend for the general welfare, are questions beyond the scope of this Article.²⁶ What is important to this Article is the Court's basis for striking down the expansion of Medicaid eligibility. The Court found that Congress had exceeded its power under the Spending Clause because states had no real choice but to

20. 26 U.S.C. § 5000A (2013).

21. See *Health Insurance Marketplace*, HEALTHCARE.GOV, <http://www.hhs.gov/healthcare/insurance/index.html> (last visited Mar. 20, 2015).

22. See *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2581–82 (2012).

23. See *id.* at 2577.

24. See Arthur J. Baker, Note, *Fundamental Mismatch: The Improper Integration of Individual Liberty Rights into Commerce Clause Analysis of the Patient Protection and Affordable Care Act*, 66 U. MIAMI L. REV. 259, 260 (2011) (“Even though the PPACA faces challenges on a number of legal grounds, the one drawing the greatest amount of public attention centers on the requirement—popularly known as the ‘individual mandate’—that most Americans purchase health insurance.” (footnote omitted)).

25. See *Nat'l Fed'n of Indep. Bus.*, 132 S. Ct. at 2606–07.

26. See *id.* at 2591, 2600.

comply with Congress's wish to expand Medicaid.²⁷ The chain of reasoning that led to this conclusion is described below.

Article I, Section 8, Clause 1 of the Constitution grants Congress broad powers to tax and spend, providing, "The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States."²⁸ The breadth of the power to spend is captured in Congress's power to "provide for the . . . general Welfare of the United States."²⁹ It has long been understood that this power is not limited by the enumeration of powers that follows in the remainder of Article I, Section 8.³⁰ In other words, Congress may appropriate federal funds to pursue its conception of the general welfare even if it lacks constitutional authority to regulate pursuant to that selfsame conception.³¹

Congress can use its spending power to go beyond the Constitution's enumeration of congressional power in two ways. First, it can engage in pure spending activity.³² For example, even if Congress lacks an enumerated power over education, it could use federal funds to establish a federal university system or even a federal system of secondary education. Second, Congress can make federal funds available with strings attached—strings that it might not otherwise use directly—to compel states to act according to its wishes.³³ For example,

27. *Id.* at 2603–07.

28. U.S. CONST. art. I, § 8, cl. 1.

29. *Id.*

30. *See* *South Dakota v. Dole*, 483 U.S. 203 (1987) (recognizing that the spending power is not confined to advancing Congress's constitutionally enumerated powers); *see also* *United States v. Butler*, 297 U.S. 1 (1936).

31. *See Dole*, 483 U.S. at 206; *see also Butler*, 297 U.S. at 65.

32. For example, the federal government spends federal funds directly on federal activities such as the operation of the National Park Service and the Environmental Protection Agency. *See* Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. No. 113-235, div. F, tit. 1, 128 Stat. 2130, 2402 ("For expenses necessary for the management, operation, and maintenance of areas and facilities administered by the National Park Service and for the general administration of the National Park Service, \$2,275,773,000, of which \$9,923,000 for planning and interagency coordination in support of Everglades restoration and \$81,961,000 for maintenance, repair, or rehabilitation projects for constructed assets shall remain available until September 30, 2016."); *id.* at tit. 2, 128 Stat. at 2422 ("For environmental programs and management, including necessary expenses, not otherwise provided for . . . \$2,613,679,000, to remain available until September 30, 2016.").

33. *See Dole*, 483 U.S. at 209 (upholding a federal statute conditioning portions of federal highway funds on state enactment of twenty-one-year-old drinking age limits, even though federal government might not have power to impose a twenty-one-year-old drinking age as substantive legislation).

Congress has provided funding for family-planning clinics on the condition that they not counsel their patients on the use of abortion as a method of family planning, and the Supreme Court has upheld this condition, even though it is clear that Congress lacks the power to directly prohibit abortion counseling.³⁴

The most controversial use of conditions on the expenditure of federal funds occurs when federal money is provided to states on the condition that the states follow federal law in their use of the funds. Two well-known examples of this involve the withholding of a portion of federal highway funds from states unless they enacted the fifty-five-mile-per-hour speed limit and the twenty-one-year-old drinking age.³⁵ This is how the PPACA's Medicaid expansion was supposed to be accomplished.³⁶ Medicaid is one of many federal-state cooperative programs through which the federal government provides funding for a program that is to be administered by the states.³⁷ These programs present a double threat to federalism norms because not only do they allow the federal government to regulate beyond Congress's enumerated powers, but they also allow Congress to enlist state governments to administer federal programs. In recent decades, the Court has found this to be contrary to federalism norms if federal funds are not involved.³⁸ In the PPACA, Congress conditioned continued federal Medicaid funding to states on the condition that the states expand their Medicaid programs.³⁹ The federal government would pay for one hundred percent of the cost of expansion for the first three years, and ninety percent of the cost thereafter.⁴⁰

Due to federalism concerns, the Supreme Court has limited Congress's ability to place conditions on state receipt of federal funds by holding that these conditions must satisfy five requirements.⁴¹ The

34. See *Rust v. Sullivan*, 500 U.S. 173 (1991).

35. See National Minimum Drinking Age Act of 1984, Pub. L. No. 98-363, § 6(a), 98 Stat. 437; Emergency Highway Energy Conservation Act of 1974, Pub. L. No. 93-239, 87 Stat. 1046.

36. See *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2601 (2012).

37. See generally Kate Stith, *Congress' Power of the Purse*, 97 *YALE L.J.* 1343 (1989).

38. The Supreme Court created the anti-commandeering doctrine in *New York v. United States*, 505 U.S. 144 (1992), in which the Court declared that "[t]he Federal Government may not compel the States to enact or administer a federal regulatory program." *Id.* at 188. The doctrine was subsequently applied in *Printz v. United States*, 521 U.S. 898 (1997).

39. *Nat'l Fed'n of Indep. Bus.*, 132 S. Ct. at 2600–01.

40. *Id.* at 2601 (citing 42 U.S.C. § 1396d(y)(1)).

41. *South Dakota v. Dole*, 483 U.S. 203, 207–08, 211 (1987). See generally Mitchell N. Berman, *Coercion, Compulsion, and the Medicaid Expansion: A Study in the Doctrine of Unconstitutional Conditions*, 91 *TEX. L. REV.* 1283 (2013) (providing an

limitations are as follows: (1) the spending must be for the general welfare; (2) the condition must be clear so that the state knows what obligations it assumes when it accepts federal funds; (3) the condition must be related to the program for which funds are provided; (4) the condition itself may not be unconstitutional, for example the government could not require that a state impose cruel and unusual punishments for a particular crime; (5) the state must not be coerced into accepting the condition. This final condition turned out to be decisive in the PPACA litigation because unlike prior conditions, which withdrew a small proportion of a program's funding for failure to comply with the condition, the PPACA provided that states that failed to expand their Medicaid programs in compliance with the Act would lose all of their federal Medicaid funding, which is an enormous amount of money.⁴² The Court, in an opinion by Chief Justice Roberts, found that the federal government figuratively had placed "a gun to the head" of the states, leaving them no choice but to accede to the expansion of Medicaid and the increased costs that expansion would entail.⁴³

While this may be factually correct, it should be deemed legally irrelevant because the majority of the Court could not deny, as Justice Ginsburg suggested in dissent, that Congress remains free to repeal the entire Medicaid program and reenact it with the increased coverage required by the PPACA.⁴⁴ But more important for present purposes,

overview of the unconstitutional conditions doctrine as established by the *Dole* Court and examining this doctrine in connection with the Supreme Court's decision in *National Federation of Independent Business v. Sebelius*).

42. *Nat'l Fed'n of Indep. Bus.*, 132 S. Ct. at 2604–05. The Court also supported its decision by characterizing the Medicaid expansion as a new program rather than an amendment to the existing program. *Id.* at 2605–06. This characterization purportedly supported the Court's decision invalidating the expansion by refuting the argument that the expansion was within Congress's statutory reservation of power to alter or amend the program, 42 U.S.C. § 1304 (2013), and by corroborating the Court's conclusion that the states accepting pre-expansion Medicaid funding would be surprised by the new condition on their acceptance of the funds.

43. *Nat'l Fed'n of Indep. Bus.*, 132 S. Ct. at 2600–06.

44. *See id.* at 2636 (Ginsburg, J., dissenting); *see also id.* at 2606 n.14 (plurality opinion) (responding that repeal and reenactment would be inhibited by practical constraints). The plurality's weak response to Justice Ginsburg's argument did not deny its legal force. Rather, the plurality responded by refusing to engage the argument:

But it would certainly not be that easy. Practical constraints would plainly inhibit, if not preclude, the Federal Government from repealing the existing program and putting every feature of Medicaid on the table for political reconsideration. Such a massive undertaking would hardly be "ritualistic." . . . The same is true of Justice Ginsburg's suggestion that Congress could establish Medicaid as an exclusively federal program.

Id.

the Court's reasoning reveals the constitutional significance of government provision of medical care to those unable to afford it. The only way to make sense of the Court's conclusion that the PPACA's Medicaid expansion is coercive is if the Court believes (1) that it is virtually inconceivable that states would stop providing medical care to the poor, and (2) that it is impossible for states to do so without federal help.

Why is it inconceivable to the Court that states would stop participating in the Medicaid program, and perhaps severely cut back government-provided medical care for the poor, rather than accept the Medicaid expansion? What is so coercive about giving states the choice between no Medicaid and expanded Medicaid? The Court's analysis focuses on the magnitude of federal Medicaid funding as a percentage of states' overall budgets, finding it unbelievable that states would feel free to walk away from federal funding that comprises ten percent or more of the state budget.⁴⁵ But this analysis assumes that the states would *continue* the Medicaid program, just without federal funding. Are the states not free to simply end their Medicaid programs, obviating the need for the federal subsidy by eliminating that state expenditure? In my view, states do not feel free to end Medicaid because providing medical care to people unable to afford it has become to be viewed as one of the primary duties of government, part of government's obligation to provide for the health, safety, and welfare of citizens. The expectation that government will provide medical care for those who cannot afford it is so ingrained in the mind of Americans that while adjustments can be made in light of changing policy and available resources, wholesale abandonment of the duty is unthinkable.⁴⁶

The obligation to provide medical care does not necessarily mean that the current Medicaid program is the only permissible method of doing so, or that Medicaid must remain in place forever. As noted, the Court expressly disclaimed the conclusion that an outright repeal of Medicaid would be unconstitutional.⁴⁷ There are many different ways that government could provide health care to people unable to afford

45. *Id.*, at 2604–05.

46. It might be suggested that states are coerced into maintaining Medicaid because officials who abandoned Medicaid know that they would not be re-elected. This cannot be the basis of a finding of coercion. The fact that the people of a state want to participate in a federal program establishes the contrary, that participation is the voluntary choice of the people of the state.

47. *Nat'l Fed'n of Indep. Bus.*, 132 S. Ct. at 2606 n.14.

it.⁴⁸ However, once a program like Medicaid is firmly in place, institutions grow up around it and alternatives become less feasible. If Medicaid had never existed, health care might have been made available through different programs, perhaps with cost controls, more publicly owned and operated health-care facilities, more public medical schools to increase the supply of medical professionals, or perhaps by a network of private charitable institutions.⁴⁹ As it is, extensive networks of institutions have taken shape in light of the Medicaid program, involving thousands of government employees and private medical providers. Eliminating Medicaid would be extremely disruptive, supporting the Court's conclusion that states would have felt coerced into accepting the PPACA's Medicaid expansion. It would also fail to recognize people's reasonable expectations in an area of significant moral weight. Given the interdependent relationships that have grown up around Medicaid, it may be accurate to conclude that Congress may not repeal Medicaid without providing a substitute.⁵⁰

I do not mean to argue that Chief Justice Roberts would agree with me and conclude that his analysis of the Medicaid expansion in the Affordable Care Act means that he is committed to recognizing a positive right to health care. In a similar context, Daniel Farber pointed out that "there is something inherently suspect about an interpretation so clever that it never would have occurred to the speaker or the audience."⁵¹ Indeed, I surmise that if my interpretation had oc-

48. For example, Congress could fund free or low-cost health care clinics, or it could establish a publicly funded health-insurance program with deep discounts or free coverage for those unable to afford premiums.

49. Although the Supreme Court did not find arguments similar to this persuasive in *DeShaney*, in which the dissenters argued that the existence of the Department of Social Services had displaced other potential child-protection institutions, acceptance of them is implicit in the Court's invalidation of the PPACA's Medicaid exception. See *DeShaney v. Winnebago Cnty. Dep't of Soc. Servs.*, 489 U.S. 189, 212 (1989) (Brennan, J., dissenting).

50. This reasoning resonates with one of Justice Brennan's arguments in dissent in *DeShaney*, that by establishing the Department of Social Services and placing responsibility upon it for preventing child abuse, the State of Wisconsin had created reliance on its institutions for this important function. *Id.* at 207–09; see also Jack M. Beer-mann, *Administrative Failure and Local Democracy: The Politics of DeShaney*, 1990 DUKE L.J. 1078, 1096 ("Government institutions invite people to rely on their programs. Reliance on government institutions leads to a strong normative argument for government responsibility because government may crowd out other sources of aid. When government fails to act as individuals legitimately anticipated, it is as if government has yanked a chair out from under a person as she settled into the chair and simultaneously discouraged others from aiding the falling person by assuring them that government would provide the chair.").

51. Daniel Farber, *The Case Against Brilliance*, 70 MINN. L. REV. 917, 927 (1986). Farber was writing about arguments by Professors Frank Michelman and Laurence Tribe that "Justice Rehnquist's opinion in *National League of Cities v. Usery*, [426

curred to Chief Justice Roberts, he would have rejected it. What I do mean to argue is that Chief Justice Roberts's reasoning is inconsistent with the rejection of a government obligation to provide health care, for the reason that if government did not feel so obligated, it would not feel coerced into expanding Medicaid in order to continue to receive federal Medicaid funding. Sometimes—and this seems to be the case here—an opinion's reasoning paints a court into a doctrinal corner it would rather not visit.⁵²

Ed Rubin has argued that the vehement resistance to the PPACA arose out of discomfort with the constitutional shift that the Act represents toward accepting positive rights.⁵³ Rubin's theory of the role of statutory enactment in constitutional change is worth considering; in a sense, it constitutes an institutional elaboration of Bruce Ackerman's theory of constitutional moments, under which constitutional change does not require formal amendment of the written Constitution.⁵⁴ Rubin believes that the enactment of the PPACA "encourages judges to reverse *DeShaney* and hold the Due Process Clause guarantees minimal levels of safety and security."⁵⁵ In a democratic society, landmark legislation like the PPACA is likely to reflect the society's normative commitments underlying what courts and other government institutions recognize as constitutional law.

U.S. 833 (1976),] which struck down the federal minimum wage for state employees, really established a constitutional right to welfare." *Id.* at 926 (citing Frank Michelman, *States' Rights and States' Roles: The Permutations of "Sovereignty" in National League of Cities v. Usery*, 86 *YALE L.J.* 1165, 1181–92 (1977); Laurence Tribe, *Unraveling National League of Cities: The New Federalism and Affirmative Rights to Essential Government Services*, 90 *HARV. L. REV.* 1065, 1075–76 (1977)).

52. An example of the Court painting itself into a doctrinal corner is Justice Rehnquist's opinion for the Court in *Parratt v. Taylor*, 451 U.S. 527, 555 (1981). In that decision, the Court held that when a state actor, pursuant to random and unauthorized action, deprives a person of property, adequate post-deprivation remedies satisfy due process. Implicit in this decision is that if the state decides not to provide a post-deprivation remedy, a claim for a due process violation is stated, and the federal court will order the state or local officials to compensate the victim of the deprivation. In other words, states may not interpose a sovereign immunity defense in such cases—there will be either a state tort remedy or a federal due process claim for damages. Five years later, when the Court realized the implication of what it had done in *Parratt*, it overruled that decision to the extent that negligent destruction of property constitutes a constitutional "deprivation," thus allowing states to immunize themselves and their officials from tort damages. See *Daniels v. Williams*, 474 U.S. 327, 328 (1986). The current Court may be more likely to overrule its decision invalidating the Medicaid expansion than it is to recognize a positive federal constitutional right to health care.

53. See Rubin, *supra* note 12, at 1643.

54. See Bruce A. Ackerman, *The Storrs Lectures: Discovering the Constitution*, 93 *YALE L.J.* 1013 (1984).

55. Rubin, *supra* note 12, at 1704.

In my view, the enactment of a single statute, even a landmark like the PPACA, does not provide a sufficient basis to create a constitutional obligation. Thus, while I sympathize with Rubin's view that *DeShaney* should be reconsidered and that statutes can be strongly indicative of society's substantive commitments, I do not go so far as Rubin and conclude that statutory enactment alone provides the basis for constitutional evolution. Rather, in my view, it is the state's felt obligation to provide health care to the poor, as recognized by the Supreme Court in its decision invalidating the PPACA's Medicaid expansion, which pushes constitutional law down the road toward recognizing positive rights.

III.

THE PROXMIRE AMENDMENT AND INTEREST-GROUP EXCEPTIONS TO HEALTH AND SAFETY REGULATION

So far we have seen that the Court's reasoning in *National Federation of Independent Business v. Sebelius* makes sense only if it assumes a government obligation to ensure access to health care. This leads to a more general consideration of government's responsibility for ensuring health and safety. As noted, in addition to legislation like the PPACA and the Medicaid program, Congress and the states have enacted numerous statutes designed to ensure a healthy environment, safe and healthy workplaces, and safe and healthy products. Building on the proposition that these government programs are evidence of a commitment to governmental action in the health and safety areas, the central question of this Part of the Article is what the legal system should have to say about instances in which it appears that the principal explanation for a statute or regulation that undercuts public health and safety is government catering to special interests. In this regard, I focus on the Proxmire Amendment, which limits the federal Food and Drug Administration's power to regulate vitamins and supplements.⁵⁶ This focus is designed to provoke a more general consideration of the propriety of interest-group procurement of exceptions to health and safety regulation.

A. *Social Welfare Programs and Safety Regulation*

The ubiquity of social welfare programs and public safety regulations does not mean that government has become an absolute insurer against risks in either area. Each society chooses for itself an appropri-

56. Pub. L. No. 94-278, 90 Stat. 410 (1976) (codified at 21 U.S.C. § 350 (2013)).

ate level and form of government welfare programs and safety regulation. Decisions to limit or alter the scope of programs in either category are not necessarily inconsistent with the programs' underlying normative bases, and often reflect trade-offs with countervailing values such as self-reliance, encouraging economic activity, and entitlement to retain the fruits of one's own labors. Also, there is always the concern that a desirable program in theory will be difficult to execute in practice due to problems inherent in the processes and practices of government. To put it as simply as possible, government programs often suffer from serious defects, many of which stem from distortions inherent in the political process.

One of the greatest difficulties confronting government programs is the tendency for government's coercive power to be subverted for private gain.⁵⁷ Although this pathology was recognized long ago by the Framers of the United States Constitution, who tried to combat it with the separation of powers and a system of checks and balances, in recent decades the problem has been the focus of legal and political scholarship under the rubric of public or social choice.⁵⁸ Many of these scholars are deeply suspicious of all government activity, both redistributive and regulatory, because they fear that government has been captured by powerful interest groups that use their power in derogation of the public interest.⁵⁹ For some, the only good government program is no government program at all.⁶⁰

Nonetheless, many government programs do serve the public interest, even if some of their elements are infected by political considerations unrelated to their overall social welfare goals. Of course, it

57. See Jack M. Beermann, *Interest Group Politics and Judicial Behavior: Macey's Public Choice*, 67 NOTRE DAME L. REV. 183, 197–99 (1991) (discussing capture theory).

58. Public-choice or social-choice theories explain the substantive content of the law by analyzing the political process that produces the law rather than by focusing on the public interest. For a general introduction to the theories from a legal perspective, see Daniel A. Farber & Philip P. Frickey, *Law and Public Choice: A Critical Introduction*, 90 MICH. L. REV. 6 (1991).

59. See James M. Buchanan, *Politics Without Romance: A Sketch of Positive Public Choice Theory and Its Normative Implications*, in THE THEORY OF PUBLIC CHOICE—II, at 11, 18–19 (J. Buchanan & R. Tollison eds., 1984); Jonathan Macey, *Transaction Costs and the Normative Elements of the Public Choice Model: An Application to Constitutional Theory*, 74 VA. L. REV. 471 (1988); Jonathan Macey, *Promoting Public-Regarding Legislation Through Statutory Interpretation: An Interest Group Model*, 86 COLUM. L. REV. 223 (1986).

60. See, e.g., FRED S. MCCHESENEY, MONEY FOR NOTHING: POLITICIANS, RENT EXTRACTION, AND POLITICAL EXTORTION 170 (1997) (“The one unambiguous solution for reducing rent extraction is reducing the size of the state itself and its power to threaten, expropriate, and transfer.”).

may be difficult, if not impossible, to be certain whether any particular program is predominantly in the public interest or if it primarily benefits powerful interest groups. The fact that a program's origins or elements of its design can be traced to interest group lobbying is not enough to condemn its existence. To take a simple example, consider the Medical Device Amendments of 1976, which granted the U.S. Food and Drug Administration federal approval authority over medical devices.⁶¹ In the Department of Health, Education, and Welfare, interest in federal regulation of medical devices had been growing for some time, and that interest became acute after thousands of women were injured by the Dalkon Shield intrauterine birth control device.⁶² The adoption of the Medical Device Amendments in the wake of the Dalkon Shield episode looks like a classic case of a regulatory program adopted to serve the public interest (or at least placate public outrage) in the wake of a disastrous event.

The problem with this description of the adoption of the Medical Device Amendments is that medical device manufacturers were one of the powerful interest groups pushing for federal regulation.⁶³ Whenever regulatory subjects favor the adoption of regulation, it raises the suspicion that the true purpose of the regulation is to limit competition, head off more stringent regulation from some other governmental unit, or both. In this case, manufacturers sought federal regulation after the State of California instituted pre-market regulatory approval requirements for medical devices, and other states enacted their own regulatory requirements.⁶⁴ The federal statute preempts state regulation of medical devices to the extent that the state laws impose "requirement[s] . . . different from, or in addition to" federal safety or effectiveness requirements imposed under the amendments.⁶⁵ This provision relieved medical device manufactures from potentially stricter state regulation and avoided the complexity of multiple and

61. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

62. See David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 101 (2005).

63. See Michael K. Carrier, *Federal Preemption of Common Law Tort Awards by the Federal Food, Drug, and Cosmetic Act*, 51 FOOD & DRUG L.J. 509, 551-52 (1996) (discussing fear of state regulation as a reason for the law's preemption provision).

64. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008) (citing 1970 Cal. Stat. 327,076; Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 703 n.66 (1997)).

65. See 21 U.S.C. § 360k(a) (2013).

inconsistent regulatory requirements.⁶⁶ The Amendments also allowed medical devices already on the market to continue being sold without any government approval, further undercutting the potential safety benefits of pre-market screening of medical devices.⁶⁷

The fact that a statute is not perfect and that its imperfections are due to lobbying by powerful interests does not mean that the statute is worthless or that the public would be safer had the admittedly imperfect regulatory program never been implemented. In a democracy, the balancing of competing interests is to be expected.⁶⁸ Often, the best that can be hoped for is that the tendency of government to cater to powerful, narrow interests can be tempered, especially when public health and safety are at stake. In public choice terms, this can be accomplished when political entrepreneurs attract the support of broad general interests with sufficient voting power to overcome the political power of narrow, moneyed interests.⁶⁹

B. Regulation of Vitamins and Supplements

Now to the Proxmire Amendment. To make a long story about FDA attempts to regulate vitamins and supplements very short, after years of considering issues surrounding the health effects of vitamins and supplements, in 1973 the FDA adopted rules requiring agency review of any vitamin or supplement with more than 150% of the rec-

66. At the time the Amendments were passed, few—if any—imagined that the federal statute would preempt state common-law product liability claims. See *Riegel*, 552 U.S. at 340–42 (Ginsburg, J., dissenting) (citing, *inter alia*, H.R. REP. NO. 94–853, at 45 (1976)). However, during the administration of President George W. Bush, the FDA advocated for such preemption, and the Supreme Court has been receptive to the arguments for preemption made then by the government and industry and more recently by industry alone. See, e.g., *id.* at 317–18 (majority opinion) (discussing how the premarket approval process supported preemption).

67. See 21 U.S.C. § 360e(b)(1)(A) (2013); see also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996) (explaining that pre-1976 devices could stay on the market without FDA approval through “grandfathering” provisions).

68. Recent world events show that in fledgling democracies, it may be difficult for elected leaders to abandon the “winner takes all” mentality that often characterizes undemocratic regimes. This leads to great dissatisfaction among those in the populace who did not support the elected leaders, and even among those who voted for the elected leaders without embracing all of the new leaders’ programs. Instability and even revolt may follow. The best example of this is Egypt, where the nation’s first freely elected government was overthrown after mass protests. See, e.g., David D. Kirkpatrick, *Army Ousts Egypt’s President; Morsi Is Taken into Military Custody*, N.Y. TIMES, July 4, 2013, at A1 (reporting on the removal of the country’s first democratically elected president).

69. See Beermann, *supra* note 57, at 189.

ommended daily allowance of a vitamin.⁷⁰ The FDA was concerned that high-dosage vitamins could have negative health effects.⁷¹ Industry fought the rules tooth and nail, ultimately getting them overturned via judicial review amid efforts in Congress to limit the FDA's authority in the area.⁷² The industry mobilized popular support, informing consumers that the FDA was trying to take away their vitamins and supplements.⁷³ The FDA tried again in 1975,⁷⁴ and this time Wisconsin Senator William Proxmire led efforts in Congress to prevent the FDA from restricting the potency of vitamins and supplements.⁷⁵ Proxmire's efforts resulted in passage of the 1976 Vitamins and Minerals Amendments, also known as the Proxmire Amendment.⁷⁶ According to the FDA's website, the Proxmire Amendment "stop[s] FDA from establishing standards limiting potency of vitamins and minerals in food supplements or regulating them as drugs based solely on potency."⁷⁷ One scholar has characterized the effects of the Amendment as follows: "congressional interference with the FDA virtually negated its mission of protecting the American public from dan-

70. See Label Statements; Findings of Fact, Conclusions, and Final Order, 38 Fed. Reg. 20,708 (Aug. 2, 1973) (final rule); Special Dietary Foods, 38 Fed. Reg. 2143 (Jan. 19, 1973) (proposed rule).

71. The indeterminate health consequences of high-dose vitamins and supplements—for instance, the recently discovered potential link between vitamin E and an increased risk of prostate cancer—have given rise to ongoing research efforts and media attention. For an overview of research in the area, see Paul Offit, *The Vitamin Myth: Why We Think We Need Supplements*, ATLANTIC (July 19, 2013), <http://www.theatlantic.com/health/archive/2013/07/the-vitamin-myth-why-we-think-we-need-supplements/277947/> ("In 2007, researchers from the National Cancer Institute examined 11,000 men who did or didn't take multivitamins. Those who took multivitamins were twice as likely to die from advanced prostate cancer.").

72. See Nat'l Nutritional Foods Ass'n v. FDA, 504 F.2d 761 (2d Cir. 1974); H.R. 643, 93d Cong. (1973) (Food Supplement Amendment, introduced by Rep. Craig Hosmer).

73. Opposition to the FDA's efforts regarding vitamins and supplements also became a libertarian cause, as exemplified by an article from 1973 that was more recently posted by a user in an online forum supporting Ron Paul. See Gary Allen, *Vitamins: Federal Bureaucrats Want to Take Yours*, AM. OP., Sept. 1973, republished at FrankRep, 1973 Article: *FDA and the War on Vitamins*, by Gary Allen, RON PAUL FORUMS (Jan. 29, 2012, 1:27 PM), <http://www.ronpaulforums.com/showthread.php?356646-1973-Article-FDA-and-the-War-on-Vitamins-by-Gary-Allen>.

74. See Food for Special Dietary Uses, 40 Fed. Reg. 23,244 (May 28, 1975).

75. See Nat'l Nutritional Foods Ass'n v. Kennedy, 572 F.2d 377, 379–82 (2d Cir. 1978) (discussing the history of the FDA's efforts to regulate vitamins and supplements, and Senator Proxmire's sponsorship of legislation limiting the FDA's authority).

76. See Health Research and Health Services Amendments of 1976, Pub. L. No. 94-278, § 501(a), 90 Stat. 401, 410 (codified as amended at 21 U.S.C. § 350 (2013)).

77. *Significant Dates in FDA History*, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2014), <http://www.fda.gov/aboutfda/whatwedo/history/milestones/ucm128305.htm>.

gerous doses of vitamins.”⁷⁸ This is by no means a universal view, and some believe that the FDA has plenty of authority to act against deceptively marketed and unhealthy vitamins and supplements.⁷⁹

Convincing people to part with their money to consume dangerous or at best useless products seems firmly engrained in American culture, alongside too-good-to-be-true investment schemes and the individual right to bear arms. Vitamins, supplements, and weight-loss products with no proof of efficacy are sold in legitimate department stores, pharmacies, and nutrition retailers, and on the Internet and late-night television.⁸⁰ For the remainder of this Article, I will assume that

78. See W. Steven Pray, *The FDA, Vitamins, and the Dietary Supplement Industry*, 33 U.S. PHARMACIST 10 (2008) http://www.uspharmacist.com/content/t/complementary_and_alternative_medicine/c/11002/. More recent legislation continues the trend begun by the Proxmire Amendment by allowing supplement makers to make unsubstantiated health claims as long as they follow guidelines established by law, including the provision of disclaimers. See W. Steven Pray, *Orrin Hatch and the Dietary Supplement Health and Education Act: Pandora's Box Revisited*, 27 J. CHILD NEUROLOGY 561, 562 (2012) (“When DSHEA was signed into law, FDA’s ability to safeguard the health of the American public was seriously compromised. DSHEA allows herbs and other ‘dietary supplements’ to be sold without proof of safety or efficacy being provided to the FDA for legitimate scientific review before they are marketed.”); W. Steven Pray, *Health Fraud and the Resurgence of Quackery in the United States: A Warning to the European Union*, 11 PHARMACEUTICALS POL’Y & L. 113 (2009); William J. Skinner, *Allowable Advertising Claims for Dietary Supplements*, 5 J. PHARMACY & L. 309 (1996).

79. See, e.g., Peter Barton Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, 31 AM. J.L. & MED. 155, 157 (2005) (arguing that modern food-safety laws “provide FDA with greater substantive authority over dietary supplements than they provide for conventional food”). Mr. Hutt is identified in the article as legal counsel to the Council for Responsible Nutrition, which describes itself as “the leading trade association representing dietary supplement manufacturers and ingredient suppliers.” *Council for Responsible Nutrition: Who Is CRN?*, COUNCIL FOR RESPONSIBLE NUTRITION, http://www.crnusa.org/pdfs/CRNFactSheet_rev011713.pdf (last visited June 28, 2015).

80. My favorite supplement (based on its advertisements, not any personal experience) is Ageless Male, which is apparently made from “an extract from the herbal shrub called eurycoma longifolia jack that has been shown to have an effect on free testosterone levels in the body.” See *Why Ageless Male?*, MY AGELESS MALE, <http://www.myagelessmale.com/how-does-ageless-male-work/> (last visited Mar. 25, 2015). It’s not clear what symptoms are caused by low testosterone levels. Just what does Ageless Male do? Supplement sellers must be careful not to make any specific health claims, so the word “support” has become the vagary used to describe the supplement’s effect on whatever aspect of health it is marketed for. “This new and innovative formula goes beyond supporting free testosterone levels so you can be the man you want to be. Just two softgel per day also gives you support for a healthy sex life, energy and incredible results in the gym.*” *Id.* The asterisk is to the disclaimer at the bottom of the webpage that keeps the FDA off of the seller’s back: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.” *Id.* To meet legal requirements, supplements cannot claim to cure or treat a disease, but they are allowed to

the Proxmire Amendment is an example of legislation bought and paid for by an industry that used the same deceptiveness to marshal political support that it uses to sell its products to consumers.⁸¹ Those who do not agree with this characterization of the Proxmire Amendment can imagine some other federal statute in its place.⁸²

Jonathan Macey's reaction to the problem of legislation catering to narrow, self-serving interest groups was to insist that statutory interpretation be based on the public-interest-oriented justifications legislators provide for public consumption.⁸³ Such justifications accompany virtually all legislation, presumably because legislators do not want supportive voters to realize that their proposed legislation aims to please powerful interest-group supporters rather than to benefit broad constituencies. Macey's proposal is a step in the right direction, but it is insufficient because even public-interest oriented interpretation of legislation can sometimes limit the reach of important health and safety regulation.⁸⁴ In what follows, I speculate on a constitutional basis for invalidating interest-group-procured health and safety regulatory exceptions.

make unsubstantiated claims that they "support" some aspect of health. See *Structure/Function Claims*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006881.htm> (last updated Dec. 23, 2014). For example, supplements can claim to "support heart health," but cannot claim to treat heart disease. See *supra* notes 94–95 and accompanying text.

81. There does not seem to be definitive scientific evidence to support taking vitamins or supplements. In fact, research collected by the *Atlantic Monthly* included studies tending to indicate that if anything, certain types of supplements are associated with increased mortality rates. See Offit, *supra* note 71.

82. Before building a legal theory on the foundation of a category of interest-group exceptions to health and safety regulation, it is necessary to pause to consider one of the undoubtedly many problems with my analysis. In practice, it will be very difficult to distinguish between limitations on the scope of health and safety laws based on good-faith public-interest considerations and interest-group exceptions procured in the darkened passageways of the legislative process. We instinctively avert our eyes when we are satisfied with the outcome of the legislative process, for the same reason that we do not want to ruin our meals by observing the sausage-making process. Interest groups naturally try to protect themselves in the legislative process. Further, in many programs, disagreements often center on the proper balance between regulation and economic productivity, which means that the simple desire of a business sector to avoid costly regulation is relevant to the public interest. The familiar phrase "it's the economy, stupid" illustrates how government is held accountable for economic well-being. Especially in a regime under which reasonable limits on campaign contributions are unconstitutional, it will virtually always be possible to trace some important aspect of legislation to the influence of narrow interest groups.

83. See Macey, *supra* note 9, at 252–56.

84. See Beermann, *supra* note 57.

C. *Health and Safety Exceptionalism and the Constitution*

It is now time to return to the subject of government's duty to protect public health and safety, and special-interest statutes like the Proxmire Amendment that violate this duty. As described in the Introduction, the health and safety of virtually every citizen of a developed country depends on myriad forms of government regulation. In the name of safety, government regulates tap water, clothing, food, drugs, cosmetics, soaps, building construction, transportation, workplaces, air quality, water, soil, furniture—you name it, government regulates it.⁸⁵ Much, if not all, of this regulation is evidence of government's recognition of its constitutional responsibility to promote public health and safety. Because of their pernicious effects and their origins in pure political favoritism, exceptions to health and safety regulation like the Proxmire Amendment should be constitutionally suspect.⁸⁶

Pervasive regulation contributes to constitutional transformation by reflecting deeply held values, creating and shaping expectations, and displacing alternative means of meeting health and safety standards.⁸⁷ Americans cannot imagine a world in which the food they buy in supermarkets or order in restaurants is not subject to safety standards established by government, if not actual government inspection. They would not tolerate, for example, tap water unsuitable for drinking, cooking, or bathing, or ineffective and dangerous prescription and over-the-counter drugs. When things go wrong, and the health and safety of people is threatened by, for instance, a poorly constructed building, adulterated food, or contaminated water, government is blamed along with those directly responsible for the dangerous product or activity.⁸⁸

85. Government regulates for additional reasons as well, including the pursuit of economic prosperity and promotion of national security. The focus of this article is on health and safety regulation.

86. This is not an argument that redistribution is inherently unconstitutional or that any legislation that appears to be a naked interest-group transfer is constitutionally suspect. The argument here is built upon the foundation of government's obligation to provide for its citizens' health, safety, and welfare.

87. See *supra* notes 48–50 and accompanying text (discussing the role of regulation and the potential displacement of private alternatives in understanding government's constitutional duties).

88. A very recent example of this is an apparent ignition defect in certain automobiles manufactured by General Motors, which led to sudden loss of power and the failure of airbags to deploy. A great deal of attention has been focused on the National Highway and Transportation Safety Administration's failure to act after receiving complaints about the problem. See Matthew L. Wald & Bill Vlasic, *House to Investigate Slow Response to Fault in G.M. Vehicles*, N.Y. TIMES, Mar. 11, 2014, at B1.

This does not mean that the Constitution requires government to regulate each and every potential health or safety risk to a feasibility standard, that is, it does not mean the government must regulate every risk as effectively as possible. It does not mean that cuts to welfare programs or deregulation relative to preexisting health and safety programs are inherently unconstitutional. There is nothing unconstitutional about taking many factors—such as economic productivity, liberty, expertise, uncertainty of benefits and costs, and government resources—into account in establishing the appropriate level of regulation and welfare. What it does mean is that government should decide whether to regulate based on an honest evaluation of relevant policy considerations and not based on bare interest-group deals that, for example, shield a favored industry sector from health or safety regulation.⁸⁹ In a sense, government's obligations develop in a process similar to the development of public international law—it is when government feels obligated to regulate that regulation is understood to be constitutionally required.⁹⁰

The Proxmire Amendment appears to violate these principles. Although the experts at the FDA thought that vitamins and supplements should be subject to regulation to protect people's health, industry stirred up opposition and used its resources to procure friends in Congress who convinced their colleagues to pass special legislation prohibiting the agency from regulating these products according to its ordinary standards.⁹¹ Vitamins and supplements are marketed as preventing or curing numerous health problems, and the Proxmire Amendment and other regulatory features allow them to be so mar-

89. I do not mean to argue that all interest-group-inspired legislation is unconstitutional. In this Article, my focus is on interest-group-procured exceptions to health and safety regulation, where the positive right to government protection should enhance judicial scrutiny and provide arguments against such legislation or regulations in the legislative and executive branches. In a sense, this is a mirror image of *Carolene Products* footnote 4—legislation that benefits a narrow, politically favored interest in an area of positive rights should be questioned the same way that legislation prejudicing a discrete and insular minority provokes heightened scrutiny. See *United States v. Carolene Prods. Co.*, 304 U.S. 144, 152 n.4 (1938).

90. See RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW § 102 (AM. LAW INST. 1987).

91. See Stephen Barrett, *Assault on FDA Continues*, 10 NUTRITION F. 21 (1993), 1993 WLNR 5115169 (“During the mid 1960s, when the FDA attempted to ban various misleading claims, the industry organized a campaign to weaken the agency’s jurisdiction over supplement products. The campaign resulted in passage in 1976 of the Proxmire Amendment to the Food, Drug, and Cosmetic Act.”); Stephen Barrett, *Proposed Labeling Rules Stir Controversy*, 9 NUTRITION F. 9 (1992), 1992 WLNR 5019149 (“The health food industry knows how to generate huge amounts of communication to government officials. A similar campaign begun 20 years ago led to passage of the Proxmire Amendment.”).

keted even if they are ineffective or even dangerous in the dosages taken by many people.⁹² Highly formulaic labeling requirements allow vitamins and supplements to be marketed without being classified as drugs subject to FDA scrutiny and approval.⁹³ For example, rather than “curing” or “treating” prostate enlargement, which causes frequent urination and other symptoms, supplements containing saw palmetto berry extract are marketed as “supporting prostate health,”⁹⁴ even though clinical tests, taken as a whole, do not support claims that the extract provides overall benefits to prostate health.⁹⁵ The promotional materials used to market vitamins and supplements create the impression that these products are intended to treat or cure medical conditions, despite the fine print at the bottom of the advertisement or webpage that contradicts any such claims.⁹⁶

Although the supporters of legislation like the Proxmire Amendment will always cite legitimate policy concerns in support of their legislation, let us assume for the sake of argument that we have identified a statute with no legitimate policy basis, one which constitutes an exception to an important health or safety program and which was made at the behest of powerful interest groups. The next question is,

92. Theoretically, dangerous vitamins and supplements can be removed from the market. This happens occasionally when a supplement causes easily traceable health problems. However, without any requirement for advance testing and proof that a vitamin or supplement is safe and effective for its intended use, it is very difficult to detect health problems caused by long-term use of vitamins and supplements.

93. See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, §6, 108 Stat. 4325, 4329 (codified at 21 U.S.C. 343(r)(6) (2013)) (describing labeling standards for dietary supplements).

94. See, e.g., *Zyflament Prostate*, NEW CHAPTER, <http://www.newchapter.com/zyflamend/zyflamend-prostate#product-information> (last visited Mar. 25, 2015) (website promoting Zyflamend Prostate) (“Nature has provided us with an array of key foods and herbs that, when sufficiently concentrated and intelligently blended, can provide support for prostate health.* You can find these select ingredients in Zyflamend Prostate, the unique herbal formula with a combined approach to prostate health: helping to support normal urine flow, supporting a healthy antioxidant response, and supporting overall prostate health.*”). The asterisks refer to a tiny box at the bottom of the web page with the traditional disclaimer: “*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” *Id.*

95. See *Prostate Cancer Health Center: Saw Palmetto*, WEBMD (Aug. 3, 2013), <http://www.webmd.com/prostate-cancer/saw-palmetto-and-the-prostate> (observing that while study results have been mixed, there is currently “not enough scientific evidence to support the use of saw palmetto for reducing the size of an enlarged prostate or for any other conditions”); see also Michael J. Barry et al., *Effect of Increasing Doses of Saw Palmetto Extract on Lower Urinary Tract Symptoms: A Randomized Trial*, 306 J. AM. MED. ASS’N 1344 (2011) (finding that increasing doses of saw palmetto extract was no more effective than a placebo in treating lower urinary tract symptoms associated with benign prostatic hyperplasia).

96. See, e.g., *supra* note 94 (describing supplement-labeling requirements).

what should a court or other government institution do when confronted with such a case? As noted, under current law, constitutional challenges to regulation of this sort would be reviewed under the “rational basis” standard and would almost always be upheld. Although I recognize that it would be a significant departure from current law and a significant enhancement of the power of the federal courts over legislation, my claim is that legislation like this is contrary to constitutional principles and should be subject to stricter judicial scrutiny. Instead of the rational basis test’s virtual rubber stamp, perhaps judicial review in such cases could look more like the Supreme Court’s review of agency rulemaking under the “arbitrary and capricious” standard.⁹⁷ In the Supreme Court’s authoritative exposition of arbitrary and capricious review under the Administrative Procedure Act (APA), the Court stated that an agency action should be rejected if the agency “offered an explanation for its decision that . . . is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”⁹⁸ Similar considerations could guide a determination that an exception to health and safety regulation made by Congress violates constitutional principles—if Congress cannot provide a truly plausible justification for its legislation, then these exceptions should be viewed as violations of the government’s duty to protect public health and safety.

I realize that this implies aggressive judicial review. The Supreme Court has recognized that the standard for judicial review of agency action was inappropriate for judicial review of statutes for minimal rationality.⁹⁹ Relatedly, during the infamous *Lochner* era, in which the Court engaged in aggressive judicial review of economic regulation, Supreme Court Justices viewed a great deal of economic regulation as having been procured by narrow group interests in contravention of the interests of the broader public.¹⁰⁰ Although my argu-

97. See *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43–44 (1983) (describing the “arbitrary and capricious” standard).

98. *Id.* at 43.

99. *Id.* at 43 n.9 (“The Department of Transportation suggests that the arbitrary and capricious standard requires no more than the minimum rationality a statute must bear in order to withstand analysis under the Due Process Clause. We do not view as equivalent the presumption of constitutionality afforded legislation drafted by Congress and the presumption of regularity afforded an agency in fulfilling its statutory mandate.”).

100. As members of the D.C. Circuit noted recently, Justice McReynolds, in dissent in *Nebbia v. New York*, viewed the milk price controls approved in that case as the product of interest-group favoritism. See *Hettinga v. United States*, 677 F.3d 471, 482 (D.C. Cir. 2012) (Sentelle, C.J., and Brown, J., concurring) (citing *Nebbia v. New York*, 291 U.S. 502, 557–58 (1934) (McReynolds, J., dissenting)). Justice Peckham’s

ment is founded upon a positive right to have one's health and safety protected, enhanced scrutiny of interest-group exceptions to health and safety regulation would be nowhere near as intrusive or complicated as the recognition of a positive right. The latter would entail judicial orders requiring the establishment and funding of a wholly new program; the former would not.¹⁰¹

I do not mean to argue that courts should invalidate statutes willy-nilly or order government to create programs and institutions to actualize courts' conception of positive rights. Rather, I merely argue that exceptions to already-existing programs should not be permitted, which would involve much less of an institutional strain on courts than enforcement of orders to create, fund, and administer new programs.¹⁰² When government's obligation to provide for health and safety is threatened, courts should insist that legislation be supported by a plausible policy basis. Courts may be predisposed to find such support, but the inquiry should be substantial and genuine in order to ensure that exceptions to health and safety laws are not naked interest-group favors.¹⁰³

My proposal should place only moderate constraints on government's ability to restructure programs designed to fulfill the duty to provide for the health, safety, and welfare of citizens. While it may be unconstitutional for government to make exceptions to such programs out of pure interest-group favoritism, if it appears that reforms arise out of genuine engagement with the policies surrounding a health, safety, or welfare program, then such reforms should be sustained. In this light, consider Congress's 1996 replacement of Aid to Families

opinion for the Court in *Lochner* itself, finding insufficient support for the stated health and welfare bases for the limitation on bakers' hours at issue in that case, speculated that some motive other than health and welfare must have been behind the law. *See Lochner v. New York*, 198 U.S. 45, 62–63 (1905) (“When assertions such as we have adverted to become necessary in order to give, if possible, a plausible foundation for the contention that the law is a ‘health law,’ it gives rise to at least a suspicion that there was some other motive dominating the legislature than the purpose to subserve the public health or welfare.”). Justice Peckham's opinion does not specify what motives he suspected were at work. *Id.*

101. *See* Rubin, *supra* note 12, at 1706–07 (discussing the difficulty of administering judicial requirements that programs be created to meet government's positive obligations).

102. Although much of this Article's analysis may support the existence of a positive right to government protection of health and safety, as an institutional matter, judicial creation of mechanisms to realize such a right is beyond the accepted role of courts. Realistically, judicial action may be acceptable only to protect programs that have already been established through legislation.

103. Industry is very successful at marshalling resources to undercut the scientific basis of regulation. *See generally* DAVID MICHAELS, DOUBT IS THEIR PRODUCT: HOW INDUSTRY'S ASSAULT ON SCIENCE THREATENS YOUR HEALTH (2008).

with Dependent Children (AFDC) with Transitional Aid to Needy Families (TANF).¹⁰⁴ These are safety-net welfare programs, the last resort for people without other sources of income or support.¹⁰⁵ The AFDC program was criticized for creating a culture of dependency that encouraged families to stay on welfare for generations.¹⁰⁶ The TANF program limits the amount of time a person can draw benefits, and requires many recipients to work in order to continue receiving benefits.¹⁰⁷ There can certainly be genuine disagreement over whether TANF's reforms to the AFDC program were desirable, and there may even be an argument that TANF benefits fall below what a wealthy and civilized society should be obligated to provide.¹⁰⁸ But given the genuine engagement with policy issues that preceded this reform, and with no obvious interest-group power grab implicated by the process, TANF would not presumptively violate government's obligation to provide for the welfare of the poor under my proposed analysis.

Recognizing that interest-group-procured exceptions to health and safety regulation raise significant constitutional concerns may be worthwhile even if courts are extremely reluctant to actually invalidate such legislation. Legislative and public discourse would be shaped by the understanding that such exceptions are illegitimate. Legislators concerned about the reaction of voters may be less likely to champion legislation with only a thin veneer of policy support, especially if challenged by other members of the legislative body, or if they faced the threat that evidence of untoward political influence might become public during litigation.

104. The TANF program was created by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. No. 104-193, 110 Stat. 2105.

105. Marianne P. Bitler & Hilary W. Hoynes, *The State of the Social Safety Net in the Post-Welfare Reform Era*, BROOKINGS PAPERS ECON. ACTIVITY 71, 71-72 (2010), http://www.brookings.edu/~media/Projects/BPEA/Fall%202010/2010b_bpea_bitler.PDF.

106. See PATRICK F. FAGAN & ROBERT RECTOR, HERITAGE FOUND., HOW WELFARE HARMS KIDS (1996), <http://www.heritage.org/research/reports/1996/06/bg1084nbsp-how-welfare-harms-kids>.

107. See Bitler & Hoynes, *supra* note 105, at 72 ("TANF . . . imposes stringent work requirements, sanctions for noncompliance, and lifetime time limits for receipt of welfare.").

108. See Laura R. Goldin, Note, *The Safety Net Revisited? The Continuing Impact of Welfare Reform in New York City and Nationwide*, 14 CARDOZO J.L. & GENDER 97, 100-01 (2007) (criticizing TANF). For a discussion of the differences between AFDC and TANF, see Minor Myers, III, *A Redistributive Role for Local Government*, 36 URB. LAW. 753, 756-61 (2004) (comparing AFDC and TANF programs).

CONCLUSION

Positive rights have not been recognized under the United States Constitution. However, the Supreme Court's recent decision invalidating the PPACA's Medicaid expansion makes sense only if state governments feel an obligation to ensure access to health care for all.

Similarly, pervasive regulation and dire social need have contributed to the creation of a legal regime under which it is understood that government has an obligation to protect public health and safety. Contemporary society is fraught with danger, much of it unseen and undetectable by the average person. People depend on government regulation to ensure the safety of virtually every human activity. The water we drink, the food we eat, the clothes we wear, the cars we drive, the buildings we live in, and more would all be far more dangerous without effective government regulation. Unsuspecting and trusting people are deceived every day by purveyors of unsafe or useless products, and due to effective interest-group advocacy, many products that should be regulated are not. Without necessarily adopting a full-blown theory of positive rights, courts, legislatures, and regulators should recognize that exceptions to health and safety regulation violate government's basic duty to its citizens and should be thought of as unconstitutional. Statutes like the Proxmire Amendment have no place in the contemporary regulatory state.

